A-1: Title Sheet

Generic Quality Assurance Project Plan for Brownfields Projects for Lafourche Parish, Louisiana
October 9, 2026
Revision 0

Conducted Under USEPA Cooperative Agreement No. BF-02F92901
Brownfields Community-wide Assessment Grant
Period of Performance: June 12, 2025- September 30,2029

Prepared for:

Lafourche Parish Government
PO Drawer 5548
Thibodaux, Louisiana 70302

Prepared by:
Terracon Consultants, Inc.
New Orleans, Louisiana

A-2: Approval Sheet

Generic QAPP for Brownfields Projects for Lafourche Parish, Louisiana
October 9, 2026, Revision 0

Approval:

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APPENDICES

Appendix A Terracon Standard Operating Procedures

Appendix B Terracon Corporate Quality Program Manual

Appendix C Analytical Laboratory Documents
(SGS North America, Waypoint Analytical, EMSL)

Appendix D Example Field Forms

REVISION HISTORY

None to date

A-4: PROJECT PURPOSE, PROBLEM DEFINITION AND BACKGROUND

A-4.1 Introduction

The United States Environmental Protection Agency (USEPA) awarded Lafourche Parish, Louisiana, an FY25 Brownfields Assessment Grant for petroleum sites totaling $500,000 (Cooperative Agreement No. BF-02F92901). Grant funds will be used to conduct public outreach, site inventory, perform Phase I and Phase II Environmental Site Assessments (ESAs), and develop cleanup plans and alternatives. Lafourche Parish (The Parish) must have an EPA approved Quality Assurance Project Plan (QAPP) in place before beginning property specific intrusive environmental assessments using the federal grant funds under its EPA Brownfield Assessment Grant. This Generic QAPP describes in detail the quality assurance (QA), quality control (QC), and other technical activities that will be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A Sampling and Analysis Plan (SAP) for each individual Phase II ESA project will be submitted to the EPA for approval prior to commencement of sample collection. Each Phase II ESA will be performed to assess potential contaminant impacts to the site, and to evaluate potential risk to human health or the environment. This information will then be used to make environmental decisions about cleanup and/or redevelopment. Project-specific data quality concerns will be fully developed in each SAP and serve to fully develop EPA's quality process for each site.

Terracon Consultants, Inc. (Terracon) have developed this Generic QAPP to address specific QA/QC requirements prescribed by the Cooperative Agreement and the specific EPA quality documents including "Quality Assurance Project Plan Standard" (CIO 2105-S-02.1 dated April 3, 2024), which replaces EPA Requirements for Quality Assurance Project Plan (QA/R-5). This Generic QAPP describes the process for producing analytical data of sufficient quality to meet data quality requirements under EPA and the Louisiana Department of Environmental Quality (LDEQ) programs.

The work described will be performed in general accordance with this Generic QAPP and with the following:

- Terracon Standard Operating Procedures (TSOPs) included as **Appendix A**.
- Terracon Corporate Quality Program Manual provided as **Appendix B**. This manual outlines internal quality control procedures, formal review procedures, and standard company practice.
- SGS North America Quality Assurance Manuals (LQM) is provided in **Appendix C**.
- Waypoint Analytical Quality Policy Manual is provided in **Appendix C**.
- EMSL, Quality Management System (QMS) Manual is provided in **Appendix C**.

A-4.2 Project Purpose/Problem Definition and Background

The project purpose and problem to be resolved will be detailed in each SAP. Information to be discussed summarizing the problem definition and background will include:

- Current property owner
- Site physical characteristics
- Proposed future use and/or redevelopment plan
- Historical and current uses
- Findings of previous investigations
- Known or perceived contaminant sources
- Contaminants of concern (COCs)
- Conceptual Site Model (CSM)
- Data gaps, if present
- Exhibits depicting relevant site features and proposed sampling locations.

A-4.3 Environmental Information and Regulatory Criteria

Environmental media samples will typically be collected for fixed-laboratory analysis of analysis of target COCs including October 2003 Risk Evaluation/Corrective Action Program (RECAP) Table 1 list for Volatile Organic Compounds (VOC) by Method 8260, Semi-volatile Organic Compounds (SVOC) by Method 8270, and RECAP Metals by EPA Method 6010/7470 per the Louisiana Department of Environmental Quality (LDEQ) RECAP Appendix B sampling protocols.

Soil and groundwater analytical results will be compared to LDEQ RECAP Table 1 Screening Standards as appropriate based on the site use. Surface water data, when collected, be compared to the values LAC Title 33, Part IX, Water Quality, Chapter 11, Surface Water Quality Standards based aquatic and human health protection.

In the event other regulatory criteria apply to sampling media or parameters (soil gas, TCLP, SPLP, etc.), applicable requirements will be defined and included in the SAP.

One common problem in comparison of the regulatory criteria with site data is overcoming matrix interferences or elevated detection limits. In many samples, a consortium of analytes and non-target analytes may be present. However, site management decisions cannot be supported because sample reporting limits had to be elevated to the point that they are above applicable action levels. Roughly 95% of such cases can be resolved. Solutions must be evaluated on a case-by-case basis. Any such data issues which may arise will be reported to the Terracon Project Manager before any corrective action is executed.

There are unfortunately a small percentage of samples which cannot be reconciled against detection limits and regulatory criteria. In these cases, the result must be scrutinized versus the entire data set and project goals as described in Section D-2. The resultant

opinion of data quality and usability will then be incorporated as an element of uncertainty in the assessment report.

A-5: PROJECT TASK DESCRIPTION

Environmental assessments will be performed at multiple brownfield properties over multiple years under this cooperative agreement. The proposed task outlines, special personnel or equipment requirements, and work schedule at each site will be outlined within the SSQAPP for each project.

In general, the clearance of public utilities and preliminary mobilization for intrusive assessments will begin within five working days and be completed within ten working days after agency approval of each SSQAPP and receipt of a signed access agreement from the current owners. Completion of the fieldwork will be property and weather dependent.

Data collection activities will be performed in a manner consistent with the TSOP. A general discussion of sample collection procedures is included in Section B-2.

Required project and QA records and reports include field documents, assessment reports, and laboratory reports. Required records and reports are further discussed in Section A-12.

A-6: QUALITY OBJECTIVES AND CRITERIA FOR MEASUREMENT DATA

A-6.1 Data Quality Objectives

This Data Quality Objectives (DQO) process was developed within the framework of the *Guidance on Systematic Planning Using the Data Quality Objectives Process EPA QA/G-4*, and *Section 3 of Quality Assurance Guidance for Conducting Brownfields Site Assessment.* Typical DQOs for each project are outlined in the following seven steps and may be developed further within the framework of the SAP:

1: State the Problem

Real environmental contamination may be present on the site sourced from former on-site operations. Redevelopment of the site is sought; however, additional assessment is needed to evaluate the site for environmental impacts relative to the proposed redevelopment.

2: Identify the Decision

The principal objective of each investigation is to provide analytical data to evaluate the presence of impacts above applicable action levels in soil, ground water, sediment, and/or surface water at the site. The data and interpretation will answer the questions:

Based on quantitative sample data of relevant site media, can the site or areas within the site be considered for redevelopment that is protective of human health and the environment without environmental remedy?

3: Identify Inputs to the Decision

Samples of each media will be collected to provide analytical data for site characterization. Samples will be collected and analyzed as outlined in Sections B-1 and B-2 of this document. The data will be compared to applicable action levels relevant to the sampled media as related in Section A-4.3 of this document.

4: Define the Study Boundaries

Spatial Boundaries: The limits of each study will be confined to the parcel boundaries.

Temporal Boundaries: The approximate schedule for each assessment will be related in the SAP.

5: Develop a Decision Rule

The decision rule is predicated on answering the question related in Step 2 above. The risk can be gauged by direct evaluation of the analytical data. If analytical data reflect risk above action levels for the appropriate exposure scenario outlined in Section A-4.3, environmental remedy would be recommended.

6: Specify Limits of Decision Errors

Statistical sampling is typically not included as a part of these assessments. Qualitative data collection is typically not planned for these assessments except those visual observations of soils made by qualified professionals during boring installation or the use of Ground Penetrating Radar to locate possible underground features; however, field-derived data are typically considered supplementary to laboratory-derived data and are not critical to the decision.

The null hypothesis is that each site has elevated levels of environmental contaminants on-site above allowable regulatory levels that pose an impediment to site redevelopment. *This hypothesis will be evaluated by laboratory analytical sampling only*. The alternative hypothesis is that elevated levels of contaminants are not present at each site at sufficient concentrations or quantities to impede site redevelopment for the intended use. Samples

of relevant media will always be collected from each identified location to evaluate false positive decision error.

False negative decision error introduced by incorrect data deductions from visual observations would result in the collection of samples that would be submitted for laboratory analyses. The false negative would then be evaluated through conventional laboratory analytical methods. One common problem resulting in decision error is comparison of the site data with regulatory criteria. Overcoming matrix interferences or elevated detection limits can often be resolved as discussed in Section A-4.3. Furthermore, our contract laboratory will conduct Tier II data verification on the data developed. It is anticipated that the performance criteria will be met by 1) an equipment blank will be used which indicates analytical concentrations below quantitation limits; and 2) analyte recovery will be within acceptable range. If one of these factors does not meet the acceptance criteria, the analytical result will be scrutinized, and determined whether the data is essential to the successful completion of the project. Sample corrective actions could include resampling, rerunning a sample, or a determination that the data failure would not have a significant impact on the data integrity or conclusions reached during the project.

7: Optimize the Design

Design optimization is in essence the selection of the most resource-effective assessment approach to meet project goals within defined study boundaries. While this process is somewhat inherent in assessments given budgetary constraints of any project, a formalized process is nevertheless warranted. The preceding DQO steps will be reviewed for concordance with the LDEQ's VCP's typical assessment approach within each SAP. Sample techniques and spatial distribution will be selected based on minimum statistical acceptance criteria established by LDEQ and USEPA. Through the systematic limitation of decision error described in Section A-6.1, Step 6, laboratory-derived data will sufficiently test the null hypothesis.

Every effort will be made to insure that the scope of each assessment is as cost effective and sufficient in scope as possible to test the null hypothesis within the defined study boundaries. In general, Terracon's approach identifies and assesses areas of environmental concern having the highest probability of environmental impairment based on available information. Rather than use overly guarded and expensive broad-scan approaches, analytical suites are selected based on valid science and an understanding of processes involved through the development of a comprehensive Conceptual Site Model.

In order to support design optimization, each planned data point will have a justifiable reason for collection, such as direct evaluation of a source area or a receptor, or in the case of the proposed soil sample locations, better spatial resolution to eliminate areas of the site from further scrutiny. Each data point must also have a reasonable analytical suite. An effort will be made to verify that the type and quality of each data point will be sufficient for characterization. The converse will also be evaluated: Is the planned analytical schedule too broad? Can a smaller number of data points or a more focused

suite of analyses provide data to test the null hypothesis? Multiple alternatives will be explored for each planned data point or consortium of data points, and the most resource-effective assessment method will be selected.

Lastly, to support the optimization process, each SAP will be approved by the Parish, USEPA, and LDEQ with regard to project goals and sample design prior to implementation.

A-6.2 Performance/Acceptance Criteria

Critical data considered for decisions will include analytical results for the environmental media samples that meet the QA/QC criteria. Specifically, whether the COC concentrations exceed, or do not exceed the regulatory standards defined in Section A-4.3. This data will determine the need for additional assessment and/or remediation, if any.

Non-critical data that are utilized to support decisions may include field soil screening measurements, GPR survey results, lithologic observations using the Unified Soil Classification System (USCS), field parameter measurements (i.e., pH, temperature, conductivity, dissolved oxygen, turbidity, color, and odor), observations during groundwater purging activities (drawdown at purging rates), and measurement of groundwater flow. The data collection should be performed under routine conditions and in accordance with the state's applicable standard operating procedures for field and laboratory activities. This information will be used to supplement the critical data; it is not needed to make the decision of whether remediation is warranted.

When conducting investigations, measurements will be made so that results are reflective of the medium and conditions being measured. The performance and acceptance criteria will be expressed in terms of data quality indicators (DQIs). DQIs will be assessed by evaluating PARCCS (Precision, Accuracy, Representativeness, Completeness, Comparability, and Sensitivity) of the data collection process.

Precision

Precision is a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions, expressed in terms of Relative Percent Difference (RPD). Analytical precision will be evaluated by comparing results from laboratory duplicate samples and field duplicate samples. The laboratory will divide a project sample into equal aliquots for analyses. The duplicate samples are then included in the analytical sample set. The splitting of the sample allows the analyst to determine the precision of the preparation and analytical techniques associated with the duplicate samples. The RPD between the duplicates is calculated and plotted according to the following formula:

$$RPD = ((Spike\ 1 - Spike\ 2) / ((Spike\ 1 + Spike\ 2) / 2))) * 100\ \%$$

Accuracy

Accuracy is the degree of agreement of a measurement with an accepted reference or true value. The accuracy of the analytical data will be assessed by examining the results obtained from the analyses of laboratory matrix spike samples and method required QA/QC samples. Accuracy in the field is qualitatively assessed through the use of rinsate blanks and adherence to all sample handling, preservation and holding times. In order to assure the accuracy of the analytical procedures, the laboratory will randomly take a project sample and spike it with a known amount of the analyte to be evaluated. The increase in concentration of the analyte observed in the spiked sample (due to the addition of a known quantity of the analyte) compared to the reported value of the same analyte in the unspiked sample, determines the percent recovery. The percent recovery for a spiked sample is calculated according to the following formula:

% Recovery = ((Spike – Sample) / Spike) * 100 %

Representativeness

Representativeness expresses the degree to which sample data accurately and precisely represents environmental conditions and parameter variations at a sampling location. Representativeness is the selection of analytical methods and sampling protocols and locations such that results are representative of the media being sampled and conditions being measured. Representativeness is a qualitative parameter most concerned with the proper design of the sampling program. The representativeness criterion is best satisfied by assuring that sampling locations are properly selected, and a sufficient number of investigative samples are collected. Representativeness is dependent upon the proper design of the sampling program and will be satisfied by ensuring that the field sampling plan is followed, and proper sampling techniques are used. Representativeness in the laboratory is ensured by using the proper analytical procedures, meeting sample holding times and analyzing and assessing field duplicate samples.

Completeness

Completeness is the amount of valid data obtained from a measurement system. Laboratory completeness is a measure of the number of valid measurements obtained from all the measurements taken in the project. The intent of this program is to attempt to achieve a goal of 100 percent completeness. Realizing that under normal conditions this goal may not be achievable, the completeness goal for this program is 95 percent. Completeness is the ratio of the number of valid sample results to the total number of samples analyzed with a specific matrix and/or analysis. Following completion of the analytical testing, the percent completeness will be calculated by the following equation:

Completeness = ((Valid Measurements)/Measurements Taken) * 100 %

Comparability

Comparability of the data collection activities must consider field conditions as well as sampling and analytical techniques. Comparability is an expression of the confidence with which one data set can be compared to another. Comparability cannot be ensured through the use of standard methods and protocols alone. In order to compare data, various

important elements will be considered. During this project, three elements will be evaluated for data comparability. These three elements include the following:

- Analytical methods,
- Quality of data, and
- Sampling design.

If, after the initial evaluation, data do not appear comparable, the Laboratory Quality Assurance Manager will attempt to identify other components possibly affecting comparability, including field conditions, sampling protocols and the occurrence of true data anomalies. Comparability is dependent upon proper design and consistent execution of the sampling program. Analytical data will be comparable when similar analytical methods are used and documented.

Sensitivity

Sensitivity will be expressed in terms of sample quantitation limits (SQLs) achievable by the laboratory. The objective of sensitivity is to have an SQL below the applicable regulatory guidance value. For soil, groundwater and sediment sample the applicable values are the LDEQ RECAP Standards. The laboratories are aware of the applicable standards and the need to meet these standards.

A common problem in comparison of the regulatory criteria with site data is overcoming matrix interferences or elevated SQLs. In some samples, a consortium of analytes and non-target analytes may be present, such as weathered hydrocarbons, samples with one or more highly elevated metals, turbidity in groundwater, and free-phase organic liquids that can create a situation in which analytes of interest cannot be detected at normal levels rendering sample results unsuitable for making site management decisions. Solutions must be evaluated on a case by case basis, but alternative solutions can include: collection/analysis of total and dissolved metals concentrations in groundwater, sample analytical extract cleanup in the case of organics, the sample may be re-analyzed at lower dilutions if possible (in such a case both the diluted and undiluted results may be reported), or an alternate test method that offers a lower reporting limit value may be used. An example of an alternate test method would be re-analyzing a metals sample using graphite furnace atomic absorption spectroscopy or inductively coupled plasma (ICP) mass spectrometry as opposed to traditional spectra-scanning methods with an ICP alone. There are, unfortunately, a small percentage of samples which cannot be reconciled against detection limits and regulatory criteria. In these cases, the result must be scrutinized versus the entire data set and project goals as described below in Section D-2. The resultant opinion of data quality and usability will then be incorporated as an element of uncertainty in the assessment report to be delivered to the Grantee and USEPA, or resampling may be a practical solution.

A-7: DISTRIBUTION LIST

The personnel listed below will receive copies of the QAPP:

EPA Region 6 Brownfields Program

- Muneerah Williams, Brownfields Project Officer, US Environmental Protection Agency (USEPA) Region 6, 1201 Elm Street, Suite 500, LCRRB, Dallas, Texas, 75270, 214-665-2121, Email: williams.muneerah@epa.gov

Lafourche Parish Government

- Kristi Lumpkin, Brownfields Project Director, Lafourche Parish Government, 402 Green Street, Thibodaux, Louisiana 70301, Phone (985) 493-6681, Email: lumpkinkm@lafourchegov.org

- Leah Voisin, Brownfields Project Manager, Lafourche Parish Government, 402 Green Street, Thibodaux, Louisiana 70301, Phone (985) 493-6673, Email: voisinlm@lafourchegov.org

- John Warren, Quality Assurance Manager, Lafourche Parish Government, 402 Green Street, Thibodaux, Louisiana 70301, Phone (985) 226-5269, Email: klb@lafourchegov.org

Environmental Consultant, Terracon

- Diana M. Day, P.E., Project Manager, Terracon Consultants, Inc., 524 Elmwood Park Boulevard, Suite 170, New Orleans, Louisiana, 70123, Phone (225) 239-2656, Email: diana.day@terracon.com.

- Steve Whitting, P.G., QA/QC Reviewer, Terracon Consultants, Inc., 2822 B O'Neal Lane, Baton Rouge, Louisiana, 70816, Phone (225) 442-7032, Email: steve.whitting@terracon.com.

- Lem Dial, P. E., Authorized Project Reviewer, Terracon Consultants, Inc., 1520 N. Hearne, Suite 120, Shreveport, Louisiana Phone (504) 777-2553, Email: lem.dial@terracon.com.

- Jason Maloney, P.E, Authorized Project Reviewer, Terracon Consultants, Inc. 524 Elmwood Park Boulevard, Suite 170, New Orleans, Louisiana Phone (504) 777-2531, Email: jason.maloney@terracon.com.

- Field Team Leader, information will be submitted in the SSQAPP.

- Field Team Technicians, information will be submitted in the SSQAPP

Environmental Analytical Laboratory (electronic copies only)

- Linda Eshelman, Project Manager, SGS North America Inc., 500 Ambassador Caffery Parkway, Scott, Louisiana, 70583; Phone: 480-204-5581; Email: Linda.Eshelman@sgs.com

- Amy Jackson, Project Manager, Waypoint Analytical, 5041 Taravella Road, Marrero, Louisiana 70072; Phone 504-350-0893; Email: ajackson@waypointanalytical.com

- Daniel Kocher, Contracts Supervisor, EMSL Analytical Inc., 200 Route 1230 North, Cinnaminson, New Jersey, 08077 Phone: 856-858-4800; Email: contracts@emsl.com

A-8: PROJECT ORGANIZATION

A-8.1 USEPA Project Officer

The EPA Region 6 Project Officer, **Munreeah Williams**, has the responsibility to oversee and monitor the grant. As part of that responsibility, Ms. Williams will ensure the Tasks described in the work plan are followed.

A-8.2 USEPA Brownfields Region 6 Designated Approving Official

When the EPA Project Officer is not the Designated Approving Official (DAO), the Brownfields Region 6 QA Manager, will assign a regional DAO to provide technical assistance to the Region 6 Brownfield Project Officer/Manager. The DAO's role is to provide technical reviews of the QAPPs (Generic and Site-specific) and any associated addenda and revisions.

A-8.3 Grantee/Brownfields Project Manager

The Parish, as the Grantee, is responsible to oversee the daily activities of the EPA Brownfields Grant Program and provide updates to EPA. The Parish will ensure that the terms and conditions of the grant are met. **Leah Voisin**, the Brownfields Project Manager, will perform this role.

A-8.4 Grantee Program Manager (Senior Manager)

The Lafourche Parish Brownfield Program Director, **Kristi Lumpkin**, is the senior manager having executive leadership authority for Lafourche Parish. The Lafourche Parish Brownfield Program Manager will provide guidance, administration, and resources for the grant on behalf of the Parish.

A-8.5 Grantee Quality Assurance Manager

The Lafourche Parish Quality Assurance Manager, **John Warren**, oversees the Parish's Quality Management Program and will provide guidance, administration and oversight of the QA for this project for the Parish.

A-8.6 Terracon Project Manager (Project Operations Manager)

The Terracon Project Manager, **Diana M. Day**, P.E., will also be the primary decision maker for the project and consult with the Grantee based on the data to determine whether further action is required at the site. The Terracon Project Manager will coordinate the project activities and is responsible for plan preparation, scheduling and the completion of field activities, conducting data evaluations, and reporting. The Terracon Project Manager will be responsible for the development of sampling programs, Work Plans, and HASPs and for ensuring that field procedures are conducted in accordance with the SAP, work order, and state and federal guidance. This individual will manage and oversee field procedures, conduct technical QA/QC audits of field methods, ensure implementation of field methods according to relevant QC documents, and coordinate QA/QC efforts with other subcontractors. The Project Manager has the authority to make project decisions and to implement corrective actions for problems encountered during field sampling activities. This individual is responsible for communication with the Parish's Brownfields Project Manager regarding project status and preparing reports for submittal to the Parish, LDEQ, and/or USEPA.

A-8.7 Terracon Quality Assurance Manager/QA/QC Reviewer

The Terracon Quality Assurance Manager, **Steve Whitting**, will be responsible for final internal review, approval, and maintenance of the SSQAPP for Terracon. The Quality Assurance Manager will also conduct and/or oversee data review processes and assist in usability determinations as described in Section D of this document.

A-8.8 Terracon Authorized Project Reviewers

The Brownfields Support Program provides a level of highly skilled senior practitioners. These individuals provide key advice and guidance on technical and programmatic issues that may require expertise beyond typical "project level'" concerns. These individuals also function as a regulatory liaison as necessary.

Jason Maloney and Lem Dial will serve as Authorized Project Reviewers (APRs) for this project. The APRs will support general QA/QC efforts and provide input on key technical issues, as well as provide project steering and evaluation of each assessment with respect to project-specific data quality objectives and overall Brownfields redevelopment goals.

A-8.9 Terracon Field Team Leaders

The Terracon Field Team Leader(s) will be responsible for completing field activities associated with Phase II ESAs. The Field Team Leader will be identified for each SSQAPP. The Field Team Leader will assist with the coordination of project activities including scheduling and completion of field activities as well as conducting data evaluations and reporting. This individual will also assist with the development of sampling programs, SAPs and HASPs. The Field Team Leader will assist with the management and oversight of field procedures and conduct technical QA/QC audits of field methods. It will also be the responsibility of this individual to ensure implementation of field methods according to relevant QC documents, and to coordinate QA/QC efforts with subcontractors.

The Field Team Leader will conduct field activities per the approved SSQAPP document and will be responsible for the supervision of sub-consultants. Upon receipt from the Project Manager, the approved SAP and subsequent revisions will be distributed to members of the field sampling team. The Field Team Leader will report any problems in the field to the Project Manager and implement corrective actions as directed and document those actions in the field logs. The Field Team Leader has the authority to stop field work if necessary and would contact the Project Manager immediately if this occurred. This individual is also responsible for Health and Safety implementation in accordance with the HASP.

A-8.10 Terracon Field Team Technicians

These individuals will perform the actual fieldwork per the SAP and at the direction of the Field Team Leader. The field team typically consists of one to two people and will be named by the Field Team Leader during fieldwork planning.

A-8.11 Contract Laboratory General Manager

The contract laboratory General Manager (GM) will be responsible for coordinating the analysis of the samples and laboratory validation of the data. This individual will coordinate the receipt of the samples at the laboratory, select the analytical team, ensure internal laboratory audits are conducted per each LQM; and will distribute the applicable sections of the Generic QAPP and subsequent revisions to members of the analytical team. The laboratory GM is responsible for instituting corrective actions for problems encountered in the chemical analyses and will also report laboratory problems affecting the project data to the Project Manager and QA/QC Reviewer. Corrective actions for chemical analyses will be detailed in a QA report that will be provided to the Terracon Project Manager via electronic mail.

A-9: PROJECT QUALITY ASSURANCE MANAGER INDEPENDENCE

The Terracon Quality Assurance Manager (QAM), Steve Whitting, serves independently from the project staff responsible for environmental information operations, including project management, field activities, sample collection, laboratory coordination, and environmental data generation. The QAM is located geographically in a different office at Terracon and not within the same internal reporting structure. The QAM is assigned specifically to provide independent quality oversight and is not responsible for conducting or directing environmental information operations associated with this project. The QAM possesses the authority to identify quality issues, stop work for quality-related concerns, require corrective action, and independently evaluate the adequacy and usability of environmental data generated during the project.

The Project Manager and personnel responsible for environmental information operations do not have authority to make quality assurance determinations on behalf of the QAM, and the QAM does not have authority to make operational project decisions on behalf of the Project Manager. Quality assurance reviews, audits, findings, and recommendations may be communicated directly to project management, Terracon management, Lafourche Parish, and USEPA as appropriate. These organizational controls ensure that quality assurance and project operations remain functionally independent throughout the project.

A-10: PROJECT ORGANIZATION CHART AND COMMUNICATIONS

The *project organizational chart* below illustrates the projected project team for Phase II ESAs and other assessment activities conducted under this EPA Brownfield Cooperative Agreement. However, subcontractors performing Phase II ESA field activities (drilling, sampling, and laboratory analysis) may change for some assessments performed under the Cooperative Agreement. Any changes in subcontractors from those illustrated and discussed below will be included in the SAP for the respective assessment.

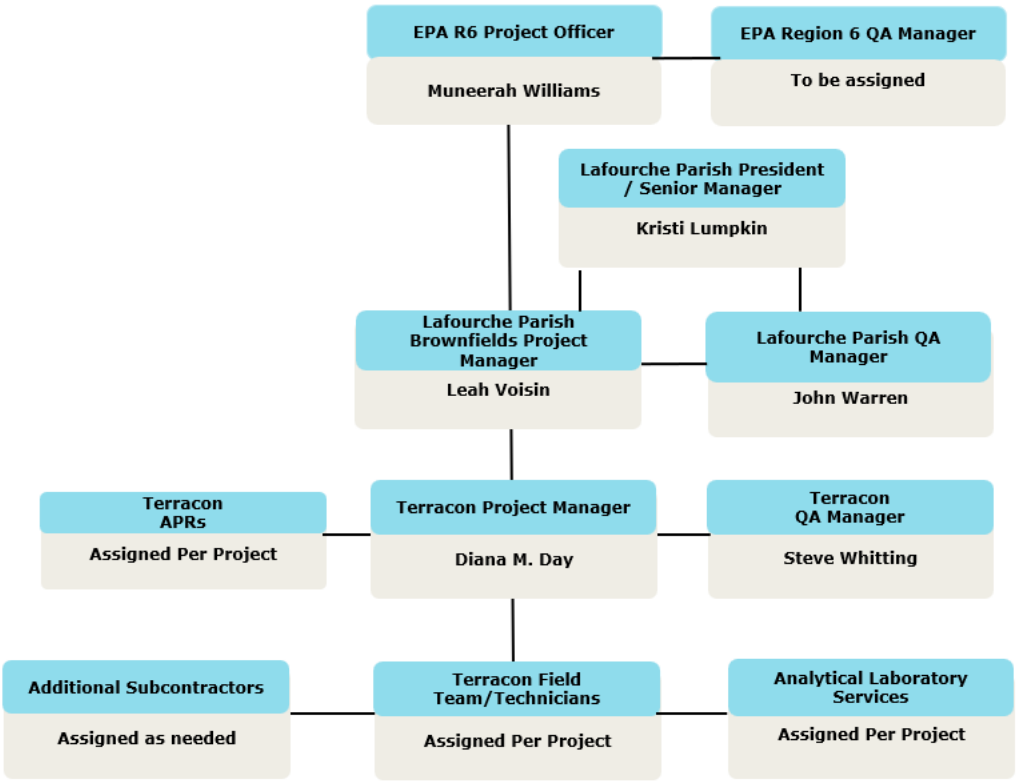


Figure 1: Project Organizational Chart

Staff assignments may vary based on assessment project. If alternatives are required, they will be identified in the SAP.

Project activities will be organized and conducted in accordance with Lafourche Parish's Brownfields Assessment Cooperative Agreement and Work Plan, this Generic QAPP, each SAP, and the Professional Services Contract between the Parish and Terracon. Grant-eligible Phase II ESA activities will be based on previous assessment findings and prospective redevelopment activities. Grant activities will be performed using appropriate Terracon resources, relevant subcontractor resources, and management guidance and oversight from the EPA. The local Terracon office for this project is in New Orleans, Louisiana.

Within the confines of typical day-to-day operations, communication will flow according to the flow chart via email, teams, or phone call communication. At times, it may be necessary for the flow of communication to deviate, during which time those in the appropriate chain will be courtesy copied on all email communication and/or informed of any developments as soon as reasonably possible.

Discrepancies and QAPP non-conformances will be addressed at the lowest level possible. In the event of a discrepancy that warrants the incident to be elevated, it will be brought to the attention of the Project Manager by the Quality Assurance Manager, who will have been made aware by the Field Team Lead.

A-11: SPECIAL TRAINING REQUIREMENTS AND CERTIFICATIONS

The Parish recognizes the importance of having all environmental sampling events performed under its USEPA Brownfield Grant in a professional and competent manner as set forth in its Professional Services Contract with Terracon, who has been retained as the Parish's Environmental Consultant under this grant award. Terracon is required under its Contract with the Parish to maintain all required professional licenses and certifications for performance of this sampling work in accordance with federal and state statues, rules, regulations, and the terms and conditions of the Brownfields Assessment Cooperative Agreement between the Parish and USEPA. Terracon states in its Contract that personnel engaged in this environmental assessment work will be fully qualified and authorized or permitted under state and local law to perform such work and has the requisite knowledge and expertise to perform the duties assigned.

All Terracon site personnel completing field work for each project will have completed the OSHA 40-hour HAZWOPER health and safety training course, including annual refreshers. If/when Parish personnel are onsite during sampling activities, staff will remain in an exclusion zone unless they meet HAZWOPER training requirements.

Field personnel have access to review activity-specific TSOPs while in the field for verification of procedural documentation requirements. Terracon field staff also complete in-house training modules through Terracon University, an on-line training system available via live webcasts, recorded webcasts, and self-paced on-line and off-line options. Materials covered include safety training presented through our Incident and Injury-Free (IIF) program, sample collection protocols, conventional and direct-push drilling investigation techniques, decontamination procedures, and investigation derived waste (IDW) management. Terracon University also includes "lessons learned" elements designed to familiarize field staff with common problems encountered during field data collection and the appropriate corrective measures as a response to those problems.

Asbestos sampling will be conducted by a LA-licensed Asbestos Building Inspector per State regulations. Lead sampling will be conducted by a LA-accredited lead inspector or risk assessor per Federal and State regulations. All well drilling and well abandonment will be conducted by LA-licensed well drillers.

All training records will be maintained in Terracon's Corporate Headquarters in Olathe, Kansas. Please refer to the Terracon Corporate Quality Program Manual included as Appendix B for more information related to training.

The Project Manager will provide technical oversight via communication with field personnel and the field subcontractor. Licensure of the subcontracted drilling operator will be confirmed during solicitation for drilling services. A LA-licensed driller will perform the drilling tasks for this project. Subcontractors are required to provide proof of their 40-hour and 8-hour refresher HAZWOPER safety training certifications. All personnel mobilizing to the site shall carry a Certificate of Training identification card on their person.

The National Environmental Laboratory Accreditation Program (NELAP)/Louisiana Environmental Laboratory Accreditation Program (LELAP) laboratory performing the analysis will analyze environmental samples for this project in compliance with all application regulations and standards. The analytical laboratory, methods of analysis, and applicable accreditation will be defined in the SAP. The laboratory Quality Assurance Manuals (LQM) are provided as Appendix C.

Terracon QA Managers and Authorized Project Reviewers undergo extensive training through Terracon's Quality Program and follow the Terracon Project Quality Manual (Appendix B) to conduct QA/QC reviews for brownfield program deliverables and reports.

Additional project-specific training requirements or certifications may be outlined in the SAP.

A-12: DOCUMENTATION AND RECORDS

Documents and Records will be maintained in accordance with the EPA Region 6 Lab Services and Applied Sciences Division (LSASD), "Field Branches Quality System and Technical Procedures", https://www.epa.gov/quality/quality-system-and-technical-procedures-lsasd-field-branches.
Descriptions of the document control system/process are discussed below for each document category.

A-12.1 Field Documents

Field personnel will maintain a dedicated field log to record pertinent information associated with sampling activities, including any problems encountered. Any photographic documentation will also be maintained with the field log. Field documents

will include site sketch maps, field log, field measurement data and equipment calibration logs, boring logs, monitoring well construction and development forms, sampling logs, chain of custody records, and other activity-specific logs. Logs documented in the field will be incorporated accordingly into the assessment reports. The significance of deviations and actions requiring corrective action will be evaluated by the Terracon Contract/Project Manager and/or the QA/QC Reviewer before report development. Copies of typical field forms are included in Appendix D.

Sample labels will be affixed to sample containers and completed by field personnel. The label will identify sample location number, date and time collected, and requested analyses correlating to the sampling log. Chain of custody records will be maintained for all samples from the time of collection until they are submitted to the laboratory for analysis.

A HASP prepared to address site-specific hazards is included as a separate document submitted with each SAP. The HASP will be reviewed and signed daily by all field personnel prior to fieldwork, indicating that they understand the plan and its requirements. A copy of the HASP will be maintained onsite and made available to all personnel during field activities. A need for special personal protective equipment (PPE) beyond standard Level D is not anticipated. However, should site conditions warrant, all on-site personnel will withdraw to a pre-designated rally point. Further information regarding health and safety considerations will be included in each site-specific HASP.

A-12.2 Hardware/Software Requirements

The hardware and software used to analyze and compile the data collected in the field and through analytical studies will vary from site to site. Below is a list of the most commonly and anticipated to be used hardware and software.

- Pro-UCL
- AQTESOLV
- BIOSCREEN/BIOCHLOR
- SESOIL
- EPA VISL calculator
- EPA RSL calculator
- gINT
- GIS
- AutoCad
- ChemStat

The hardware and software that is used will be stated in each individual assessment report as well. When a specific hardware/software, not listed below is required for project, such requirements, descriptions, and references will be included in the site-specific SAP. The hardware and software configuration falls to the responsibility of Terracon Information Technology (IT) Department, who will ensure that access will be available to any further required programs.

A-12.3 Assessment Reports

Following completion of field activities, laboratory work, and internal review and data validation, Terracon will prepare a report documenting assessment activities, laboratory analytical results, investigative findings, and assessment conclusions for each site. The report format will include sections describing the site background, perceived environmental problem being evaluated, sampling strategy, sampling methods, data validation, non-critical data implications, qualitative critical data comparison to regulatory criteria, tabular data summaries, figure exhibits, conclusions, recommendations, and appendices. Deviations will be discussed within the report. The significance of such deviations and actions requiring corrective action will be evaluated by the Terracon Contract/Project Manager before report development.

Technical reports will be reviewed by Authorized Project Reviewers (APRs), Subject Matter Experts (SME), and QA/QC Reviewer for conformance with the Brownfields program, then submitted to the Parish, and to the EPA to document compliance with the Cooperative Agreement, the SAP, and this Generic QAPP. Revisions and responses to associated comment letters will be similarly distributed by the Terracon Contract/Project Manager. The Project Manager will submit the draft report to the Parish's Brownfield Project Manager within 30 days of completion of the field activities, or as specified in the SAP. Final reports will be subsequently developed following incorporation of the internal review comments and forwarded to the Parish and the EPA. In addition, final reports will become public record, and the Grantee will provide additional copies to the public as requested.

A-12.4 Laboratory Reports

Laboratory reports will be evaluated through a process and management system that will ensure data quality meets standard method requirements. Please refer to Tables 1 and 2 in Section B-2.7 for information related to holding times for laboratory data deliverables. The laboratory standard turnaround time is approximately 10 working days, or turnaround time indicated in the SAP. Laboratory reporting will be consistent with its LQM. Laboratory reports will include a final data quality documentation package for all analyses and a Level II Standard QC Data Package with laboratory data deliverables is as follows:

- Cover letter/sheet with authorized GM signature
- Chain of custody record and sample receipt summary
- Analytical results summary
- Data qualifier definitions and legend
- Batch QC data summary (Method Blank, Matrix Spike/Spike Duplicate (MS/MSD) summary with control limits, Laboratory Control Sample (LCS) summary with control limits, and surrogate recoveries for Gas Chromatograph (GC) and GC/Mass Spectrometry (GC/MS) analyses)
- Reporting limits
- Electronic Data Deliverable (EDD), when requested
- Narrative to Include:

- Dates of sample receipt, preparation, and analysis
- Condition of samples upon receipt
- Sample preparation and analysis. Any problems encountered during sample handling, storage, preparation or analysis and their solution
- Variances from SOPs
- Discussion of the quality of the reported analytical data

Laboratory audit and associated corrective action records will be maintained within laboratory QC records. Individual records may be reviewed as determined relevant to ensure QC on a project-by-project basis. Corrective actions taken in response to audit or QC data review findings will be evaluated by the Terracon Contract/Project Manager and/or the QA/QC Reviewer and discussed accordingly in the corresponding assessment reports.

A-12.5 Retention Time and Report Storage Locations

A copy of all the final documents, including QAPPs (which are maintained by the Project QAM) will reside for a period of no less than five years, on file with the Grantee. Each final report to be submitted for this grant will maintain electronic files on the local Terracon office server. This information is backed up daily from Terracon's Corporate Data Center. Once the final report is generated, all electronic files except the final report are deleted. At initial project closing, hard copy files are purged of all documents not provided to the client or other third party. Final reports, site photos, internal memos, permits, and laboratory data are retained. Project closing is 30 days after the last project activity has ceased. A second purge is conducted at three years after project closing. All documents are removed from the file except final reports and documents provided to the client or third parties. These documents are retained at the local office for 10 years.

B-1: IDENTIFICATION OF PROJECT ENVIRONMENTAL INFORMATION OPERATIONS

This Generic QAPP was prepared in general accordance with the technical intent of the Environmental Protection Agency (EPA) National Contingency Plan. All soil borings, monitoring well installation, decontamination, and sample collection activities will be conducted in a manner consistent with the TSOP and US EPA Region 6 Field Branches Quality System and Technical Procedures.

The specific EIOs to be conducted for each assessment project will be described in the SAP, including how the EIOs will satisfy the project purpose, the DQOs, and the performance and acceptance criteria outlined in A-4 and A-6. These EIO descriptions for both field and laboratory operations will be incorporated into the discussion of the specific

scope of work, and sampling and analytical design processes in the SAP for each environmental site assessment.

For each project, samples will be routinely collected in a manner consistent with the media being sampled and the analytes of interest, and consistent with TSOPs. As specified above in Section A-8, the Project Manager and Field Team Leader will oversee sampling collection activities. Samples will be collected to evaluate concentrations of COCs. In the event additional sample types are evaluated as part of an assessment, applicable requirements will be further defined in the SSQAPP.

In addition to each SAP, Terracon will provide a project Health and Safety Plan (HASP) under separate cover for each intrusive assessment. The HASP will be prepared in accordance with the requirements set forth in Occupational Safety and Health Administration Regulation 29 CFR 1910.120, where applicable, and applicable state, city, or local safety codes. Specific tasks to be performed are outlined below. Note that samples derived from techniques described in subsequent sections will be documented using a handheld GPS unit and/or measured from a fixed, known point.

B-2: METHODS FOR ENVIRONMENTAL INFORMATION ACQUISITION

Each SAP will identify and describe both field and laboratory methods for how environmental information will be acquired for the project, including any implementation requirements, method numbers and versions, and regulatory citations. The SOPs utilized on the project will be included (or referenced in this Generic QAPP) and the individual responsible for updating and maintaining the SOPs will be identified. Any expected SOP modifications to be made during the project will be identified. A general discussion of the anticipated methods and procedures for environmental assessments to be conducted for this grant are provided below.

In general, the sampling process design for each SAP will include:

- Type and number of samples required
- Sampling design rationale
- Sampling locations and frequency
- Sample matrices
- Sample holding times, container selection and preparation, volumes, and preservation methods
- Classification of measurement data as either critical or noncritical data
- Appropriate validation study information, for nonstandard situations
- Procedures/SOPs for characterizing Investigation Derived Waste (IDW)

Subjective (biased) selection of judgmental sampling locations will be based on historical information, visual inspection, in-field screening of media, and/or professional judgment

of the Terracon Contract/Project Manager, Field Team Leader, and samplers. Qualitative critical data will be evaluated against the null and/or alternate hypotheses.

Note that in conjunction with Phase 1 ESAs, Terracon may collect samples of building materials for asbestos and/or lead-based paint (LBP). Building materials sampling will be addressed in SSQAPs. Note that LDEQ requires asbestos and lead inspectors to be licensed/certified (see Section A-11) and prescribes state-specific sampling and analysis protocols (see Section B-2.6).

B-2.1 Authorizations, Permits, and Clearances

Field operations will be conducted in accordance with LDEQ's RECAP Appendix B Site Investigation requirements well as each TSOP for each different media type being sampled. Below are explanations for each type of analytical testing that may occur during the site investigations associated with this brownfield project.

On-site activities associated with this project will not commence until the proper authorizations, permits, and clearances are obtained as applicable. These may include, but are not limited to, the items listed below.

- Cable/Utilities Clearance: Prior to the field activities, LA811 will be contacted to conduct a utility survey. In addition, any site maps available will be reviewed; a geophysical survey may be conducted, if necessary, to clear on-site utilities not demarked by LA811.

- Written legal access to the property

- Site Eligibility, SAP, and Monitoring Well Installation Approval

B-2.2 Soil - Sampling Design

Typically, to accomplish project goals outlined in Section A-6 and to test the null hypothesis, soils testing is often required. Soil sampling is typically conducted using a direct-push continuous core sampler.

Continuous core samples will be collected using decontaminated equipment from depths appropriate to test the null hypothesis and meet LDEQ data needs. Typical sample protocol requires an aliquot from each sample location will be placed into the stainless-steel bowl. Samples for VOCs (where applicable) will be collected prior to mixing. Subsequent to VOCs sampling, the soils will be mixed using the quartering method and placed into the laboratory-supplied sampling containers using a decontaminated stainless-steel spoon. Soil samples will be submitted for laboratory analyses as specified in each SAP. Note that for the composite samples, VOCs samples will only be collected from the last subsurface composite location and will be discrete from each interval at that location.

Sample containers will be supplied by the selected contract analytical laboratory. The samples will be pre-preserved by the laboratory in accordance with the analytical method to be performed. The laboratory has provided preservation methods for the various analytics as described in the LQM. Samples will be placed in a cooler, on ice, and delivered to the laboratory along with chain-of-custody documentation.

Non-disposable equipment to be used repeatedly between samples (i.e. stainless-steel spoons, spatulas, hand augers, etc.) will be field decontaminated before mobilization to the site, and subsequent to each use. Field decontamination will be accomplished using an Alconox®/tap water solution, followed by a distilled, deionized water rinse, and finally a 70% isopropyl alcohol rinse. Sampling equipment will be wrapped in plastic or aluminum foil during transport to prevent contamination.

A non-critical determination of the lithological description using USCS (from ASTM D 2487 and D 2488) will be made for each soil sample. In addition, soil samples will be collected in two foot intervals to be screened in the field for volatile organic vapors with a Photoionization Detector (PID) type OVA. Procedures for field screening with an PID will generally consist of:

- Warm up and calibrate the PID according to manufacturer's specifications prior to collection of the first soil sample;
- Prior to collection of soil samples, collect a blank field screening sample by utilizing the following field screening procedure on a sample bag filled with ambient air;
- Collect and place soil samples from specified sample intervals into a clean, dedicated, sealable, glass jars with an aluminum foil cover. The same type of container should be consistently used at the site for comparison purposes;
- Shake or knead the container for 30 seconds to thoroughly mix the contents until the contents are uniform;
- Let the sample equilibrate by allowing at least 15 minutes for VOCs to equilibrate within the headspace;
- Shake or knead the container again for 30 seconds;
- Measure and record the headspace concentration with the PID by inserting the PID probe as quickly as possible into an opening in the bag and quickly sealing after the seal has been broken. Allow the PID to analyze the headspace for 10 to 15 seconds and record the highest instrument reading.

Sample aliquots used in field screening should not be the same sample aliquot utilized for laboratory analysis. If sampling decisions are to be made based on field screening results, corresponding sample aliquots should be preserved, headspace-free, in a sealable container and placed in an iced cooler until sample decisions are made.

B-2.3 Ground Water - Sampling Design

As needed for each project, Terracon will assess ground water quality at the site through the installation and sampling of single-cased monitoring wells or direct-push temporary

monitoring wells. If double-cased or other specialty wells are required for a project, the details will be outlined in the SAP. Monitoring wells will be installed by a LA-certified well driller in accordance with R.S 38:3098 Subsurface Water-Well Drillers and LAC 46 Water Well Drillers – Licensing.

The borings for the single-cased monitoring wells will be drilled with 4-1/4-inch I.D. hollow stem augers (or other conventional drilling methodology as dictated by subsurface conditions). The wells will be constructed using ten feet of two-inch diameter, 0.010-inch machine slotted PVC well screen with a threaded bottom cap, and 2-inch diameter, threaded, flush-joint PVC riser pipe to the ground surface. Addition of pre-sieved 20/40 grade silica sand for annular sand pack will be installed around the well screen from the bottom of the boring to approximately two feet above the top of the well screen, followed by two feet of hydrated bentonite pellets above the sand pack. If the formation will allow, the wells will be completed as temporary wells; however, should potential borehole collapse be observed during advancement, the wells will be completed above the bentonite seal with a cement/bentonite slurry to the surface. As necessary, the surface completion will consist of an 8-inch flush-mounted steel protective cover or a 4-inch square steel standup protective cover set in a 2X2-foot square concrete pad, depending on sample location. The monitoring wells will be developed by surging and removing ground water until fluids appear relatively free of sediment. All investigative derived waste (IDW) will be managed in accordance with state regulations.

Direct-push wells will be advanced using direct-push technology provided by a track-mounted Geoprobe® rig. At each location, a disposable point will be driven to depth, and then the rods will be retracted to expose a four-foot screen. Prior to ground water sample collection, each monitoring well will be purged to decrease turbidity.

Prior to ground water purging and sampling, the depth to ground water will be measured at each well using an electronic water level indicator. The water level indicator will be decontaminated before and after use at each well. Water levels will be measured in the wells which have the least amount of suspected contamination first. All ground water level measurements will be made in reference to the established reference point which will be the top of the well casing. Ground water level measurements will be recorded, and the calculated elevations will be reported to the nearest 0.01 foot. In addition, the total depth of the well will also be measured in reference to the top of the well casing. The water level and total depth measurements will be recorded in a bound field notebook and the ground water sampling log. These water level data will typically be used to develop a potentiometric surface map as described below.

The monitoring wells will be purged with a peristaltic pump. Water purged from the wells (IDW) will be properly stored and secured on-site until analysis of the waste purge water has been received and appropriate disposal can be arranged.

During the purging process, the field parameters of temperature, pH, turbidity, and specific conductance will be measured periodically to ensure representative ground water is obtained. Dissolved oxygen concentration, and ORP will also be monitored. The

measurements will be taken frequently to evaluate stability. Water quality is considered stable if for at least three consecutive readings:

- pH measurements remain constant within 0.1 Standard Unit (SU);
- turbidity is below 10 NTUs or varies no more than 10 percent (between the three readings, not compared to an average value);
- specific conductance varies no more than 10 percent (between the three readings, not compared to an average value); and
- Temperature is constant.

Upon completion of the purging activities, ground water samples will be collected using a peristaltic pump. Ground water samples will be analyzed as specified in each SAP. Ground water quality results will be compared to the RECAP Screening Standards presented in Section A-4.3.

Terracon will conduct a field survey to determine the horizontal and vertical (elevation) location of the newly installed monitoring wells in relation to an established on-site datum. The survey will reference the well locations to the fixed landmarks such as property boundaries, utilities, and site building. Monitoring well top of casing (TOC) elevations will be referenced to an established on-site datum. The TOC elevations will be used to calculate the ground water elevations and hydraulic gradient.

B-2.4 Sediment and Surface Water - Sampling Design

Sediment samples may be collected from ditches, streams, rivers, lakes and/or ponds. In flowing surface water bodies, samples will be collected starting at the downstream location. Sediment samples will be collected using field-decontaminated hand augers or stainless-steel spoons directly into a clean, stainless steel bowl. The sediment samples are then treated in the same manner as a soil sample as described in Section B-2.2 above.

Surface water samples may be collected from water bodies. Samples will be collected directly into the laboratory-provided sample containers. Please note that for samples collocated with sediment samples, the surface water samples will be collected before the sediment sample in order to mimic site conditions and not artificially increase turbidity. Once the sample is collected, surface water samples are treated in the same manner as ground water samples as described in Section B-2.3.

B-2.5 Soil Gas – Sampling Design

Terracon will assess the potential for vapor intrusion for each project using temporary monitoring points. Soil gas samples may be collected from various depths within the vadose zone, from within the footprint of a planned structure and/or from directly below the concrete slab of an existing building. The different types of soil-gas testing and the situational applications of each are as follows:

- Deep soil-gas testing: soil-gas samples are collected from greater than 5 feet below ground surface and at least 5 feet above the saturated zone.

- Near slab or shallow soil-gas testing: the industry standard depth for this type of testing is 5 feet deep but may be as shallow as 2.5 feet deep if installed near the foundation of a structure. Near-slab testing is typically conducted within 10 lateral feet from an existing structure.

- Sub-slab soil-gas testing: soil-gas samples are collected from immediately below the lowest floor slab of a building.

Soil borings for deep soil-gas monitoring points will be installed using a drill rig equipped with hollow stem augers or with a Direct Push Technology (DPT) rig. Near slab/shallow surface soil-gas monitoring points will be installed using a hammer drill, drilling rig, DPT rig or a hand-auger (2.5 to 5 feet deep) to advance a boring to the target depth. A stainless steel sampling port with a mesh screen will be attached to a length of Teflon-lined, polyethylene tubing and emplaced at the bottom of the soil boring with the other end of the tubing extending above the ground surface. The annulus of the boring will be filled with clean, filter sand to approximately 0.5-feet below the ground surface. Bentonite pellets or fine-grained bentonite will be used to fill the remainder of the annulus and extend above the ground surface. The bentonite will be hydrated to affect a seal.

The screened interval for sub-slab soil-gas monitoring points will be installed directly below the concrete slab with the sampling port extending above the concrete surface. The entire thickness of the slab will then be sealed around the sampling port using an impervious material.

Equilibration times following soil gas implant installation, leak testing, and purging are important sampling considerations. A proper amount of equilibration time will be allowed between soil gas implant installation and sample collection. Recommended equilibration times are contingent on the method used to emplace the soil-gas monitoring point and are as follows:

- Hand auger and hollow stem auger: 48 hours

- DPT rig: 8 hours

- Hammer drill: 2 hours

A proper leak test for the seal of each temporary soil-gas monitoring point will be completed using a helium shroud and a helium detector prior to sample collection. Samples will only be collected if the leak test passes.

The void volume of the system (including sand placed around a probe) will be calculated, and a minimum of three purge volumes will be removed prior to sampling. The vacuum

induced during purging should be noted. If the formation is too tight to purge, no soil gas sample will be collected. Samples will be collected by connecting the aboveground end of the tubing to the sampling port of a 1.4-liter Summar canister. Sampling times will typically be between 30 minutes and 1 hour, contingent on the soil type.

Soil-gas sample collection density will be determined by the square footage of the existing or planned footprint of the structure as follows:

- 0 – 1,500 square feet (s.f.): 2
- 1,501 to 5,000 s.f.: 3
- 5,001 to 10,000 s.f.: 4
- 10,001 to 20,000 s.f: 5
- >20,000 s.f.: 6 or more

Samples will be submitted to Eurofins Air Toxics Laboratory for VOCs analysis per EPA Method TO-15.

B-2.6 Receptor Survey

Terracon may conduct a survey of all available or ascertainable records for public and private wells used for drinking water supply within a one-half mile radius of the site and wells used for irrigation or other non-drinking water use within a one-quarter mile radius of the site as prescribed by the LDEQ. Concurrently, Terracon will perform a windshield survey to identify wells in the noted radii and any other potential receptors. The survey will include a map of identified features and a tabulation of owner's names (if available) and street addresses.

B-2.7 Asbestos & Lead Paint Sampling

Samples of suspect ACM may be collected for laboratory analysis. Bulk sample collection will be conducted in general accordance with the sampling protocols outlined in USEPA 40 CFR 763.86, and State of Louisiana LAC Title 33, Part III Chapter 27, and LAC Title 33, Part III Chapter 51 Subpart M. Asbestos. A laboratory accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) will analyze bulk material samples by visual estimation using polarized light microscopy (PLM). If PLM results merit re-analysis by the more quantitative point counting technique, Terracon will contact the client for authorization if additional costs will be incurred.

Terracon will visually assess building components and perform a lead paint (LP) survey that will consist of collecting paint chips samples from various painted components. Sample collection will be conducted in accordance with HUD Guidelines for the Evaluation and Control of Lead-Based Hazards in Housing, second edition dated July 2012 Chapter 7

and Appendix 13.2 protocol and LAC 33: III.2803. Representative building component surfaces that may be sampled include, but are not necessarily limited to, woodwork/molding, door jams and trim, window still, and sashes, cabinets, walls, ceilings, counter tops, stair railings, floors, radiators, balcony railings, and base boards. The paint chip samples will be submitted to a laboratory participating in the Environmental Lead Laboratory Accreditation Program (ELLAP) for lead content analysis.

B-2.8 Analytical Methods and Requirements

The following tables describe standard analytical methods. Additional methods needed for a particular project will be outlined in the SAP.

Table 1 – Standard Analytical Methods for Solid Matrix Samples

Contaminant of Concern	Analytical Method	Packaging and Preservation	Maximum Holding Times
VOCs	USEPA 5035/8260	(1) 40-mL vial with Methanol, (2)-40mL vials with deionized water, 4oz CWM, ≤6°C	48 hours, 14 days if frozen within 48 hours
Extractable Petroleum Hydrocarbons	MADEP EPH(1)	8oz glass jar, ≤6°C	14 days
SVOCs	USEPA 8270	8oz glass jar, ≤4°C	14 days
Chlorinated Herbicides	USEPA 8151	8oz glass jar, ≤4°C	14 days
Organophosphorus Pesticides	USEPA 8141	8oz glass jar, ≤4°C	14 days
PAHs	USEPA 8270-SIM	8oz glass jar, ≤4°C	14 days
PCBs	USEPA 8082	8oz glass jar, ≤4°C	14 days
Chlorinated Pesticides	USEPA 8081	8oz glass jar, ≤4°C	14 days
Metals (except mercury)	USEPA 6010/6020	8oz glass jar, ≤4°C	180 days
Mercury	USEPA 7471A	8oz glass jar, ≤4°C	28 days
TCLP Extraction	USEPA 1311	8oz glass jar, ≤4°C	Depends on Contaminant(s)
SPLP Extraction	USEPA 1312	8oz glass jar, EnCore device for volatiles; ≤4°C /frozen for volatiles	
pH	USEPA 9045C	8oz glass jar, 4°C	ASAP
Lead (paint chips)	3050B	1 gram, sealable plastic bag	None
Asbestos	PLM 600R-93/116	1 to 10 grams, sealable plastic bag	none

(1)Under LDEQ RECAP, this is the preferred method for fractionation

Table 2 - Standard Analytical Methods for Aqueous Samples

Contaminant of Concern	Analytical Method	Packaging and Preservation	Maximum Holding Times
VOCs	USEPA 8260C	(3) 40-mL vial with HCL, ≤4°C	14 days
1,2-Dibromo-3chloropropane	USEPA 8011	(3) 40-mL vial with HCL, ≤4°C	14 days
SVOCs	USEPA 8270C	(2) 1-L Amber Glass No preservative, ≤4°C	7 days
Extractable Petroleum Hydrocarbons	MADEP EPH	(3) 60ml amber vials with HCL	14 Days
Volatile Petroleum Hydrocarbons	MADEP VPH	(3) 40ml vials with HCL, ≤6°C	14 days
Chlorinated Herbicides	USEPA 8151	(2) 250-mL Amber Glass, ≤4°C	7 days
Chlorinated Pesticides	USEPA 8081	(2) 250-mL Amber Glass, ≤4°C	7 days
PAHs	USEPA 8270-SIM	(2) 250-mL Amber Glass, ≤4°C	7 days
PCBs	USEPA 8082	(1) 1-L Amber Glass, ≤4°C	7 days
Organophosphorus Pesticides	USEPA 8141	(2) 250-mL Amber Glass, ≤4°C	7 days
Metals (except mercury)	USEPA 6010/6020	500-mL plastic poly with HNO_3, to pH <2, ≤4°C	180 days
Mercury	USEPA 7470A	500-mL plastic poly with HNO_3, to pH <2, ≤4°C	28 days
pH	USEPA 9045C	8oz glass jar, 4°C	ASAP

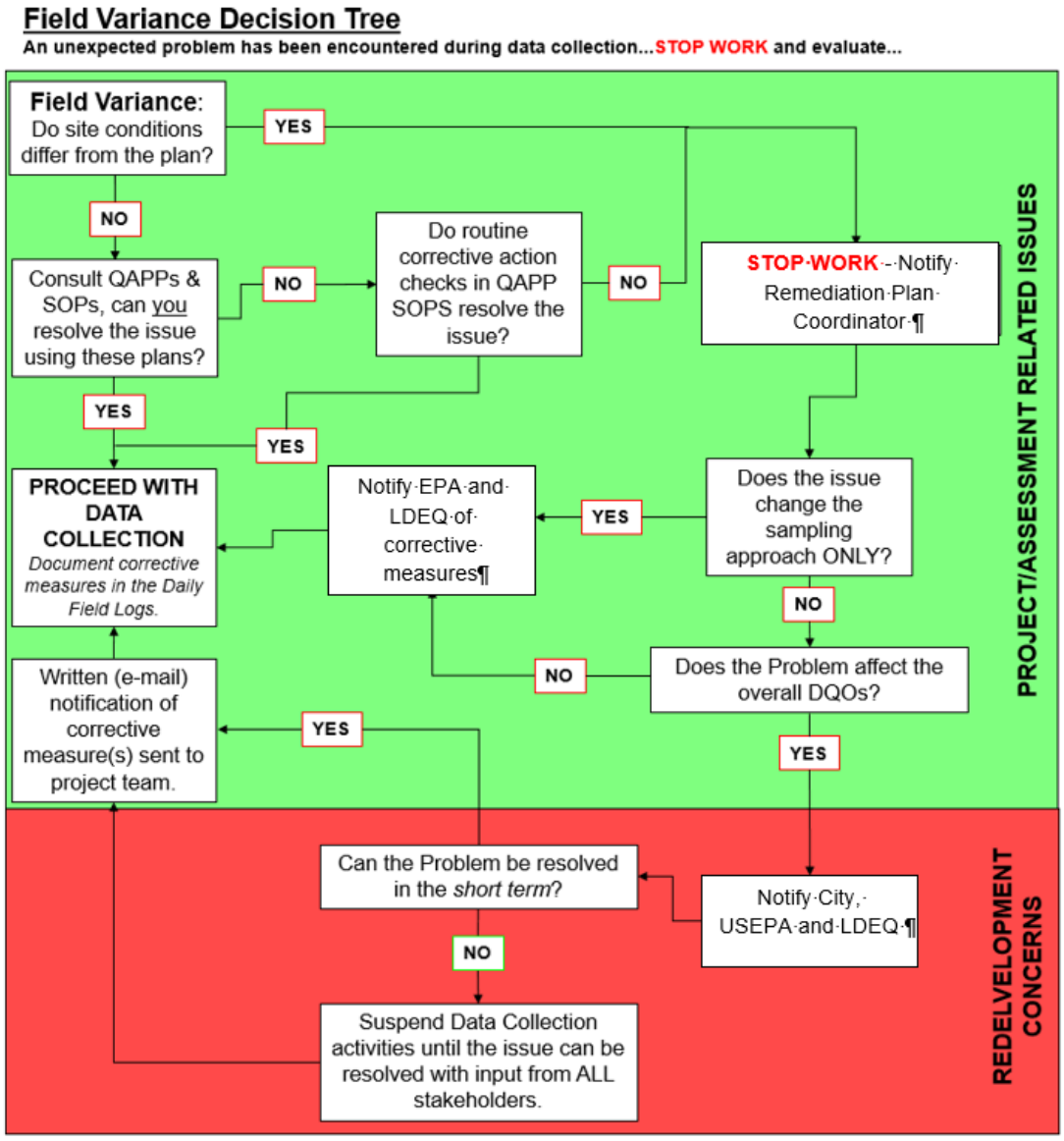
The selected laboratory will perform the measurement of COCs in sample media. The laboratory selected to perform the analyses must be accredited by LDEQ. Once the samples are received and logged in at the laboratory, the samples will be analyzed by EPA Methods identified on the chain of custody record, which correlates to the COCs and analytical methods as specified in the SAP. The laboratory GM is responsible for overseeing the success of the analysis and for implementing corrective actions if deemed necessary. The laboratory SOPs in Appendix C describe procedures to be followed when a non-compliance or failure occurs including how the effectiveness of any corrective action taken will be determined and documented.

The detection limit requirements for each analyte are typically below regulatory limits for the parameters of interest. The Project Manager will review the laboratory QC samples and control limits identified in the LQMs. The quality of the data generated using the LQMs will provide analytical data of known quality and precision for this project. The use of non-standard or unpublished methodologies is not anticipated; however, if applicable, additional validation criteria will be provided in the SAP.

In general, the laboratory turnaround time for hardcopy and electronic laboratory data deliverables is anticipated to be approximately 10 business days. A project-specific schedule, including turnaround time, will be provided in the SAP.

B-2.9 Field Corrective Action

Field safety and sampling procedure checks will be performed at a frequency of at least 10 percent of the environmental assessment sample locations. Even with the best planning, data collection activities are always subject to field variances (including lost samples, broken equipment, etc.), which may require changes to the planned approach. The linchpin of data quality is the ability of field staff to make sound decisions with regard to corrective measures. Routine corrective measures during all sampling activities will be taken at the discretion of the Field Team Leader and Project Manager. All corrective measures will be thoroughly documented in field logs. However, difficulties may arise when issues are encountered and decisions on corrective actions move "beyond the routine." Whenever there appears to be a problem that could adversely affect data quality and resulting decisions affecting future response actions pertaining to each site, the *Field Variance Decision Tree*, included as Figure 2 below, has been developed, with respect to the *Project Organizational Chart* in Section A-10, to provide a clear picture of the assessment and response process for field variances.



Once field data collection has been completed and any corrective measures have been documented, analytical data validation will be performed by the laboratory to evaluate any corrective actions reported for the analyses. Terracon will conduct a review of data and provide documentation of corrective actions in the site assessment report.

B-2.10 The Use of Existing Information

Environmental information from previous environmental assessments and investigations may be used in the project if deemed suitable and compatible for inclusion. Terracon will ensure that each assessment and/or investigation was signed by a qualified Environmental Professional and that any analytical information included in the report was completed by a licensed and certified laboratory. These previous reports have been provided to Terracon from the CAR and/or property owner when available. Due to the ever-changing nature of analytes found in the environment, analytical detection levels from previous investigations will be used to show changes in the concentration and will

be taken into account when determining resampling and/or remediation actions, if deemed necessary.

B-2.11 Environmental Technology

Environmental technology is an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. For environmental information operations involving environmental technology, no technology for pollution prevention, contamination containment, storage, or remediation is anticipated during assessment activities aside from the equipment and processes discussed herein in Section B.2 Methods for Environmental Information Acquisition. In the event specific environmental technologies are recommended and approved, a Site Specific QAPP Addendum will be prepared, and the following information will be included regarding Environmental Technology proposed:

- Identify whether the technology is primarily for pollution prevention, contamination containment, storage, or remediation.
- Describe the physical parameters or processes using environmental technologies.
- Describe the specific systems, devices, and their components.

B-3: INTEGRITY OF ENVIRONMENTAL INFORMATION

Each SAP will identify the laboratory to be used for the project and the back-up laboratory (if required). The processes for ensuring the laboratory maintain current accreditation and certification for applicable analytes and matrices are provided in the SOPs for each laboratory in Appendix C. A general discussion of how the integrity of environmental information will be maintained for environmental assessments performed under this cooperative agreement is below.

The integrity of environmental information will be ensured by the QAM, the Field Team Lead, as well as the Field Technicians. This will be accomplished by verifying that the Field Technicians are properly trained and aware of procedures to accurately take field notes, complete boring logs, and conduct sampling in accordance with the applicable ASTM.

Field logs will be used for any site investigations associated with this brownfield, which will include the date and time that the field work is performed, the current weather conditions, as well as the names of the personnel that are present for the investigation. Packaging will be accurately labeled with the project number, site location, date and time of sample collection. Samples will be stored on ice to ensure the conditions of the media stay as true to in-situ conditions. Samples will be picked up by a lab provided courier, with

sample pick up available three times a week, to ensure that samples are tested prior to their hold-time expiration.

Samples will be placed into appropriate laboratory supplied pre-cleaned containers for each analysis, as listed above on Tables 1 and 2 in Section B-2.7. Chain of custody records initiated by the laboratory will be completed by Terracon during the sampling activities and maintained with the sample coolers until the coolers are delivered to the laboratory. The TSOPs and the LQMs describe the sample handling and custody requirements.

Chain of custody procedures will begin with the laboratory preparation of a field kit that includes appropriate sample containers for the requested matrices and analytical methods. During sample collection, a label is completed specifying the sample location identification, date, time, preservative, analysis, and field technician's initials (printed in ink) will be affixed to each sample container, and the sample information will be entered on the chain of custody record. Each sample will have its own unique identification number. The numbering scheme will provide tracking for the retrieval and usage of analytical field data for each sample. The sample identification will correlate on field data sheets and/or logbooks, chain of custody records, and all other documentation used during the project.

Samples will be packaged in a manner to prevent breakage or cross contamination. Ice will be placed into the cooler prior to placement of samples. Packing materials such as plastic bubbles will be placed into coolers to prevent shifting. Enough ice will be provided to ensure that the temperature of the samples is cooled and maintained at approximately 4°C. The SAP will describe handling procedures for non-routine samples when handling procedures for the media and intended analysis differ. Sample containers from the specific sampling location will be placed into the same cooler, except in cases where multiple sample storage coolers will be transported the same day. Then, the sample containers for VOC analysis will be consolidated into a single cooler to minimize the number of required trip blanks.

The chain of custody record will be updated whenever the samples are transferred to another person or party. If sample shipment is required via commercial service, each cooler lid will be securely taped shut, and at least two custody seals will be signed, dated, and placed across the lid opening. Additionally, if a commercial carrier is used, the laboratory will be contacted and notified of ship time and estimated receipt time by the laboratory. The samples will be submitted to the receiving laboratory by Terracon personnel in a time-efficient manner to ensure that the applicable holding times are not exceeded. Chain of custody procedures end with the signature, date and time provided by the representative at the laboratory receiving the samples. The LQMs describe the sample logging and tracking of samples. An example of a chain of custody record form is provided the LQMs included as Appendix C.

B-4: QUALITY CONTROL

Specific QC activities needed to meet the projects' information/data quality objectives and performance/acceptance criteria, including QC type, frequency, and associated corrective

actions for each activity, will be addressed in the SAP. A general discussion of field and laboratory quality control requirements is below.

B-4.1 Field Quality Control Requirements

The following Quality Control (QC) samples will be assessed during the investigation(s) and confirmation sampling activities:

- Matrix Spike/ Matrix Spike Duplicate (MS/MSD) samples (1 per 20 samples per media sampled)
- Field Duplicate (1 per 20 samples per media sampled)
- Temperature Blanks (one per shipped cooler)
- Trip Blank (1 per shipped cooler with VOCs)
- Equipment Blank (1 per day)
- Field Blank (1 per day)

MS/MSD samples are collected to help identify matrix effect problems and determine the recovery of the analyte. The laboratory will add known concentrations of analytes of interest to the samples prior to sample preparation and analysis. A MS/MSD will be collected at a frequency of 5%, or 1 per 20 samples collected per matrix (soil, groundwater, surface water, sediment, soil-gas). MS/MSD samples will be collected concurrently with site characterization samples and collected from as close to the original sampling location as possible.

Duplicate samples for groundwater, surface water, sediment, soil-gas, and soil will be collected simultaneously using the same sample collection system to measure the quality of sample collection and/or the laboratory analysis process. These will be collected at the rate of 1 per 20 samples. The duplicate samples will be collected simultaneously with the characterization samples.

Trip blanks will be supplied by the laboratory and are a sample of analyte-free water analyzed by the laboratory to ensure that any analytes detected in samples are not the result of contamination during the handling/sampling process.

Equipment blanks will be collected at the rate of one per day. These are collected by pouring ultra-pure water over a sampling instrument and collecting the runoff in the appropriate laboratory-supplied containers.

Field blanks are collected once per day by pouring analyte-free water into the appropriate, laboratory-supplied containers at the start of the workday, left open during the workday, and then closed for shipment to the laboratory. The purpose of the field blank is to assess potential contamination from field conditions. A single temperature blank will be added to each sample shipping container prior to shipment. This blank will be evaluated for temperature by the laboratory upon sample receipt to ensure the temperature of the samples is 6 degrees Celsius or less.

When situations arise where corrective action is required, the following steps will be followed to determine and document the effectiveness of the corrective action:

- Identification of Issues: Problems or deviations from the planned procedures are identified during routine monitoring or audits.
- Implementation of Corrective Actions: Specific actions are taken to address the identified issues. This may involve changes to procedures, retraining of personnel, or adjustments to equipment.
- Verification: The effectiveness of the corrective actions will be verified through follow-up assessments. This step ensures that the actions taken have resolved the issues and that the project is back on track.
- Documentation: All steps, including the identification of issues, the actions taken, and the verification of effectiveness, are thoroughly documented in writing and communicated with the project team and EPA. This documentation will be essential for transparency and for future reference.

The following procedures will be used to calculate applicable statistics:

- Precision is a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions, expressed in terms of Relative Percent Difference (RPD). Analytical precision will be evaluated by comparing results from field duplicate samples. The duplicate samples are then included in the analytical sample set. The duplication of samples allows the analyst to determine the precision of the preparation and analytical techniques associated with the duplicate samples. Field duplication samples are used to evaluate errors associated with sample heterogeneity, sampling methodology and analytical procedures. The RPD between the duplicates is calculated and plotted according to the following formula:
  - RPD = ((Spike 1 – Spike 2) / ((Spike 1 + Spike 2) / 2))) * 100 %
  - The precision goal for field duplicates is an RPD of 20%

- Accuracy is the degree of agreement of a measurement with an accepted reference or true value. It is a measure of the bias or systematic error of the entire data collection process. To assess sample accuracy, field QC samples such as filed blanks, are typically incorporated into the sampling scheme. The data acquired from the analysis of blanks are useful in their ability to evaluate errors, which can be caused by cross-contamination. The occurrence of cross-contamination can result from improper handling of samples in the field and/or lab personnel, improper decontamination procedures, improper shipment and storage and on-site atmospheric contaminations. Adherence to proper field procedures is necessary so that deficiencies can be quickly documented and corrected.
- Representativeness expresses the degree to which sample data accurately and precisely represents environmental conditions and parameter variations at a sampling location. Representativeness is the selection of analytical methods and sampling protocols and locations such that results are representative of the media being sampled and conditions being measured. Representativeness is a qualitative parameter most concerned with the proper design of the sampling program. The representativeness criterion is best satisfied by assuring that sampling locations are properly selected, and a sufficient number of investigative

samples are collected. Representativeness is dependent upon the proper design of the sampling program and will be satisfied by ensuring that the field sampling plan is followed, and proper sampling techniques are used. Representativeness in the laboratory is ensured by using the proper analytical procedures.

- Completeness is the amount of valid data obtained from a measurement system. Laboratory completeness is a measure of the number of valid measurements obtained from all the measurements taken in the project. Although every effort will be made to collect and analyze all of the samples specified in the Project Specification, the loss of a small number of samples, provided that they are not concentrated at a single sample site, will likely have a little effect on the false-negative error rate. The intent of this program is to attempt to achieve a goal of 100 percent completeness. Realizing that under normal conditions this goal may not be achievable, the completeness goal for this program is 95 percent. Completeness is the ratio of the number of valid sample results to the total number of samples analyzed with a specific analysis. Following completion of the analytical testing, the percent completeness will be calculated by the following equation:
    - Completeness = ((Valid Measurements)/Measurements Taken) * 100 %
- Comparability of the data collection activities must consider field conditions as well as sampling and analytical techniques. Comparability is an expression of the confidence with which one data set can be compared to another. Comparability is dependent upon proper design and consistent execution of the sampling program. Analytical data will be comparable when similar analytical methods are used and documented.

B-4.2 Laboratory Quality Control Requirements

The selected laboratories are LDEQ-certified to perform the analytical procedures in accordance with Standard Methods. A copy of the Laboratory Quality Assurance Manual (LQM) is available in the LQMs provided in Appendix C.

Laboratory quality control checks include:

- Laboratory Control Samples / Duplicates
- Matrix Spikes / Duplicates
- Method Reagent Blanks
- Instrument Blanks
- Surrogate Spikes

The laboratory generates precision and accuracy targets from the matrix spikes and matrix spike duplicates to assess precision and accuracy. Evaluation criteria for laboratory control samples are dependent upon sample matrix, analytical instrumentation, and analytical method requirements. Re-analysis is performed in the event samples do not conform to acceptance criteria. Validation and verification procedures are discussed below in Section D-1.2. Quality control requirements for analytical data will be referenced in the SAP. The Contract/Project Manager monitors the project to ensure QA requirements are met. If QC

issues are identified, for example with precision or bias, or corrective actions are required, the laboratory SOPs in Appendix C describe procedures to address and document those issues.

B-5: INSTRUMENT/EQUIPMENT CALIBRATION, TESTING, INSPECTION AND MAINTENANCE

B-5.1 Field Equipment Calibration

Testing, inspection, and maintenance of all field sampling equipment, field instrumentation, and health and safety monitoring instrumentation will be performed by Terracon personnel prior to any deployment for field activities. Testing, inspection, and maintenance will be performed in accordance with referenced TSOPs and manufacturers' recommendations. Terracon maintains an inventory of field equipment at its Baton Rouge office. In cases when equipment malfunctions, or is already in use at another project, needed equipment will be rented from a local or national vender or shipped from another Terracon office.

Field instrumentation and health and safety monitoring instrumentation will be calibrated and logged prior to obtaining measurements and verified by measurement of the calibration standard solution or gas after use in accordance with manufacturers' recommendations and/or instrument-specific TSOPs provided in Appendix A. An example field instrument daily calibration sheet is included in Appendix D.

B-5.2: Laboratory Equipment Calibration

The LQMs in Appendix C outline laboratory analytical instrumentation, calibration testing, inspection, preventive maintenance, frequency, and actions. Only personnel who are thoroughly trained are allowed to operate the instruments. Instrument manuals are always available, along with the SOPs for reference. Written records are maintained to document all maintenance, troubleshooting, and modifications. Daily and routine maintenance improves productivity by minimizing instrument down time. If the instrument cannot be fixed by laboratory staff, then a service call is put in to the manufacturer. No analysis will be run when an instrument is out-of-service. Any maintenance or repair that the service technician does is documented.

Laboratory instrument calibration is outlined in the LQMs contained in Appendix C. All equipment is properly cleaned, and maintenance procedures are documented traceable to equipment.

B-6: INSPECTION/ACCEPTANCE OF SUPPLIES AND SERVICES

Sample containers and other dedicated consumables will meet EPA criteria for decontamination procedures required for low-level chemical analysis. Sample containers will have Level II certification provided by the manufacturer or supplier, in accordance with pre-cleaning criteria established by EPA in "Specifications and Guidelines for Obtaining Contaminant-Free Sample Containers." The certificates of cleanliness are maintained by the container suppliers and can be obtained upon request using the container batch and lot numbers. The inspection and acceptance of supplies will fall within the responsibility of the Quality Assurance Manager upon initial receipt of said supplies The Field Team Leader and Project Manager are responsible for the inspection and acceptance of field supplies and consumables. This will occur during the internal pre-task planning meetings, as well as daily while in the field, prior to use. The following is a list of non-inclusive equipment:

- standard materials and solutions,
- sample bottles,
- calibration gases,
- reagents,
- tubing,
- deionized water,
- potable water, and
- electronic data storage media

If supplies are found to be in conditions that are compromised, new supplies will be acquired, and if deemed necessary, a new provider will be procured to ensure that future supplies will be acceptable. The laboratory GM is responsible for the inspection and acceptance of laboratory supplies and consumables.

Below is a list of subcontracted services Terracon may use during investigations and/or remedial activities:

- Drilling service – Terracon personnel will inspect all drill rigs prior to the start of work to insure there are no fluid leaks, emergency power cutoffs work, augers, and sampling equipment are properly decontaminated. Terracon will inspect all materials used for the construction of wells to verify the material is clean and free of obvious flaws.

- Analytical testing service – Terracon will use only certified laboratories for chemical testing of soil, groundwater, air, asbestos, lead, etc. The laboratory narratives and Quality Assurance/Quality Control analyses for each data package will be reviewed by Terracon personnel.

- Waste (soil/water/product) disposal service – Terracon will provide oversight for the removal of impacted soil, water, and/or product by a subcontractor for proper disposal. The subcontractor used will meet all Department of

Transportation standards/regulations, will have proper disposal manifests, and will provide final disposal paperwork to Terracon.

- Excavating service – Terracon will provide oversight of all soil excavations that may occur. Excavating and hauling equipment used on site will be inspected to ensure there are no fluid leaks or obvious repairs needed. Additionally, Terracon will verify all contractors have the proper insurance and licenses needed to operate.

- In-situ remediation service – Terracon will use only qualified, appropriately licensed, and insured subcontractors to perform injection services for remediation. Terracon personnel will provide oversight for all in-situ remediation work. The subcontractor equipment will be inspected by Terracon to ensure all equipment is in working order (e.g., hoses, valves, pressure gauges, pumps, etc.).

- Surveying service – If surveying services are necessary, Terracon will use a licensed, professional land surveyor. Terracon will ensure that any survey is referenced to a recognized benchmark.

B-7: ENVIRONMENTAL INFORMATION MANAGEMENT

Data may be produced in two locations: on-site (in the field) and at the laboratory. Data collected on-site will be recorded in field logbooks and field log sheets, which become part of the project file and data are included in the assessment report appendices. Select field logs are contained in Appendix D. The Terracon Project Manager (Diana M. Day, P.E.) will review copies of the field sheets, field equipment calibration logs and the field activity reports for errors and accuracy and will submit them the Terracon QAM (Steve Whitting, P.G.) who will complete a second review. Documents and records are maintained in general accordance with TSOPs and EPA requirements. A computer compatible with MS Office Suite® will be used to help process, compile, and manage the data. Terracon maintains project records in a project-specific folder identified by a project number. Field data forms are scanned and placed in an electronic project folder, which also includes, laboratory reports, and final reports. The Terracon Information Technology Department maintains the security of the network with up to date software and virus protection. The restricted access network retains sample results provided from the laboratory in protected electronic form to ensure that laboratory reports remain in their original format.

The laboratory will manage the original raw laboratory data from this project (both hard copy and electronic). The laboratory GM retains and maintains laboratory records. Laboratory records will be managed in accordance with LQMs in Appendix C. The laboratory GM will submit laboratory data to the Project Manager within a standard turn-around time of approximately 7 working days from the laboratory's receipt of the samples. Upon receipt, the data is reviewed for errors and accuracy by the Project Manager, followed by the Terracon QA/QC Reviewer as described in Sections D-1 and D-2 prior to evaluating project management decisions. The Terracon Project Manager will be

responsible for ensuring the analytical report meets project data usability requirements and for forwarding it to the Parish's Brownfields Project Manager when applicable.

A copy of all the final documents will reside for a period of not less than five years, on file with the Grantee. Terracon maintains electronic files on the local office server. This information is backed up daily from Terracon's Corporate Data Center. Hard copies and electronic files for brownfields projects are retained at our local Terracon office for 10 years.

Additional discussion of information and data management, including software used to process, compile, and analyze information, can be found in section A-12.

C-1: ASSESSMENTS AND CORRECTIVE ACTIONS

Because of the relatively short duration of each on-site sampling event, no field audits of sampling procedures will be performed; however, Terracon will provide the USEPA with five working days' notice prior to initiation of field activities should the Agency wish to visit any site concurrent with sampling.

Peer review assessments, management systems reviews, technical systems audits, performance audits, audits of data quality, data usability, or other assessments will be conducted as specified in the SAP. Safety and sampling procedure field checks of fieldwork events may occur on a random basis. Laboratory audits are outlined in the LQMs in Appendix C**.** Peer reviews are performed for all report documents by the QA/QC Reviewer for verification and validation of reported data prepared by the Project Manager, prior to the Project Manager submittal of the report to the Parish's Brownfields Project Manager, LDEQ, and EPA Region 6 Project Officer.

The Field Team Leader in consultation with the Project Manager will be responsible for corrective actions related to field activities. All corrective measures will be thoroughly documented in field logs. If there appears to be a problem that could adversely affect data quality, the *Field Variance Decision Tree* provided in Section B-2.8 was developed with respect to the *Project Organizational Chart* in Section A-10, to provide a clear picture of the assessment and response process for field variances.

C-2: OVERSIGHT AND REPORTS TO MANAGEMENT

The Terracon APRs are responsible for oversight activities of reporting to ensure that response actions and mechanisms are in place to capture the project status and any QA issues that arise during implementation and through assessments. Following completion of field activities, laboratory work, and internal review and data validation, Terracon will develop a report documenting assessment activities, associated data, investigative findings, and assessment conclusions. Necessary deviations will be discussed accordingly. The significance of any deviations requiring corrective action will be evaluated by the Terracon Project Manager before report development.

Any draft plans or reports will be submitted electronically to the Parish following the schedule indicated in the SAP. Final reports will be subsequently developed following incorporation of the Parish's comments and forwarded to LDEQ and USEPA by Terracon directly on behalf of the Parish. Revisions and responses to associated comment letters will be similarly distributed back to the Terracon Project Manager. Final reports will become public record.

D-1: ENVIRONMENTAL INFORMATION REVIEW

D-1.1 Field Data Evaluation

The Project Manager will validate the field data and discuss any problems identified during the project with the Field Team Leader. Data will be reviewed for integrity by checking all field entries for errors and consistency. Data validation will be accomplished through a series of QC checks and reviews intended to ensure that the reported results are of a verifiable, reproducible, and acceptable quality. After data validation, a data usability review, which includes an assessment of field procedures including field notes, boring logs, field screening results, and field analytical data calibration and sensitivity, completeness, comparability, representativeness, precision, and bias (accuracy) of the data, will be performed by the Project Manager in conjunction with the Quality Assurance Manager. The findings of this review will be documented and presented in the final report.

If data validation indicates that field data or samples have been collected and/or analyzed out of compliance with criteria specified in the SAP (for instance deviations from the acceptance criteria for quality control), the Parish's Brownfields Project Manager will be informed by the Project Manager, and resampling may be required. Field modifications regarding sampling analysis may be necessary for circumstances such as drilling refusal, limited access areas, or if ample sample volume could not be collected do to field conditions. Re-sampling may be necessary if results are deemed unacceptable for various reasons such as exceeding laboratory holding times, etc.

If data are accepted that deviate from the SAP, the data will be annotated as such and evaluated by the Project Manager in conjunction with the QAM whether the variance is significant with respect to the decision rule outcome. The Project Manager must contact the Parish's Brownfields Project Manager, LDEQ, and the EPA Region 6 Project Officer in the event that there are any significant deviations from the SAP that adversely affect DQOs and the decision rule outcome. The Parish's Brownfields Project Manager, with input from LDEQ and USEPA, will determine if the data is acceptable or if resampling is required.

D-1.2 Laboratory Data Evaluation

Quality control criteria will be included in the SAP. A summary of validation activities is outlined below:

Table 3 - Validation Activities

Item	Activity
Data Deliverables and QAPP	Ensure that all required information on sampling and analysis was provided (including planning documents).
Analytes	Ensure that required lists of analytes were reported as specified.
Chain of Custody	Examine the traceability of the data from time of sample collection until reporting of data. Examine chain of custody records against contract, method, or procedural requirement. Ensure chain-of-custody time of collection match field record time of collection.
Holding Time	Identify holding time criteria, and either confirm that they were met or document any deviations. Ensure that samples were analyzed within holding times specified in method, procedure, or contract requirements. If holding times were not met, confirm that deviations were documented, that appropriate notifications were made (consistent with procedural requirements), and that approval to proceed was received prior to analysis.
Sample Handling	Ensure that required sample handling, receipt, and storage procedures were followed, and that any deviations were documented.
Sampling Methods and Procedures	Establish that required sampling methods were used and that any deviations were noted. Ensure that the sampling procedures and field measurements met performance criteria and that any deviations were documented.
Analytical Methods and Procedures	Establish that appropriate extraction analytical methods were used and that any deviations were noted. Evaluate the calibration curve reliability of any samples that were diluted due to matrix interferences or concentrations. Ensure that the QC samples met performance criteria and that any deviations were documented.
Data Precision and Accuracy	Establish that data precision (RPD) and accuracy (%R) goals were met
Deviations	Determine the impacts of any deviations from sampling or analytical methods and SOPs. Consider the effectiveness and appropriateness of any corrective action.
Sampling Plan	Determine whether the sampling plan was executed as specified (i.e., the number, location, and type of field samples, duplicates and field blanks were collected and analyzed as specified in the Site-Specific QAPP).
Sampling Procedures	Evaluate whether sampling procedures were followed with respect to equipment and proper sampling support (e.g., techniques, equipment, decontamination, volume, temperature, preservatives, etc.).
Co-located Field Duplicates	Compare results of co-located field duplicates with criteria established in the Site-Specific QAPP.

Item	Activity
Project Quantitation Limits	Determine that quantitation limits were achieved, as outlined in the Site-Specific QAPP and that the laboratory successfully analyzed a standard at the quantitation limit.
Confirmatory Analyses	Evaluate agreement of laboratory results.
Performance Criteria	Evaluate QC data against project-specific performance criteria in the Site-Specific QAPP (i.e., evaluate quality parameters beyond those outlined in the methods).
Data Qualifiers	Determine that the data qualifiers applied were those specified in the Site-Specific QAPP and that any deviations from specifications were justified.
Validation Report	Summarize deviations from methods, procedures, or contracts. Include qualified data and explanation of all data qualifiers.

The laboratory GM will review and verify the laboratory data generated under their corrective action system for accuracy according to the laboratory's QAM, as discussed above in Section B-6, and validation process outlined in the QAM, in Appendix C. Any problems identified during this process will be reported to the Contract/Project Manager. Data anomalies associated with the laboratory will be documented in the laboratory QA narrative report provided in the analytical report, which will be provided as an appendix in the assessment report.

The Contract/Project Manager will validate the field data and discuss any problems identified during the project with the Field Team Leader. Any problems and associated corrective actions will be documented in the field activity report. The Project Manager in conjunction with the QA/QC Reviewer will perform QC checks for verification of the analytical data by using a validation process review of analytical QC results for each sampling event. The QA/QC Reviewer will evaluate the data usability. The validation process includes review of the following:

- Narrative
- Quality control blanks
- Quality control data (spikes, duplicates)
- Surrogate spike recoveries
- Data qualifiers assigned (by lab) if necessary (data qualifiers are defined in the LQMs in Appendix C)
- Precision and accuracy

Precision comparison of duplicate sample results will be made to evaluate the reproducibility of the sample results based on the laboratory analysis and sample collection procedures. Precision is evaluated by the calculating relative percent difference (RPD).

$$\%RPD = \frac{(Duplicate\ 1 - Duplicate\ 2)}{\frac{(Duplicate\ 1 + Duplicate\ 2)}{2}} \times 100$$

Results: <35% RPD = "good/acceptable", >35% to <50% = "slightly high", >50% = "high"

Based on the data qualifiers provided by the laboratory and RPD, analytical data will be categorized as fully quantified, qualified, or unusable. Unusable data will not be utilized in the project decision process. Laboratory reports will be included in all submitted project reports.

The data usability evaluation is outlined in Table 4. The Contract/Project Manager will review the quality control samples, hold times, calibration, surrogate recovery, as well as the precision and accuracy of data. Accuracy of analytical data, based on percent recoveries of know compound spike concentrations relative to QC limits established by the laboratory, are reviewed to evaluate whether the data will be accepted or rejected. Any data limitations will be noted on data summary tables and discussed within the assessment report. In the event data are rejected, the QA/QC Reviewer, Contract/Project Manager, and the Parish's Brownfields Manager will discuss the reasons for the rejection of data and what steps should be initiated including additional site sampling if deemed necessary.

Table 4 - Data Usability Assessment

Item	Assessment Activity
Data Deliverables and QAPP	Ensure that all necessary information was provided, including but not limited to validation results.
Deviations	Determine the impact of deviations on the usability of data.
Sampling Locations, Deviations	Determine if alterations to sample locations continue to satisfy the project objectives.
Chain of Custody Deviation	Establish that any problems with documentation of custody procedures do not prevent the data from being used for the intended purpose.
Holding Times, Deviation	Determine the acceptability of data where holding times were exceeded.
Damaged Samples, Deviation	Determine whether the data from damaged samples are useable. If the data cannot be used, determine whether resampling is necessary.
SOPs and Methods, Deviation	Evaluate the impact of deviations from SOPs and specified methods on data quality.
QC Samples	Evaluate the implications of unacceptable QC sample results on the data usability for the associated samples. For example, consider the effects of blank contamination.
Matrix	Evaluate matrix effects (interference or bias).
Meteorological Data and Site Conditions	Evaluate the possible effects of meteorological (e.g., wind, rain, temperature) and site conditions on sample results. Review field reports to identify whether any unusual conditions were presented and how the sampling plan was executed.

Item	Assessment Activity
Comparability	Ensure that results from different data collection activities achieve an acceptable level of agreement.
Completeness	Evaluate the impact of missing information. Ensure that enough information was obtained for the data to be useable (completeness) as defined in the SAP.
Background	Determine if background levels have been adequately established (if appropriate).
Critical Samples	Establish that critical samples and critical target analytes/constituents of concern, as defined in the QAPP, were collected and analyzed. Determine if the results meet criteria specified in the SAP.
Data Restrictions	Describe the exact process for handling data that do not meet data quality objectives (i.e., when measurement performance criteria are not met). Depending on how those data will be used, specify the restrictions on the use of those data for environmental decision-making.
Usability Decision	Determine if the data can be used to make a specific decision considering the implications of all deviations and corrective action.
Usability Report	Discuss and compare overall precision, accuracy representativeness comparability, completeness, and sensitivity MDL for each matrix, analytical group, and concentration level. Describe limitations on the use of the project if criteria for data quality indicators are not met.

D-2: USEABILITY DETERMINATION

Assessment of site media is generally conducted to evaluate the site for potential COC impacts related to a perceived environmental problem to determine if an environmental remedy is needed relative to the proposed redevelopment. Valid data of known and documented quality is required for all media sampled in order to make the decision. The process for reconciling the data with the project DQOs includes the evaluation of the following questions:

1. Were the appropriate collection procedures followed with the samples collected?

2. Were the collected samples handled in accordance with the SOPs?

3. Were the samples collected from the pre-determined or specific sampling locations?

4. Were the collected samples properly preserved?

5 If applicable, were field sampling problems documented in field logs?

6. Were the analytical methods specified in the SAP used in accordance with the chain of custody procedures?

7. Were any problems identified during laboratory analysis?

8. Was the laboratory data able to meet the MDLs, PQLs, and QA/QC requirements specified in the SAP, and was this documented?
9. What were the results of data validation? Do any of the data points require rejection?
10. If data is problematic, is re-sampling or re-analysis required?
11. If data is rejected, how does the result affect the ability to evaluate the site?

Data generated with significant deviations from the requirements established in the SAP will be rejected. Because biased sampling locations are evaluated during the site assessment, all data will have the same expected uncertainties and there will be no limitations on use of the data, except for rejected data. Once reliable and representative data are obtained, the data will be compared to the appropriate regulatory standards to determine whether the site, or areas within the site, can be considered for redevelopment without environmental remedy. The usability determination will be documented in the Phase II Assessment Report by the Terracon Project QA Manager and any known or anticipated limitations on the use of the environmental information will be communicated to Project Manager.

REFERENCES

Terracon made primary use of the following references in preparation of this document.

U.S. Environmental Protection Agency (EPA), April 1992. *Specifications and Guidance for Obtaining Contaminant-Free Sample Containers*.

U.S. Environmental Protection Agency (EPA) (Online version, multiple dates), *Field Branches Quality System and Technical Procedures*. (https://www.epa.gov/quality/quality-system-and-technical-procedures-lsasd-field-branches)

U.S. Environmental Protection Agency, March 1987. *Data Quality Objectives for Remedial Response Activities, Volume I, Development Process*, USEPA 540/G-87/003A.

U.S. Environmental Protection Agency, April 3, 2024, *Quality Assurance Project Plan Standard*, CIO 2105-S-02.1

Louisiana Department of Environmental Quality, October 2003, *RECAP Screening Standards*

ACRONYMS AND ABBREVIATIONS

μmhos/cm ..... micromhos per centimeter
AAI ..... All Appropriate Inquiry
ACM ..... Asbestos-Containing Material
AHERA ..... Asbestos Hazard Emergency Response Act
AICP ..... American Institute of Certified Planners
AIHA ..... American Industrial Hygiene Association
ARARs ..... Applicable or Relevant and Appropriate Requirements
AST ..... Aboveground Storage Tank
ASTM ..... American Society for Testing and Materials
BTEX ..... Benzene, Toluene, Ethylbenzene, and Xylenes
CAD ..... Computer-Aided Drafting
CERCLIS ..... Comprehensive Environmental Response, Compensation, and Liability Information System
CFR ..... Code of Federal Regulations
CIH ..... Certified Industrial Hygienist
COC ..... Contaminants of Concern
CORRACTS ..... RCRA TSD Corrective Action Facilities
CSM ..... Conceptual Site Model
CTLs ..... Cleanup Target Levels
CWM ..... Clear Wide Mouth Glass Jar
DAO ..... Designated Approving Official
DO ..... Dissolved Oxygen
DQO ..... Data Quality Objective
EDR ..... Environmental Data Resources, Inc.
EPA ..... Environmental Protection Agency
ESA ..... Environmental Site Assessment
ESC ..... Environmental Science Corporation
eV ..... electron-volt
f/cc ..... fibers per cubic centimeter of air
GC ..... Gas Chromatograph
GCTLs ..... Groundwater Cleanup Target Levels
GIS ..... Geographical Information System
GPS ..... Geographical Positioning System
GRO ..... Groundwater Remediation Objective
HASP ..... Health and Safety Plan
HAZWOPER ..... Hazardous Waste Operations and Emergency Response

ACRONYMS AND ABBREVIATIONS (cont.)

HCl ..... Hydrochloric Acid
HNO_3 ..... Nitric Acid
HUD ..... United States Department of Housing and Urban Development
ICP ..... Inductively Coupled Plasma
IDW ..... Investigation Derived Waste
IMPDMENT ..... Impoundment
L ..... liter
LBP ..... Lead-Based Paint
LCS ..... Laboratory Control Sample
LDEQ ..... Louisiana Department of Environmental Quality
LQAP ..... Laboratory Quality Assurance Programs
LQM ..... Laboratory Quality Assurance Manual
LUST ..... Leaking Underground Storage Tank
mg/kg ..... milligrams per kilogram
mL ..... milliliter
MS/MSD ..... Matrix Spike/Matrix Spike Duplicate
MWSR ..... Monitoring Well Sampling Record
NaOH ..... Sodium Hydroxide
NELAC ..... National Environmental Laboratory Accreditation Conference
NESHAP ..... National Emissions Standards for Hazardous Air Pollutants
NFR ..... No Further Remediation
NIST ..... National Institute of Standards and Technology
NLLAP ..... National Lead Laboratory Accreditation Program
NTU ..... Nephelometric Turbidity Units
OSHA ..... Occupational Health and Safety Administration
OVM ..... Organic Vapor Meter
oz ..... ounce
PAH ..... Polycyclic Aromatic Hydrocarbon
PCB ..... Polychlorinated Biphenyl
PE ..... Professional Engineer
PPE ..... Personal Protective Equipment
PG ..... Professional Geologist
PLM ..... Polarized Light Microscopy
PQL ..... Practical Quantitation Limit
QA ..... Quality Assurance
QAPP ..... Quality Assurance Project Plan
QAM ..... Quality Assurance Manager
QC ..... Quality Control
RECAP ..... Risk Evaluation/Corrective Action Program
RCRA ..... Resource Conservation and Recovery Act
RPD ..... Relative Percent Difference
SCTLS ..... Soil Cleanup Target Levels
SOP ..... Standard Operating Procedure

ACRONYMS AND ABBREVIATIONS (cont.)

SVOC..... Semi-Volatile Organic Compound
TCLP..... Toxicity Characteristic Leaching Procedure
TLS .....Terracon Learning System
TSOP .....Terracon Standard Operating Procedure
USEPA ..... United States Environmental Protection Agency
VOC .....Volatile Organic Compound

APPENDIX A

Terracon Standard Operating Procedures

E.10
PROJECT MOBILIZATION

Last Review / Revision: December 2013
Reviewer / Office: DEK/Corporate

OBJECTIVE

Allow field personnel an opportunity to review the requirements and objectives for performing the necessary field tasks and discuss with the project manager concerns associated with the project, safety, and methodologies.

Key to Terracon's Incident and Injury Free culture is pre-task planning. Pre-Task Planning is the most proactive skill we can learn to create and sustain an IIF workplace and make sure all of our employees go home safely every day. It is required from the very beginning when preparing proposals and starting projects, as well as when we assign work and execute the tasks throughout the day. This includes mobilization for projects.

PROCEDURE

Field personnel should discuss the proposed field activities with the project manager prior to initiating the site work. This will be a formal "sit down, face-to-face" transfer of project information and objectives from the Project Manager to the designated field or task manager. All parties will engage in the planning. This should include, but not be limited to, discussions on:

Project Objectives

Assure that personnel have an understanding of the objectives prior to initiating the field activities. This will provide a greater insight and allow field personnel to make appropriate decisions based on site specific conditions. This briefing provides background information which allows the field personnel to think about field operations in a way which will optimize performance and data gathering efficiency.

Discuss the regulatory framework within which the report and results of field work will be used. Identify special requirements of specific regulatory programs.

Specific to EPA Brownfield Grant or Pilot Projects of Any Type
The mobilization Team will have in hand as part of planning mobilization copies of the following;

- Site eligibility determination approved by EPA Project Officer
- Access agreement signed by the property owner, not a tenant
- EPA-approved Quality Assurance Project Plan (QAPP)
- EPA-approved Sampling and Analysis Plan

Site Safety Plan (SSP)

Staff will implement IIF using the Terracon *Pre-Task Planning Quick Reference Sheet*, available here if viewing this electronically or it can be printed from the Terranet Corporate Safety Website under the IIF Toolbox section.

The team will then review the SSP with the project manager and sign the acknowledgement. Confirm that you have the proper monitoring equipment, protective clothing and respiratory device and confirm that you are aware of the monitoring requirements and safety level.

Permits/Right of Entry (R.O.E.)/Utility Clearance

Make sure that the proper permits, R.O.E. and utility clearance have been secured. This will avoid delays at the job-site. Determine that all parties, including the client, property owner or tenant, and regulatory official have been notified, if necessary.

Drilling/Development/Sampling Requirements

Review the drilling/development/sampling requirements to allow for satisfactory completion. Determine location of all borings/monitoring wells and the soil and groundwater sampling sequence for chemical analysis and definition of the stratigraphy.

Decontamination

Review cleaning procedures and TSOPs for the drilling equipment and/or sampling equipment. This is imperative to minimize cross-contamination and maintain safe site conditions.

Communications

Establish a communications link in the event that field personnel must consult with the project manager or designee in instances when the project manager cannot be reached.

Chain-of-Custody

Review the procedures to provide for proper Chain-of-Custody maintenance from sample collection through analysis.

Equipment

Confirm that the proper equipment is available, functional, cleaned, and calibrated. The project manager should provide a checklist of all equipment required, especially when the equipment needs to vary from the norm.

DOCUMENTATION

The project manager is responsible for providing the following documentation to the field crews prior to field activities:

- Site Safety Plan (completed)
- Mobilization Sheet
- Site Location Map
- Site Diagram
- Field manuals and references as appropriate
- Site photography, when appropriate and allowed

E.20
STANDARD SAFE OPERATING PROCEDURES FOR HAZARDOUS WASTE OPERATIONS

Last Review or Revision: June 2010

I. PURPOSE

This document defines standard safe operating procedures for use on project sites where intrusive activities will be preformed and where soil/groundwater contaminants are known or are reasonably expected to exist. These procedures will be incorporated in the project safety and health plan which is mandatory for intrusive activities conducted at all such project sites.

II. SAFETY AND HEALTH RESPONSIBILITY

A. The Project Manager is ultimately responsible for ensuring that work on environmental investigation/remediation projects are performed in accordance with provisions outlined in the project safety and health plan. A Site Safety and Health Officer (SSO) will be designated at each project site to monitor compliance with this safety-related practices during field activities. The SSO will ensure that a copy of the safety and health plan is available on site for the duration of project activities.

B. The Corporate Safety and Health Manager will be consulted for each intrusive environmental investigation/remediation project. The Corporate Safety and Health Manager will develop the site safety and health plan, and will be available to consult with Project Manager/SSO in the event of questions, concerns or changed site conditions. The Corporate Safety and Health Manager will specify air monitoring and personal protective equipment requirements for the project, and will assist in obtaining specialized equipment required for the project.

C. If hazardous conditions develop during the course of project activity, the SSO in conjunction with the Terracon Corporate Safety and Health Manager, will coordinate actions required to safeguard site personnel and members of the general public. Additional safety measures will be verbally communicated to all project personnel, recorded in writing and appended to the site safety and health plan.

D. Terracon and subcontractor task leaders will be responsible for:

- Presenting the contents of the site safety and health plan to all subordinate site personnel.
- Monitoring compliance with applicable provisions of the safety and health plan.

- Periodically inspecting heavy equipment and other machinery and maintaining such equipment in compliance with applicable federal, state or local safety regulations.

- Enforcement of corrective actions.

III. MEDICAL SURVEILLANCE

A. All Terracon personnel participating in intrusive projects with known or reasonably anticipated contaminants must be enrolled in the Terracon Medical Surveillance Program. Each project participant will be certified by a licensed physician as fit for respirator and semi-permeable/impermeable protective equipment use. Medical clearance will be current to within one year of the project start date.

B. Certificates of medical examination for all project personnel will be maintained by the Corporate Safety and Health Manager and/or by the SSO in the project command center or support vehicle.

C. At the discretion of the Terracon consulting physician, an "exit" physical examination will be conducted at the completion of project activities or upon termination of a project participant. Follow-up medical examinations will also be provided in the event of job site injury or unprotected exposure to contaminants in excess of eight-hour time weighted average permissible exposure limits.

IV. TRAINING REQUIREMENTS

A. Terracon personnel participating in hazardous waste operations will have completed 40 hour Hazardous Waste Operations Training and at least three days supervised field activity. A current 8-hour annual refresher training certificate will be required for all personnel. Training certificates for all project personnel will be maintained by the Corporate Safety and Health Manager.

B. The SSO will conduct a pre-project safety and health briefing for all project participants. The personnel responsible for project safety and health will be addressed, as will site history, scope of work, site control measures, emergency procedures and site communications. The briefing will address site contaminants, air monitoring protocols, action levels for upgrade/downgrade of personal protective equipment and level of personal protective equipment to be employed for each project task.

C. Project participants will sign the Acknowledgment of Instruction form contained in each safety and health plan following the initial site briefing.

V. CHEMICAL HAZARDS

A. The Project Manager is responsible for obtaining available information regarding site contaminants, including analytical information obtained from samples previously collected at the project site, and for forwarding the information to the Corporate Safety and Health Manager for research and hazard analysis. A site specific safety and health plan will be developed notifying personnel of the

potential chemical contaminants, their health hazards, routes of entry, warning properties and symptoms of exposure.

B. Evaluation of chemical contaminants/concentrations will be used in the development of the air monitoring and personal protective equipment requirements contained in the site safety and health plan.

VI. PHYSICAL HAZARDS

A. Drilling Projects

- All personnel working around drill rigs will be familiarized with emergency shut-down procedures and the position of "kill" switches.
- No loose fitting clothing, jewelry or unsecured long hair is permitted near the rig.
- Keep hands and feet away from all moving parts while drilling is in progress. Shovel auger cuttings with long handled shovel. *DO NOT* use hands or feet.
- Daily inspection of all ropes, cables and moving parts is mandatory.
- A first aid kit and fire extinguisher will be immediately available at all times.
- All drill crews shall consist of at least two persons.
- No drilling is permitted during impending electrical storms, tornadoes or when rain creates a hazardous work environment.
- A minimum horizontal and vertical clearance distance of **10 feet** must be maintained between the drill rig and overhead power lines; use spotters to help rig operator position the vehicle when near overhead power lines.

B. Excavation Project Sites

- Wherever possible, soil samples will be collected from backhoe buckets. Personnel will enter excavations only as a final option and only in accordance with the regulatory requirements outlined above.
- AT NO TIME WILL TERRACON PERSONNEL ENTER EXCAVATIONS TO COLLECT SOIL SAMPLES UNTIL A PROPER MEANS OF EGRESS/EXIT IS PROVIDED AND THE EXCAVATION HAS BEEN INSPECTED BY A COMPETENT PERSON AND APPROPRIATELY SHORED OR SLOPED IN ACCORDANCE WITH THE OSHA EXCAVATIONS STANDARD (29 CFR 1926, SUBPART P).
- Personnel will remain at least 3 feet from the sides of excavations during sample collection and excavation observation.
- Personnel will remain outside the swing radius of backhoe buckets during excavation, and will stand behind the backhoe or within line-of-sight contact with the backhoe operator at all times.

VII. ACCIDENT PREVENTION

- The Site Safety Officer will hold daily safety briefings at the beginning of each day of site activity.

- Traffic control measures will be arranged for all projects conducted within or immediately adjacent to active roadways. Signage, warning and/or channelizing devices will conform to the Manual on Uniform Traffic Control Devices. Flagging operations will be conducted only by personnel who have received training in proper traffic flagging procedures. The preferred method of traffic control will be to contract these services to a reputable traffic control service knowledgable in local traffic control regulations.

- Safety orange work vests will be worn by personnel working within 10 feet of any active roadway.

- The Site Safety Officer will ensure that unauthorized personnel do not enter the work zone. Authorized visitors will be briefed on site contaminants, personal protective equipment requirements and the decontamination provisions of the site safety and health plan.

- The Site Safety Officer will continually inspect the work area for infractions of safety and health requirements as contained in the site specific safety and health plan.
- The Site Safety Officer will investigate and immediately report all accidents to the Corporate Safety and Health Manager.

- Site activities will be conducted only during daylight hours unless adequate portable lighting is mobilized to the project site.

- The "buddy system" will be observed at all times during intrusive site investigations. A minimum of two people will work together and remain within eye sight or not greater than 100 ft. apart.

- Teamwork and the use of mechanical lifting devices will be employed where practical to ease lifting tasks and reduce the potential for muculoskeletal injury.

VIII. SITE CONTROL

A. An Exclusion Zone, Contaminant Reduction Zone and a Support Zone will be established on hazardous waste operations sites requiring Level C or Level Bpersonal protective equipment. Defined access and egress points will be established and personnel will enter only through those points.

B. As permitted by site topography, the area within a 50 foot radius of a drill rig and 100 foot radius of UST removal excavations will be considered the Exclusion Zone. Only those personnel designated by the Project Manager/SSO are allowed to enter the Exclusion Zone. Where practical, or where their use will prevent public injury, temporary signs or barricade fencing will be established to define the Exclusion Zone. ABSOLUTELY NO SMOKING WILL BE PERMITTED WITHIN

THE EXCLUSION OR CONTAMINANT REDUCTION ZONES ON ANY PETROLEUM CONTAMINATED SITE.

C. If unauthorized personnel attempt to enter the exclusion zone, the SSO will verbally inform the individual(s) to leave the project site. If unauthorized individuals refuse to leave the Exclusion Zone or are considered in danger or pose danger to project personnel, the SSO will cease project activities (i.e., shut down drill rigs, excavation equipment, etc.) and notify the client representative or the local police of the situation.

IX. AIR MONITORING

A. Air monitoring protocols will be designed to prevent personnel exposure to airborne contaminants in excess of established permissible exposure limits. The results of field air monitoring will be used to determine the continued adequacy of initial personal protective equipment.

B. Task Leader(s) will be knowledgeable in the operation and troubleshooting of air monitoring equipment. A manual on the operation of each air monitoring instrument and an appropriate calibration kit will be mobilized to the project site with the instrument. Air monitoring instruments will be calibrated under field conditions each day prior to use. Task Leaders are instructed to consult the operator's manual for appropriate calibration gas and calibration techniques.

X. PERSONAL PROTECTIVE EQUIPMENT

Personal protective equipment requirements for each hazardous waste operations site and task will be specified in the site safety and health plan. Personal protective equipment selection will be based upon the site contaminants and tasks to be performed. Personal protective equipment ensembles will be selected in general accordance with standard EPA levels of protection as follows:

A. **Level A** - To be selected when the greatest level of skin, respiratory, and eye protection is required. Level A personal protective equipment ensembles will consist of:

1. Positive pressure, full face-piece self-contained breathing apparatus (SCBA), or positive pressure supplied air respirator with escape SCBA, approved NIOSH.
2. Totally-encapsulating chemical-protective suit.
3. Coveralls.(optional, as appropriate)
4. Long underwear.(optional, as appropriate)
5. Gloves, outer, chemical-resistant.
6. Gloves, inner, chemical-resistant.
7. Boots, chemical-resistant, steel toe and shank.
8. Hard hat (under suit).(1)
9. Disposable protective suit, gloves and boots

B. **Level B** - To be selected when the highest level of respiratory protection is necessary but a lesser level of skin protection is required. Level B personal protective equipment ensembles will consist of:

1. Positive pressure, full-facepiece self-contained breathing apparatus (SCBA), or positive pressure supplied air respirator with escape SCBA (NIOSH approved).
2. Hooded chemical-resistant clothing (overalls and long-sleeved jacket; coveralls; one or two-piece chemical-splash suit; disposable chemical-resistant overalls).
3. Coveralls.(optional, as appropriate)
4. Gloves, outer, chemical-resistant.
5. Gloves, inner, chemical-resistant.
6. Boots, outer, chemical-resistant steel toe and shank.
7. Hard hat.

C. **Level C** - To be specified when the identity and approximate concentration of airborne contaminants is known and the criteria for using air purifying respirators are met. Level C personal protective equipment ensembles shall consist of the following:

1. Full-face (typically) air purifying respirators (NIOSH approved).
2. Chemical-resistant clothing (coveralls; two-piece chemical-splash suit; disposable chemical- resistant overalls, as appropriate).
3. Gloves, outer, chemical-resistant.
4. Gloves, inner, chemical-resistant.
5. Boots (outer), chemical-resistant steel toe and shank.
6. Disposable boot-covers, outer, chemical-resistant (optional)
7. Hard hat.(1)

D. **Level D** - A work uniform affording minimal protection. Level D or modified Level D personal protective equipment will be used when contaminant concentrations are low and not readily absorbable through the skin and where atmospheric monitoring indicates no need for respiratory protection. The following constitute Level D equipment; it may be used as appropriate:

1. Coveralls.
2. Chemical-resistant gloves.(style selected based on contaminants)
3. Boots/shoes, chemical-resistant steel toe and shank.
4. Boots, outer, chemical-resistant (disposable).
5. Safety glasses or chemical splash goggles (where appropriate).
6. Hard hat.

XI. DECONTAMINATION

A. Equipment decontamination is necessary on all contaminated project sites. Personnel decontamination for projects below personal protective Level C will consist of washing off safety footwear, proper cleaning or disposal of outer and inner gloves and thorough washing of face, arms and hands. A full body shower will be required as soon as possible upon leaving the project site.

B. For projects involving personal protective equipment at Level C or above, a decontamination station will be established on the interface of the Exclusion Zone. A Contaminant Reduction Zone will be established and will extend 10 feet beyond the decontamination station.

- Two Wash Tubs
- Scrub Brush
- Plastic Bags
- Water and Alconox Detergent

The wash tub on the exclusion zone side of the site will contain a solution of water and Alconox detergent; the second wash tub will contain clean rinse water. Personnel decontamination will consist primarily of detergent washing and rinsing of reusable exterior protective gear. Coveralls will be removed by turning the clothing inside out.

Personnel may not leave the contaminant reduction zone without proceeding through the decontamination sequence described below.

- Wash work gloves, boots and polylaminated protective coveralls,
- Rinse work gloves, boots and coveralls,
- Remove tape at wrists and ankles,
- Remove protective coveralls,
- Remove respirator
- Dispose of spent cartridges; wash and rinse respirator
- Remove outer gloves
- Remove inner gloves

Expendable personal protective equipment will be placed in plastic trash bags, sealed and disposed of per client agreement. Decontamination solutions will be containerized or disposed of as arranged by Project Manager.

C. Decontamination of equipment will be performed to limit the migration of contaminants off-site. All equipment will be cleaned prior to site entry to remove grease, oil and encrusted soil. Decontamination of large equipment will consist of physically removing gross contamination with shovels, brushes etc. followed by detergent and water high pressure wash with a clean water rinse. The Project Manager is responsible for determining if decontamination solutions must be containerized. If so, a decontamination sump or polyethylene sheeting and fluid containers will be mobilized and established in the decontamination area. Decontamination of hand samplers and similar small equipment will be performed at a designated location within the Contaminant Reduction Zone. Decontamination of such equipment will consist of detergent solution wash and clean water rinse. Specialized decontamination solutions (acids, solvents, biocidal, etc.) may be specified in site specific site safety and health plans.

XII. SITE COMMUNICATIONS

Communication between personnel on most hazardous waste project sites will be via verbal communication or hand signals. Visual contact between members of task teams should be possible throughout the course of project activities. Contact with the SSO will be through direct

verbal communication. The following hand signals will be used whenever verbal communication is limited:

Signal	Meaning
Thumbs Up	OK, all is well
Grab throat with both hands	Can't breathe
Shake head, thumbs down	NO, negative
Point right (when facing equipment operator)	Move/steer left
Point left when facing equipment operator)	Move/steer right
Grab partner's wrist	Leave area immediately

XIII. EMERGENCY RESPONSE PROCEDURES

A. The Project Manager is responsible for obtaining and recording emergency telephone contacts in the appropriate section of the site safety and health plan prior to site mobilization: A mobile telephone will typically be available on hazardous waste operations project sites.

B. In the case of personal injury, appropriately trained personnel will be requested to provide first aid and emergency rescue. For minor injuries, such as cuts, burns, exhaustion, heat cramps, insect stings, etc., the affected employee will be removed to an uncontaminated area. The SSO or other designated employee trained in first aid procedures will administer appropriate first aid. If the injury requires additional medical attention, the injured employee will be cleaned and transported to the nearest hospital or emergency medical facility.

C. For more serious injuries the SSO or designee will summon an ambulance to the project site. No attempt will be made by Terracon personnel to move the victim, without the aid and/or instructions of qualified medical personnel.

D. If the victim cannot be safely moved without a stretcher or other specialized equipment, the victim will be removed at the earliest possible moment by appropriately attired Terracon personnel with the direction and/or assistance of qualified medical response personnel. The injured employee will be immediately decontaminated and transported to the nearest medical facility. A crew member designated by the SSO will inform the ambulance crew of contaminants of concern and provide assistance with additional decontamination if required.

XIV. EVACUATION AND SHUTDOWN PROCEDURES

A. On project sites posing a significant risk of chemical or physical hazard exposure, the site safety and health plan will instruct the SSO to establish and notify site personnel of emergency "rally" points. In the event of a site emergency, personnel will immediately exit the site and assemble at the designated rally point. Evacuation routes will be dependent on site topography and wind conditions. The routes will be selected and presented by the SSO daily prior to site activity.

B. If emergency evacuation becomes necessary, the SSO will sound the emergency alarm (e.g. support vehicle horn or compressed air horn). Personnel will safely

shutdown all electrical and mechanical equipment and quickly proceed to closest designated rally point. The SSO will then account for each crew member on site.

C. In the event that a Terracon employee does not report to the designated rally point within 5 minutes of the evacuation alarm, the SSO will perform an immediate assessment of site conditions. If site conditions do not pose an immediate hazard to life or health, the SSO will initiate search and rescue efforts utilizing two crew members attired in appropriate personal protective equipment.

E.25
BASIC RECORDKEEPING AND FIELD DOCUMENTATION

LAST REVIEW/REVISION: February 2014
REVIEWER/OFFICE: DEK/Corporate

OBJECTIVE

To provide a basic level and quality of documentation throughout Brownfield projects that complements and supports other data collection forms in the course of conducting field activities during environmental assessments, sampling, or remediation. The intent is not to place into writing an extensively detailed "diary" of every activity, but rather to log and record significant information that is useful as a measure of field activities during report writing and discussions with clients and agencies. The information should be legible and readily understood by other than the author; later being used as a reference by managers, other project staff and quality assurance reviewers.

PROCEDURES

Appropriate documentation will be maintained to track project activities and document quality control. The following sections describe the specific records that will be maintained through the duration of the project.

Individual TSOPs, agency- or client-approved sampling plans or other referenced guidance may prescribe specific additional documentation that staff will complete specific to field tasks. These forms will be fully completed unless otherwise approved by the Project Manager. Errors in all documents shall be deleted with one line through the erroneous text, and initialed by the author. At the start and end of work day on the site, the time shall be noted and each initialed or signed by the author.

Common and routine field documentation includes, but is not limited to the following;

Safety



Every environmental project should be accompanied by a formal project-specific Health and Safety Plan (HASP or HSP). The on-site copy of the HSP will be incorporated into field documentation for on-site use, reference and field notations of required safety measurements. Any pre-task planning should be included.

Copies of Work Scope

The on-site copy of the final site-specific sampling and analysis plan will be incorporated into field documentation for reference and field notations relative to field-dictated changes in sample collection, field screening, and laboratory analysis procedures. Field copy of the sampling plans will include drawings and maps that illustrate property location, property features, and proposed sampling locations relative to these features. The rationale behind each proposed location and laboratory analysis will be provided in text and/or tables of the sampling plan for reference by field staff.

If a formal sampling and analysis plan is not required for the sampling activity or if the plan is field-derived (i.e., Triad approach), a field copy of the final proposal with scope of work will be incorporated into field documentation for reference and field notations relative to field-dictated changes in sample collection.

If a formal Quality Assurance Project Plan (QAPP) is required for the sampling activity, a field copy of the QAPP will be maintained with field documents for in-progress reference and discussions with off-site managers/supervisors during the course of field activities.

Field Logbook



Field site managers will document activities on daily log forms. The site manager will maintain the daily log forms with a field copy of the QAPP and Property-Specific Sampling and Analysis Checklists. Between field mobilizations, the Terracon Project Manager or Field Site Manager will maintain the daily log forms in a project file that will be placed at a central file location (see Sections **Error! Reference source not found.** and **Error! Reference source not found.**) following completion of the project. The daily log forms will include documentation relative to observed site conditions, sample collection information, problems encountered, sampling plan deviations, photograph logs, and other relevant information.

Custody Records

Field site managers will maintain a copy of completed chain-of-custody records for collected laboratory samples. The Field Site Manager will provide the Terracon Project Manager copies of the completed chain-of-custody forms following completion of field activities. The Project Manager will subsequently maintain these records at the central office file location.

Photographic Documentation

A photographic log will be maintained to document project activities and site conditions. Photographs will be taken during each day of major field activity. Photographs will be stored electronically and as hard copies with the project file. Logs will be maintained to document photograph details such as date, direction, photographer, and photo descriptions.

In taking photographs to document site conditions, field staff should keep in mind the following general rules;

- Include objects of scale in the photographs. Preferably items of known dimension in close-up pictures (e.g., rulers, tape measures, survey rods) and common objects for wider view documentation of the property (e.g., car, street sign).
- Keep in mind how the documentation will be used and presented in the final report. If unsure, ask the Project Manager.
- To the extent practical, document the site from a distance and from different directions so that other users have a perspective of the “total” site.
- Take and document more pictures than you will need for the final report.

E.30
CHAIN OF CUSTODY DOCUMENTATION

Last Revision: June 2010

OBJECTIVE AND APPLICATION
This document defines standard operating procedures for documenting sample collection using proper chain-of-custody techniques. The purpose of proper chain-of-custody techniques is to provide accountability for and documentation of sample integrity from the time samples are collected until sample disposal.

This procedure is intended to document sample possession during each stage of a sample's life cycle, that is, during collection, shipment, storage, and the process of analysis.

EQUIPMENT
- Terracon chain-of-custody record(s) or laboratory-specific chain-of-custody forms (typically supplied with sample containers),
- If samples are being shipped via courier, custody seals for coolers,
- Indelible ink marker, and
- Zip top bag.

PROCEDURE
Sample containers will be labeled in advance of sampling with the sample date, location (well identifier), sampler's initials, and project name. Written sample custody procedures will be followed whenever samples are collected, transferred, stored, analyzed, or destroyed, in order to trace possession and handling of a sample from collection to disposal. Accountability for a sample begins when the sample is collected. Each sample will be accounted for with the use of sample labels, chain-of-custody forms, a record of sample collection, and field data notebooks.

The following chain-of-custody procedures will be implemented by the field staff:

- Entries in the field notebook and chain-of-custody form will be made in ink. Documentation of each sample must be completed at the time of sampling.
- The chain-of-custody should include at a minimum:
  - Project name and/or number
  - Name and contact information for the sampler collector
  - Collector's signature
  - Sample designation

  - Date sampled
  - Time sampled
  - Sample media
  - Number and size of containers for each sample
  - Types of sample preservatives used
  - Analyses requested
- The original chain-of-custody must accompany the samples at all times after collection, until receipt at the analytical laboratory. A copy of the chain-of-custody form will be kept by the field staff until filing at the office.
- The original chain-of-custody form should be sealed in a Ziplock bag if shipping samples on ice via courier. The sealed Ziplock bag will protect the document from moisture that may be present due to sample preservation. The chain-of-custody should be the last item packed in a sample cooler, so that it is easily accessible if the cooler is misplaced by the courier or shipped to an incorrect address.
- If shipping samples, a chain-of-custody specific to the contents of each cooler will be packaged with the respective samples. Chain-of-custody forms should not be shipped in separate containers than the samples they document. At least one custody seal should be completed by the collector and applied to each cooler sent to the laboratory. The custody seal should be affixed to the cooler in such a manner as to ensure breakage of the seal upon opening of the cooler (e.g., across the cooler lid opening).
- When the possession of samples is transferred, the individuals relinquishing and receiving the samples will sign, date, and note the time on the chain-of-custody form.
- If samples are shipped, strict chain-of-custody is violated. However, at the discretion of the project manager the procedures can still be followed.

ATTACHED REFERENCES

Terracon Form COC-7/92 *Chain-of-Custody Record*, revised 4/93

Quality Environmental Containers *Custody Seal*

OTHER SUPPORTING DOCUMENTS

ASTM D4840-99 *Standard Guide for Sampling Chain-of-Custody Procedures*

E.2240
SITE SECURITY PROCEDURES

Last Review or Revision: June 2010

Objective
To establish procedures for the security of the subject site and remediation systems during hours when employees are not present.

Equipment

a) Keyed-a-like locks.

b) Site key file box.

c) Site diagrams.

d) Operation and Maintenance procedures.

e) Materials specified by the Project Manager.

Procedures

a) Site Security

The Project Manager will determine the specific security requirements for each site. Coordination with the client may be necessary to provide additional keys if needed. Keyed-a-like locks should be the same throughout the entire system. A benchstock of commonly used locks is maintained for the field crews to replace broken or damaged locks. If open excavations or sensitive materials are located on-site, the Project Manager may specify the use of access control, such as fencing or barricading.

b) Key Control

Keys for each system will be maintained in the central key control box in the Terracon Office. Additional keys may be maintained by field crews and the project manager for routine access. The site keys will be contained on a tab and clearly marked with the site name, job number and location.

c) Site Monitoring

The field crew conducting field services is responsible for the security of the site. A final review must be conducted daily prior to leaving the site to check and document site security. The field crew will complete the "Daily Job Report" to indicate that the site is secure or that exceptions were encountered at the site. The project manager will then be able to schedule the necessary corrective action.

d) Site Documentation

Documentation must be maintained at each remediation site to assist field crews in routine operation, maintenance, and emergency activities. The following documents are to be maintained on site:

1. Site diagram of all wells associated with the site;
2. Schematic of the system including free product and water lines;
3. Electrical diagram;
4. Site Safety Plan;
5. Maintenance checklist and schedule;
6. Current settings and operational limits of the system (switch settings, and flow rates);
7. Summary of system operational characteristics (flow rates, inventory levels,
8. Operational and Maintenance manuals for all system components;

All components of the system are to be labeled for identification. This includes pump controls, flow lines, product lines, level probes, and valves.

e) Signs

Each site should have a sign identifying the site and indicating critical information concerning the operation of the system in the event unusual operations are encountered. This could include the client's name and phone number, or Terracon's name and phone number.

f) Vehicles

Secure all vehicles left on-site during non-working hours. Lock all doors and close all windows. Store the keys in the central key control box.

Following is an example of a Daily Job Report. Either this form or another similar form will be utilized to document daily on-site activities.

Job No _____

Test Date _____

DAILY JOB REPORT

Time on Job _____

Job Name _____

Time in Lab _____

Job Location_____

Time in Office _____

Contractor _____

Travel Time _____

TOTAL CHARGEABLE HOURS _____

Client _____

MILEAGE _____

Description of technical and/or engineering field operations including field test data*, locations (show direction of north), elevations, and other information:

_____

_____

_____

_____

_____

_____

_____

_____

TERRACON states that the above tests and/or field engineering services have been performed and the results are reported herein. This report, however, does not relieve the contractor of the responsibility to comply with the plans and specifications.

*Indicate when the field test data is estimated, pending final laboratory test results.

Attested to: _____

Position: _____

Company: _____

TERRACON
By: _____

FORM 113 - 6/85

E.2405
CLEANING – GENERAL

LAST REVIEW OR REVISION: June 2010

OBJECTIVE AND APPLICATION

To prepare the equipment for field activities in a manner that minimizes the potential for obtaining biased or erroneous data due to contaminant transfer. Cleaning is performed as a quality assurance measure and a safety precaution. It minimizes cross-contamination between samples and also helps to maintain a clean working environment. This procedure provides general guidelines and should be used in conjunction with more specific procedures applicable to the cleaning method used.

EQUIPMENT

- As determined by the project manager
- Expendable supplies:
  - Disposable chemical-resistant gloves
  - Garbage bags
  - Aluminum foil or plastic
  - Laboratory glassware detergent such as Alconox or Trisodium Phosphate (TSP)
  - Containers for collection of waste liquids, if necessary
  - Dilute acid, methanol, ethanol, isopropyl alcohol or other cleaning fluid
- Source of potable water without chemicals that would interfere or be identified in chemical analysis of samples. The project manager may require laboratory testing of cleaning water as a background for evaluating chemical analyses.

PROCEDURES

Cleaning procedures will vary considerably based on the equipment, type of contaminant, type of sample and detection levels. Initial cleaning should take place at the site prior to demobilizing. This will minimize the spread of contamination. The extent of on-site cleaning will vary based on specific conditions; however, an attempt should be made to decontaminate as thoroughly as possible on site. The more care one applies on keeping the equipment clean, the less energy will be required on cleaning.

All field equipment must be prepared at the laboratory/office prior to use. This will include additional cleaning, inspection, and maintenance.

Equipment such as hand trowels, bailers, mixing bowls, hand augers, etc., should be cleaned and wrapped in aluminum foil (with shiny side out) or plastic, as appropriate, prior to mobilization.

Sampling and monitoring equipment is normally cleaned by washing and rinsing with liquids such as a soap or detergent solution, potable tap water, deionized water (DI), isopropyl alcohol, methanol, or a dilute acid.

The extent and type of contaminant will determine the degree of cleaning. If the level of contamination cannot be readily determined, cleaning should be based on the assumption that the equipment is highly contaminated.

Waste products produced by the cleaning procedures such as waste liquids, solids, gloves, used Chem-wipe® cleaning pads, etc., should be collected, stored in USDOT-approved 55-gallon drums on-site and disposed based on the nature of the contaminant. Specific details for the handling of these wastes should be addressed by the project manager.

E.2410
CLEANING – MANUAL WASHING

LAST REVIEW OR REVISION: June 2010

OBJECTIVE AND APPLICATION

To prepare the equipment for field activities in a manner that minimizes the potential for obtaining biased or erroneous data due to contaminant transfer between sampling locations. Cleaning is performed as a quality assurance measure and a safety precaution. It minimizes cross-contaminants between samples and also helps to maintain a clean working environment.

EQUIPMENT

- As determined by the project manager
- Expendable supplies:
  - Disposable chemical-resistant gloves
  - Chem-wipe® cleaning pads
  - Garbage bags
  - Laboratory glassware detergent such as Alconox or Trisodium Phosphate (TSP)
  - Containers for collection of waste liquids, if necessary
  - Dilute acid, methanol, isopropyl alcohol, ethanol or other cleaning fluid
- Wash rack facility
- Cleaning containers with brushes (plastic, steel or stainless steel buckets)
- Aluminum foil or plastic
- Source of potable water without chemicals that would interfere or be identified in chemical analysis of samples. The project manager may require laboratory testing of cleaning water as a background for evaluating chemical analyses.

PROCEDURES

Cleaning procedures will vary considerably based on the equipment, type of contaminant, type of sample and detection levels. Initial cleaning should take place at the site prior to demobilizing. This will minimize the spread of contamination. The extent of on-site cleaning will vary based on

specific conditions; however, an attempt should be made to decontaminate as thoroughly as possible on site. The more care one applies on keeping the equipment clean, the less energy will be required on cleaning.

All field equipment must be prepared at the laboratory/office prior to use. This will include additional cleaning, inspection, and maintenance.

Equipment such as hand trowels, bailers, mixing bowls, hand augers, etc., should be cleaned and wrapped in aluminum foil (with shiny side out) or plastic, as appropriate, prior to mobilization.

Sampling and monitoring equipment is normally cleaned by washing and rinsing with liquids such as a soap or detergent solution, potable tap water, deionized water (DI), methanol, isopropyl alcohol or a dilute acid.

The extent and type of contaminant will determine the degree of cleaning. If the level of contamination cannot be readily determined, cleaning should be based on the assumption that the equipment is highly contaminated.

Listed below is a cleaning procedure which may be employed for field equipment such as a water level indicator at a monitoring well which contains dissolved petroleum hydrocarbons. If different or more elaborate procedures are required, they should be specified by the project manager during the project initiation meeting.

- Remove gross contamination from the equipment using a Chem-wipe® cleaning pad or brush.
- Wash with a soap or detergent solution
- Rinse with D.I. water
- Rinse with methanol or isopropyl alcohol (if method requires) and repeat rinse with D.I. water
- Repeat the entire procedure or any part of the procedure as necessary.

Waste products produced by the cleaning procedures such as waste liquids, solids, gloves, used Chem-wipe® cleaning pads, etc., should be collected and disposed of based on the nature of the contaminant. Specific details for the handling of these wastes should be addressed by the project manager.

E.2420
CLEANING – HIGH-PRESSURE, HOT-WATER WASHING

Last Review or Revision: June 2010

Objective

To prepare the equipment for field activities in a manner which minimizes the potential for obtaining biased or erroneous data due to contaminant transfer. Decontamination is performed as a quality assurance measure and a safety precaution. It minimizes cross-contaminants between samples and also helps to maintain a clean working environment.

Equipment

- As determined by the project manager
- High pressure hot/cold water washing device or steam cleaner
- Expendable supplies:
- Disposable chemical-resistant gloves
- Chem-wipes
- Garbage bags
- Detergent (Alconox or TSP)
- Containers for collections of waste liquids, if necessary D.I. water
- Dilute acid, methanol, ethanol or other cleaning fluid
- Wash rack or other approved decontamination fluid collection system
- Cleaning containers with brushes (plastic, steel or stainless steel buckets)
- Aluminum foil or plastic, as appropriate
- Safety monitoring devices as specified in the safety plan.

Procedures

Decontamination procedures will vary considerably based on the equipment, type of contaminant, type of sample and detection levels. Initial decontamination should take place at the site prior to demobilizing. This will minimize the spread of contamination. The extent of on-site decontamination will vary based on specific conditions; however, an attempt should be made to decontaminate as thoroughly as possible on site. The more care one applies on keeping the equipment clean, the less energy will be required on decontamination.

All field equipment must be prepared at the laboratory/office prior to use. This will include additional decontamination, inspection, and maintenance.

Equipment such as hand trowels, bailers, mixing bowls, hand augers, etc., should be cleaned and wrapped in aluminum foil (with shiny side out) or plastic, as appropriate, prior to mobilization.

Decontamination of larger objects, such as the working end of the drill rig or the downhole tools is accomplished using a high pressure wash.

Sampling and monitoring equipment is normally cleaned by washing and rinsing with liquids such a soap or detergent solutions, tap water, D.I. water, methanol, or a dilute acid.

The extent and type of contaminant will determine the degree of decontamination. If the level of contamination cannot be readily determined, cleaning should be based on the assumption that the equipment is highly contaminated.

Listed below is a decontamination procedure which may be employed for field equipment such as a water level indicator at a monitoring well which contains dissolved petroleum hydrocarbons. If different or more elaborate procedures are required, they should be specified by the project manager during the project initiation meeting.

- Remove gross contamination from the equipment using a chem-wipe or brush.
- Wash with a soap or detergent solution
- Rinse with D.I. water
- Rinse with methanol or other alternate cleaning agent (if method requires)
- Rinse with D.I. water
- Repeat the entire procedure or any part of the procedure as necessary.

Waste products produced by the decontamination procedures such as waste liquids, solids, gloves, chem-wipes, etc., should be collected, stored in USDOT-approved 55-gallon drums on the site, and disposed based on the nature of the contaminant. Specific details for the handling of these wastes should be addressed by the project manager.

E.3000
BULK SAMPLING OF SUSPECT ASBSETOS-CONTAINING MATERIAL (ACM)

Last Review or Revision: June 2010

I. PURPOSE

The purpose of this standard operating procedure (SOP) is to provide information on the hazards of asbestos and procedures to follow to sample suspect materials for laboratory analysis. The following guidelines contained in this document apply to Terracon personnel who engage in bulk sampling of suspect ACM and are designed to provide standardization with respect to sample collection. This procedure should ensure that potential asbestos-containing material samples are collected in a manner which allows for accurate analysis of the material and that sampling personnel are protected against potential asbestos fiber releases through controlled sampling techniques or appropriate personal protective equipment.

The objective of bulk sampling building materials and components suspected to contain asbestos is to characterize the items that contain asbestos in quantities equal to or greater than 1% or other contaent limit as specified by local or state guidelines. By characterizing the locations and quantities of asbestos-containing materials (ACM), exposure hazards can be greatly reduced.

II. BACKGROUND AND REFERENCE

Asbestos has been a common component used in several building materials because of its strength enhancing and fire resisting properties. However, asbestos has been recognized as a human carcinogen and respiratory hazard. Due to its health hazards, building inspections and asbestos bulk sampling is requested for schools and many public or commercial properties prior to building renovation or demolition activities. Therefore, identifying, locating and quantifying materials containing asbestos is essential in the effort to prevent worker exposure to asbestos and prevent environmental contamination.

As a consequence of inhalation of asbestos fibers, a body of federal and state regulations has been developed. Federal regulations pertaining to asbestos are included in AHERA (Asbestos Hazard Emergency Response Act) US EPA 40 CFR 763, Subparts E, F; NESHAP (National Emissions Standards for Hazardous Air Pollutants (EPA 40 CFR 61); OSHA Asbestos Standards (29 CFR 1910.1001 and 29 CFR 1926.1101), and ASHARA (Asbestos School Hazard Abatement Reauthorization Act). Many states and local authorities have additional requirements including state-specific licensing and certification.

Terracon will comply with applicable federal, state and local regulations when conducting asbestos-related services.

III. EQUIPMENT

The minimum equipment necessary to conduct bulk sampling of suspect materials, in addition to the personal protective equipment outlined below in the Health and Safety Section, is listed below.

- Utility Knife, Chisel, Hammer, Screwdriver, Coring Tool
- Duct Tape
- Sample Containers (preferably ziplock-style clear plastic bags)
- Sample Labels and Indelible Marker
- Spray Atomizer containing Detergent Amended Water, Paper Towels/Wet Wipes
- Spray Adhesive
- Roof Patch Kit (if necessary)
- Measuring Wheel
- Camera
- Flashlight
- Field ACM Sample Log

IV. CERTIFICATION

Individuals conducting asbestos sampling must have the certifications listed below. Copies of these certifications and licenses should be taken to the site during the sampling event.

- United States Environmental Protection Agency Building Inspector training (and refresher training, if applicable)
- Asbestos Inspector State-license for the state of the project location (where necessary)

In addition, Terracon requires company-based training courses and hands-on experience of employees prior to commencing asbestos-related field services. Each employee must also receive respirator training, be medically monitored and successfully pass a fit-test utilizing issued respirator(s).

V. HEALTH AND SAFETY

Asbestos has been recognized to cause asbestosis, cancer of the lungs and digestive tract and mesothelioma. Asbestosis is a lung disorder characterized by a diffuse interstitial (between cell) fibrosis. The onset of asbestosis probably depends upon the asbestos dust

concentration, the morphology of the fiber and length of exposure. Cigarette smoking is strongly implicated as a co-carcinogenic among asbestos workers.

Under the OSHA asbestos standards, the employer has an obligation to protect employees against exposure to asbestos fibers in excess of 0.1 fibers per cubic centimeter of air (0.1f/cc). Personnel engaged in asbestos-related activities (including building inspections) must be trained, medically cleared and fit-tested for respiratory protection. Therefore, enrollment in a medical surveillance program in compliance with the OSHA asbestos and respiratory protection standards is mandatory. Terracon employees are not permitted to engage in asbestos-related activities unless they are enrolled in the Terracon medical surveillance program and have been medically cleared for respirator use by a physician.

The following safety and health protocols apply to Terracon personnel who engage in asbestos-related services. The guidelines contained in this document are based upon potential health hazards from exposure to asbestos fibers and physical hazards which may be encountered on survey project sites. Field activities will be performed in accordance with the procedures outlined in this document and applicable federal/state health and safety regulations.

Terracon personnel will use professional judgment during sample collection to prevent exposure to other building occupants. If unauthorized personnel attempt to enter a sampling area which could reasonably pose a fiber release hazard, the inspector will curtail bulk asbestos sample collection activity and request that the individual(s) leave the work area. If unauthorized personnel refuse to leave the work area, immediately contact the Project Safety Officer and/or a client representative. Sample collection activities should recommence only after unauthorized personnel have left the work area.

In the event that minor amounts of suspect asbestos containing materials such as thermal system insulation, sprayed-on or trowled-on surfacing materials, ceiling texture, etc. are released during the course of sampling, sampling team members will immediately evacuate the area and don Level C personal protective equipment. The area of potential ACM release will then be approached and suspect materials will be thoroughly wetted with amended water, slowly and deliberately swept to a centralized pile, re-wetted, and containerized in heavy mil asbestos disposal bags. Affected surfaces will then be re-wetted and swabbed with clean cloths or paper towels. Used wipes will be disposed of as asbestos-containing waste.

In the event that large quantities of potential ACM is released during sample collection activities, personnel will immediately evacuate the area and notify the Project Safety Officer and the client representative. The Project Safety Officer will request that the area be sealed until a properly attired response team can be mobilized to the area with a high efficiency particulate air filter (HEPA) vacuum and other equipment necessitated by site conditions.

If suspect materials are in deteriorated condition and fiber release appears likely, or if sampling must be conducted overhead and/or above drop ceilings, personnel will upgrade to Level C personal protective equipment as itemized above. Level C personal protective

equipment should be donned before moving drop ceiling panels, attic access panels, etc. where friable fireproofing or thermal system insulation are known to be present.

The indicated personal protective equipment shall be mobilized to asbestos sampling project sites on each day of sample collection and utilized, if necessary:

- Tyvek (standard) protective coveralls
- Half face or full face air purifying respirator equipped with HEPA (P-100) cartridges
- Impermeable gloves (nitrile or latex).
- Tyvek boot covers or washable outer footwear

Additional Health and Safety protocols such as those established by the owner/operator of the project site and Terracon's company policy regarding ladder safety, confined space entry and electrical hazards shall be followed.

VI. SAMPLING HAZARDS

a. Elevated Surfaces

Asbestos building inspections may include roofing materials and ceiling spaces containing suspect ACM. Appropriate ladders or other suitable devices (e.g., manlifts) will be used for gaining access to elevated sampling locations. Ladders will be inspected prior to use. Spreaders will be fully extended on all step ladders and firmly positioned prior to use. Where footing is uncertain, a sample team member will hold or otherwise secure ladders while in use by another sample team member. Personnel must always face ladders during both ascent and descent. Extension ladders will not be positioned more than one-quarter of their working length from buildings, walls, etc. (4:1 pitch). Sample team personnel will not walk on steeply pitched roof surfaces and will not walk on low pitched roofing surfaces while wet. Remain on designated roof walkways wherever present. Terracon personnel will visually inspect roofs prior to beginning sample collection activities and will avoid all areas which appear to be structurally unsound.

b. Confined Space Entry

Terracon asbestos inspectors will not enter any pit, shaft, tunnel, etc. which has limited means of egress, the potential for an oxygen deficient or toxic atmosphere or which was not designed for human occupancy without first developing a written safety plan which includes a confined space entry permit and procedures. Readily accessible spaces such as pipe tunnels in which personnel may stand can be entered to a distance where continuous visual and verbal communication can be maintained with another sample team member.

Adequate portable lighting must be utilized during sample collection in tunnels and similar spaces. No Terracon or sample team member may attempt to walk through a pipe tunnel,

etc. beyond the sight of a stand-by team member unless written confined space entry procedures have been prepared for the project.

c. Electrical Contact Hazards

Personnel will remain cognizant of the location and condition of electrical wiring during the collection of bulk asbestos samples. A visual assessment of each work space will be made prior to sample collection and electrical contact hazards will be evaluated. Unguarded junction boxes, exposed wiring, knife switches, etc. will be avoided during the collection of bulk ACM samples, and coring tools will not be used in near proximity to electrical switches or receptacles.

VII. PROCEDURES FOR BULK SAMPLING OF SUSPECT ACM

The primary purpose of this section is to identify the methods and techniques of controlled sampling, sampling site control and use of appropriate personal protective equipment to protect Terracon personnel and members of the general public from exposure to asbestos fibers during sampling activities. Adherence to these procedures should enhance personnel safety during sample collection activities and aid in the suitability of samples for analysis. Field activities will be performed in accordance with the procedures outlined in this document and applicable federal/state health and safety regulations.

Protocols for inspection and bulk sampling are defined in AHERA regulations. These are applicable for any type of survey; for example, a school, an area prior to renovation, a building prior to demolition and inspections undertaken to rebut the OSHA presumption that certain materials contain asbestos.

An accredited Building Inspector must perform the inspection. A summary of AHERA sampling protocols is as follows:

1. Visually inspect the building interior and/or exterior and identify locations of suspect ACM. Identify homogenous areas of friable and non-friable suspect ACM. Document locations, condition, classification and estimated quantities of each suspect material. It is recommended to depict locations of materials on a building diagram and take photographs of sampled materials.

2. Touch each suspect ACM to determine its friablity.

3. Collect representative samples of suspect ACM. Terracon recommends a minimum of three (3) samples of each material be collected from each homogeneous area. However, specific materials may require additional samples such as surfacing material and insulation

as described below. Judgment should be used on the need for and quantity of additional sample collection.

Surfacing materials: Collect, in a statistically random manner, at least 3 bulk samples from each homogenous area of 1,000 sq. ft. or less, at least 5 bulk samples from each homogenous area that is greater than 1,000 sq. ft. but less than or equal to 5,000 sq. ft., and at least 7 bulk samples of each homogenous area larger than 5,000 sq. ft.

Thermal System Insulation (TSI): Collect, in a randomly distributed manner, at least three bulk samples from each homogeneous area of TSI; collect at least one bulk sample from each homogeneous area of patched TSI if the patched section is less than 6 linear or square feet; collect bulk samples from each insulated mechanical system where cement or plaster is used on tees, elbows, etc. in a manner sufficient to assess whether the material is ACM.

If fiber release appears likely, wet methods will be employed in the collection of suspect ACM samples. Water amended with a minimum of 10% commercially available window cleaning solution or other suitable surfactant should be used to moisten materials prior to sampling. Bulk asbestos samples will not be collected over the heads of, or in near proximity to, non-project personnel. Respiratory protection is not required when sampling non-friable suspect materials or materials below the breathing zone which are adequately wetted with amended water.

4. Bulk ACM samples should be immediately placed in sample containers and sealed while the materials are wet. If collecting samples of friable ACM or normally non-friable materials which are in deteriorated condition, precautions must be taken to prevent the release of fibers to the work area. Precautions include aggressively wetting the surface or potentially isolating the material (e.g. glove bagging) prior to disturbance.

5. Reusable sampling equipment will be gently rinsed with amended water. Dry the equipment with paper towels to be disposed of as contaminated materials.

6. The following decontamination sequence should be used following sample collection activities requiring Level C personal protective equipment:

- Remove coveralls slowly turning the outside inward.
- Place in heavy mil asbestos disposal bag.
- Remove gloves and shoe covers (if utilized)
- Remove respirator and carefully dispose of respirator cartridges in asbestos disposal bag.
- Securely seal protective clothing and any potentially contaminated disposable sampling equipment in heavy mil asbestos disposal bags.
- Do not smoke or eat with soiled hands.

- Wash hands, face and forearms thoroughly before eating, drinking smoking or using toilet facilities.
- Shower thoroughly as soon as possible upon leaving the project site.

7. Bulk sample analysis for asbestos content is performed by polarized light microscopy (PLM). The analytical testing procedure is based on U.S. Environmental Protection Agency (EPA) methods and National Voluntary Laboratory Accreditation Program (NVLAP) requirements. Terracon will use NVLAP accredited and appropriately licensed laboratories for analysis of asbestos bulk samples. Samples will be controlled with the analytical laboratory through chain of custody documentation.

E.4010
(Formerly E.590)

AIRBORNE LEAD AND PARTICULATE MATTER MONITORING SAMPLE COLLECTION

Last Revision/Review: March 2014
Reviewer / Office: DEK/Corporate

Objective and Application

Indoor air sampling requires the participation / review of a Terracon industrial hygienist (IH) in selecting methods and scoping work. Engaging an IH is encouraged for any airborne contaminants. For direction to local or regional assistance, contact the Chair of the Industrial Hygiene Practice Resource Group on the Terracon Environmental Services Webpage. Click here if viewing electronically.

The following procedure is for collection of samples for measurement of total airborne particulate matter and airborne lead particulate. The methods will provide representative samples for laboratory analysis using NIOSH Method 7300.

Equipment

The following equipment and supplies will be needed for this testing:

- Air monitoring cassettes containing mixed cellulose ester filters with a 0.8 µm pore size pre-weighed and numbered by the laboratory.
- Rotometer or other flowmeter accurate to the 0.1 L/min. Flowmeters used for calibration of air sample pumps will be calibrated against a primary standard on a quarterly basis.
- Air monitoring pump (battery operated or ac powered depending on application) capable of provided a 1 to 4 L/min flow rate through the sample filter.
- Vinyl tubing to connect pump to cassette.
- Cassette stand or other means to fix cassette in place as appropriate to testing location.
- Chain of Custody.

Procedures

Select a location for sample that is subject to full ambient air flow but not subject to vibration that could dislodge particulates from the surface of the filter. A location protected from precipitation should be selected, if available. Excessive moisture will interfere with sample analysis and could effect the flow rate.

Label cassette and record laboratory identification number on chain of custody. Assemble sampling pump, tubing and stand in sample collection location. The base of the cassette should be a press fit into the interior of the tubing. The joint between the tubing and cassette may be reinforced with tape if site conditions make this necessary. Cassette must be tilted downward at a 45º angle from horizontal. Cassette and pump should be placed so that the sample does not have to be moved after sample calibration.

A short section of vinyl tubing should be used to connect the flowmeter to the inlet port of the cassette. An adapter fitting may be needed to connect the tubing to the cassette. If a rotometer is used for flow calibration, the instrument must be held upright for accurate readings. Turn on the pump and measure the flow rate. Using the flow control on the pump, adjust the flow to the desired reading between 1.0 and 4.0 L/min. Record the sampling start time and beginning flow rate.

After completion of the sample collection, inspect the pump and cassette for any problems that may affect the sample validity (wet filter, stand blown over, etc.) and record any problems noted. Measure the flow rate using the procedure described above. The average of the two flow rates will be used by the laboratory to calculate the sample volume. Turn off the pump and cap the inlet and outlet ports on the filter cassette. Record the sampling completion time and ending flow rate.

Documentation

In addition to chain of custody documentation, the following must be provided to the laboratory performing sample analysis:

- Average flow rate (average of beginning and ending readings)
- Sample duration
- Filter number
- Requested analytical method

The following additional information must be collected for Terracon's project files:

- Sample date
- Sample times
- Sample location
- Activities performed by during the sampling
- Wind orientation (upwind, downwind, etc.)
- Weather conditions

Attached or Referenced Supporting Information

- Industrial Hygiene Technical Manual – Chapter II: Standard Methods for Sampling Air Contaminants

- NIOSH Method 7300 – Elements by ICP

APPENDIX B

Terracon Corporate Quality Program Manual

PROJECT QUALITY MANUAL

Prepared by:
Quality and Project Delivery Committee

Adopted by:
Executive Committee
June 3, 2021

Revision:
CORP-PQM-6-21-00

This document is an internal manual and is not to be distributed in any format outside of Terracon for any reason.

Terracon



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REVISION RECORD

Rev. Date	Section	Type	Description of Change





Employee-owner,

Quality is a part of everything we do at Terracon. It is woven throughout our Strategic Plan, our safety culture, and our overarching goal of on-time project delivery. Our values of excellence, integrity, curiosity, and caring inform our approach to quality in all aspects of project management and delivery, and quality is non-negotiable if we are to live our values of integrity and prosperity and achieve our vision of being dominant in our markets. Above all, quality is how we honor and demonstrate our commitment to the safety of our employees, clients, and everyone in the communities who are touched by the work we do. Every client, every project, every day.

If our Strategic Plan is the touchstone for our quality approach, our Project Quality Manual (PQM) serves as a roadmap and "instruction manual" to ensure consistency and discipline around quality across the company.

All the quality leaders mentioned in this document – from project managers and authorized project reviewers to service line directors and operations mangers – set the tone for all employees in following our quality procedures and in keeping a mindset of quality as part of client experience, on-time project delivery, and maintaining and growing our brand and reputation in the markets we serve.

As you use this manual, be sure to explore beyond the surface of the processes and policies to consider why they are so important to the safety and success of our employees, clients, and communities, and how you can lead Terracon to attain the highest standards of quality on every project.

Thank you for your commitment to quality, to our clients, and to our company.



M. Gayle Packer
Chair, President, and CEO





1.0 PURPOSE AND SCOPE

This Project Quality Manual (PQM) defines Terracon's project quality management processes, consistent with our Quality Program Manual, for the processes, tasks and deliverables associated with projects performed by the company.

Terracon's projects often result in opinions, conclusions and recommendations supported by field and laboratory data gathered in the process of conducting the project as well as calculations using that data. Terracon also engages in projects where we provide repair, remediation and design documentation. This manual sets out the approach to quality associated with the execution of the project and how those opinions, conclusions, and recommendations are developed and finalized. Aspects of quality related to the gathering of such field and laboratory data, and the performance of calculations and designs are addressed in a companion document, ***Quality Management System (QMS)***.

Terracon also maintains and implements project-specific quality control or quality assurance manuals and/or programs as required or when applicable by project contracts that align to or incorporate this document. In addition, Terracon utilizes other comprehensive quality-related documents on designated projects, such as the ***NQA-1 Quality Assurance Manual,*** when necessary.

Specific key words are ***bolded and italicized*** when first utilized in the text of the manual. The definitions for these words can be found in Appendix A.

This manual expands on specific ***Quality Control (QC)*** and ***Quality Assurance (QA)*** responsibilities. QC and QA are terms that are used interchangeably but are distinct in their purpose that when used in conjunction, creates an effective Quality Program. In the Terracon quality program, Quality Control occurs at the project level and includes the various reviews of documents, deliverables, calculations and data. Quality Assurance includes development and oversight of the quality control program, including verification that appropriate reviews were completed, and validation of the program through audits, surveys and reviews of those who are authorized to perform the quality control.

The foundation of Terracon's quality program is the ***Project Manager (PM)*** and ***Authorized Project Reviewer (APR).*** Every project at Terracon has an assigned PM and an APR, regardless of size. The PM responsibilities include overall project performance, on-time delivery, management of budget and scope while maintaining a safe work environment, managing risk and delivering a quality product to meet the satisfaction of the client. The APR's responsibilities include the oversight of quality of the work and the *guidance* of the project's aspects of schedule, budget, risk, scope, safety and client satisfaction.

Projects at Terracon are identified as either ***TYPE I*** or ***TYPE II.*** All projects require an APR; however, ***TYPE II*** projects are required to follow the ***TYPE II PROJECT PROCESS*** and includes the additional designation of a ***Project Executive (Project EXEC)***. Section 3 further defines Type I and Type II projects, as well as the ***TYPE II PROJECT PROCESS***.





2.0 ROLES AND RESPONSIBILITIES

Terracon's QC and QA process relies on the partnership and leadership of four primary groups:

- PMs;
- APRs and their supporting role players in the quality process—***Data-Only Reviewers (DORs)***, ***Subject Matter Experts (SMEs) and Project EXECS***;
- Service Line Leadership: ***APR Review Committee (APRRC) members, Service Line Directors (SLDs),*** and ***Assistant Service Line Directors (ASLDs)***; and
- Operations Management: ***Department Managers (DPMs)***, ***Office Managers (OMs), Division Managers (DMs), and Operating Group Managers (OGMs)***

The ***Chief Development Officer (CDO)*** oversees the processes related to the project QC roles through various QA activities. Appendix B provides a summary of Terracon's Roles and Responsibilities for each of these groups.

The following sections address roles and responsibilities of specific staff engaged with projects.

2.1 PROJECT MANAGER (PM)

The PM is an integral position to the success of a project, not only financially but in terms of quality, client experience, and on-time delivery. In this manual, the term **Project Manager** refers to the role of PM, as well as the Terracon Job Title of Project Manager. The **role** of PM is assigned on a project when a proposal or project is registered in Terracon's ***Project Exchange System (PX)***.

Terracon employees are selected and approved as PMs by the DPM or OM through experience, training and competency as guided by the Terracon Project Manager Selection and Approval Requirements.

The PM is assigned to a project by the DPM and is ultimately responsible for **all** aspects of the project. The following critical items must be performed by everyone assigned the role of PM and responsible for managing projects at Terracon, including, but not limited to:

Proposal Preparation and Follow-up *(Excellence)*

- Prepare proposals with a well-defined scope of work, schedule, budget, and considerations for safety. Each project should have a calculated (planned) WU/WD in the proposal folder.
- Ensure the proposal and the project are accurately and completely set-up and validated in PX, including working with the DPM, OM, APR, ASLD and Project EXEC as required, to identify the project type.
- Create and manage an adequate scope, schedule and budget to deliver the project.





Signed Contracts and Change Orders *(Prosperity)*

- Ensure all projects have signed contracts prior to initiating services.
- Anticipate and seek written client approval for scope, schedule and budget changes prior to performing additional work outside the originally approved scope, schedule and budget.

Kick-Off Meetings *(Curiosity, Client Engagement)*

- Plan and conduct project ***Kick-Off Meeting(s).***
- Conduct ***Client-Engaged Kick-Off Meetings*** using the Client Portal whenever appropriate.
- Determine and initiate ***Critical Juncture*** meetings consistent with the schedule established in the project kick-off meeting.

Safety / ***IIF*** *(Caring, Best at People)*

- Take personal responsibility for the safety of those that work on your projects and assign all work in an *IIF* manner.
- Establish safety protocols throughout the life of the project consistent with Terracon's Core Safety Rules and Practices and Life Safety Absolutes as well as any project-specific safety requirements.
- Understand safety hazards on the project site(s) and assure that all staff have adequate information, training, and certification to safely perform their assigned tasks and services.
- Perform periodic site check-ins during field activities throughout the duration of the project to engage staff in conversations that include critical safety and other project-related issues.

Financial Management *(Prosperity)*

- Use the available systems and tools (including the PM Dashboard) to manage project financials including meeting budget at planned write up/write down (WU/WD).
- Provide and maintain tracking of planned WU/WD, costs, budget status, accurate and timely invoicing, WIP, collections, schedule and budget forecasting, submit change orders promptly, and eliminate unrecognized revenue (UR).
- Perform and provide project cost estimates at completion (EAC) and estimates to complete (ETC).

Client Experience (CX) / Client Development (CD) *(Client Engagement, Prosperity)*

- Provide consistent, intentional and focused effort with existing and/or new Clients that result in high client engagement (measured by the work they ask us to perform for them), and mutual success.

Risk Management *(Integrity)*

- Understand and manage project technical, schedule, financial, contractual and client risks.
- Complete project closeout in a timely manner, consistent with the requirements of this PQM.
- Responsible for the integrity and management of project files and data.

Quality *(Excellence)*

- Understand and follow the expectations of the PQM.
- Understand and follow the APR process for all projects and apply the additional requirements for Type II projects when required.





- Manage all aspects of quality – quality of our services, quality of our communication, and quality of our deliverables and report(s).
- Engage the APR at critical junctures from proposal preparation through project completion to allow the APR to perform their duties as described below in Section 2.2.
- Engage with the ASLD and Project EXEC at appropriate times to meet expectations set forth in project planning meetings, kick-off meeting(s) and implementing the project management requirements established by the Project EXEC on Type II projects.
- Collaborate with the APR to identify the need for and selection of SMEs.
- Maintain adequate project records and filing in accordance with Terracon's Records Management Policies up through project closeout.
- Ensure that licensing and certification requirements for the project are met.
- Manage overall quality of the project and deliverables.

Communication *(Best at People, Integrity)*

- Establish and maintain effective and regular client communication and professional relations during the project.
- Communicate openly at all levels and collaborate by engaging staff in achieving project goals (including project personnel, APRs, NAMs, etc.).

Teamwork *(Best at People)*

- Lead the project team so they understand their roles and budgets.
- Coordinate with subcontractors, SMEs and other design team members to successfully execute the project.

On-Time Delivery *(Excellence, Integrity, Market Dominance, Client Experience)*

- Develop schedules for all projects, make sure the project team and the client know the schedule, share it, track it, and communicate status on a routine basis with the project team, client, and other relevant parties.
- Deliver on time in all aspects of our services, including but not limited to proposal, services, reports, invoicing, collections, change orders, meetings, and overall client communications.
- Manage the project schedule to allow for adequate time for all reviews prior to submission of a work product to the client.

Consistent Standards *(Excellence)*

- Maintain established Terracon standards for project delivery.
- Maintain consistency in use of formats, forms and features.

The PM should proactively coordinate with the APR during the proposal phase and keep the APR, and SME when applicable, involved throughout the project, particularly at the kick-off meeting and other critical junctures. For Type II projects when a Project EXEC assigned, the PM should also engage the Project EXEC similar to the APR in the descriptions noted below and as discussed in Appendix N of this PQM. The PM is specifically responsible for the following tasks as the project progresses from proposal through execution.





Project Proposal

- Verifying, notifying and communicating directly with the APR when they are selected in PX.
- Engaging the APR and SME during proposal preparation and contract review to discuss the following:
  - Project scope, staffing, scheduling and budget reviews and discussions;
  - Contract or risk issues so appropriate reviews and approvals are obtained;
  - Project safety requirements for consideration in scope, schedule and budget; and
  - Project delivery schedule and client milestone dates

Project Execution

- Confirming the DORs for Materials or Facilities service line projects with deliverables or tasks not containing opinions, recommendations, or conclusions. The PM may serve as a DOR.
- Verifying, notifying and communicating directly with the APR when they are selected upon project award, and if there has been an APR change after project has been won, bring the new APR up-to-date on the proposal and project.
- Having discussions with the APR to determine when/if an SME is needed for the project. As with the APR, notify and communicate directly with the SME when they are selected upon project award. SME's may be added to the project team during the life of a project due to a scope change or other technical or management needs.
- Reviewing Risk Management Policy No. 4 for the requirement to include specialized SMEs to the project team.
- Initiating project kick-off meeting(s) that includes the APR, SME(s), Project EXECs (if appropriate) and other key project staff. (Note: Separate or conjoined client-engaged kick-off meetings should be held whenever possible.)
- Establishing critical junctures for subsequent interaction with the APR, the client and the design team as a part of the kick-off meeting(s).
- Coordinating with the APR and any SMEs throughout the project and keep the APR, SMEs and Project EXEC up-to-date on schedules and critical junctures, as set out in Section 4 of the PQM.
- Engaging the APR (and Project EXEC when required) at critical junctures to review project status, including ability to meet scope, schedule and budget.
- Providing interim project deliverables, as established in the kick-off meeting(s), to the client and to the design team to enhance collaboration.
- Set, monitor and keep all project milestones as established in the kick-off meeting(s).
- Performing periodic site safety check-ins with field staff during the project and engage the APR to review and discuss safety issues throughout the project.
- Engaging the APR to discuss anticipated change orders (supplements, contract modifications), and create a plan to gain client approval in advance.
- Providing the APR and any SMEs, in a timely manner, with necessary documentation for review, including the project deliverables (including access to client communications) and access to calculations and supporting documentation.
- Providing draft deliverables to the APR in appropriate advance time of the established milestones, unless other arrangements have been made with the APR. The draft deliverable shall be prepared using care, expertise, and attention to detail as to expect little or no changes or review comments from the APR. The draft deliverable shall include





appropriate supporting materials such as field notes, photographs, etc. to aid the APR in their review.

- Making any necessary modifications as mandated by the APR consistent with the schedule expectations of the client and deliver final documents to the client as required by the project schedule.

Project Closeout

- Performing project closeout consistent with Terracon's policies, processes and procedures presented in **Section 4.3** in this PQM.

2.2 AUTHORIZED PROJECT REVIEWER (APR)

APRs play a critical role, driven by curiosity, excellence, integrity, and courage as a project quality champion. An APR is assigned to every project. For the majority of Terracon's projects, the APR is the "senior" member of the project team, and in this role, APR oversight and involvement is expected in four critical areas:

- Project Quality – The APR is responsible to confirm that the proper expertise is provided for the project from the proposal stage, and the deliverables meet Terracon's standards as well as the client's expectations. The APR should work with the PM in reviewing Risk Management Policy No. 4 to consider whether one or more aspects of the project require SMEs and, if SMEs are deemed necessary, to select appropriate SMEs during the proposal stage and/or Project Setup, or when deemed necessary as the project progresses. Additionally, the APR may select an SME to support the project and collaborate with the PM. In some cases, the SME may be selected to provide independent review of the project as determined by the APR and PM and, if so, would be assigned for the duration of the project.
- Project Delivery - The APR is expected to provide oversight and guidance on project delivery and other aspects of the project, including safety, schedule, budget, Terracon standards and client expectations. Throughout the course of the project, the APR is responsible to 'check in' at predetermined critical juncture, or more frequently, with the PM to verify the status of the project's plan to meet scope, schedule and budget. The APR is expected to use their experience to coach other members of the project team into successful results in the areas of the project for which they are assigned as appropriate and to work actively with operations management to correct any shortcomings in those areas if corrective measures are not being taken by the project team members.
- Risk Management – The APR has oversight responsibility for evaluating project-specific risk factors (e.g. critical assumptions, subcontractors, project staff availability and experience, definition of out-of-scope items, contractual risk elements, technical issues, potential client dissatisfaction, compliance with Terracon's Risk Management Policies, etc.) and is expected to collaborate with the PM to mitigate identified risks. The APR should be engaged in the identification of TYPE II projects that represent significant risk/opportunity for Terracon.
- Coaching - The APR is responsible to coach the PM from proposal to successful closeout of the project. Part of this coaching involves educating PMs on the role of the APR so there is a mutual understanding of the role and responsibility of the APR on the project and the importance of frequent communication and client/design team collaboration at critical





junctures defined for the project. The APR is responsible for coaching professionals on the project team and holding all accountable for the safe and successful completion of the project, consistent with Terracon's Core Safety Rules and Practices as well as any project-specific safety requirements; meeting expectations of the project's objectives of scope, schedule, safety, budget, technical quality, risk management and client satisfaction.

The extent of oversight and involvement by the APR may vary depending on the complexity of the project and/or the experience of the PM and project team. However, certain basic requirements and expectations are necessary for all projects, and the APR must ensure that their own involvement and the involvement of others is appropriate to deliver a successful project.

The APR selection is made by the PM, in discussion with the DPM and/or OM. The PM establishes the assignment at the time of proposal or project set up through PX. Prior to entering the project into PX, PMs shall engage the APR to confirm their availability to work on the project.

The APR is expected to accurately track their time spent on both proposals and projects and add their hours to their weekly timesheet accordingly.

APRs may be assisted in their quality responsibility by Data-Only Reviewers, Subject Matter Experts, and Project Executives, as well as other APRs.

2.2.1 Data-Only Reviewer (DOR)

A DOR is the person(s) responsible for the review of factual data associated with final deliverables. For certain Materials and Facilities final deliverables that do not include professional opinions, recommendations or conclusions, we have designated staff who are authorized for "Data-Only Reviews." The DOR is the responsible party for the final deliverable as an official role. In this manual, the term "DOR" is only referenced for Materials and Facilities final deliverables.

2.2.2 Subject Matter Expert (SME)

The APR may not always have the specific technical expertise required for certain aspects of a project. In this situation, SMEs can be added to a project team to provide additional support and to perform focused review in those areas. SMEs are experts within a specific subject matter and can also be appointed for other project delivery areas where additional expertise may be necessary, such as specific safety, quality, or project financial management assistance.

It is the responsibility of the PM and APR to collaborate and identify SMEs. The PM and APR should consult with the potential SME prior to assignment to ensure that the SME has the expertise needed.

An SME does not necessarily need to be an APR. Some of the project needs for an SME might be in areas where the organization does not have APRs such as accounting or legal. In addition, some technical experts may exist in the company who are not APRs, yet they should have opportunity to add value to projects using their expertise.



The SME should guide the technical performance of specific aspect(s) of a project within their specified area(s) of expertise. The SME does not replace the APRs involvement on the project. When an independent review is deemed necessary by the APR, SMEs should be called upon throughout the life of the project for guidance and review, from proposal through final project completion, as an independent reviewer from the project team.

Terracon performs certain project services that include specialized or increased risk, guided by Risk Management Policy No. 4, where specialized SMEs are required to be selected and made an active part of the project team. Specialized SMEs are approved by the Services Lines as having the necessary background and expertise associated with the specialized or increased risk service. Approved specialized SMEs by practice area and service line are found on the Quality and Project Delivery pages on TerraNet.

2.3 PROJECT EXECUTIVE (Project EXEC)

Project EXECs maintain the responsibility of executive-level oversight of TYPE II projects for successful delivery and for monitoring the project throughout its life to ensure that the project is proceeding in accordance with expectations. Project EXECs are not necessarily APRs, and a Project EXEC will not serve simultaneously as an APR on the same project for which they are assigned as Project EXEC. Projects are selected to have a Project EXEC assignment at the proposal stage, and in some cases the pursuit stage, as those of significant risk, exposure or opportunity. The PM, APR, or DPM each have responsibility to consider projects to be identified as TYPE II. It is the responsibility of the ASLD, in partnership with the DM, to confirm the identification of Type II Projects and the selection of the Project EXEC. By default, within PX, the ASLD is initially designated as the Project EXEC, unless there is agreement that a different Project EXEC should be designated.

The individual Project EXEC should serve on a TYPE II Project from the inception of the work scope development and fee estimation through the completion of the project and final closeout. The Project EXEC will define additional project management requirements to include activities such as Project Management Plans, project reviews, reporting, etc. The Project EXEC is expected to report project progress, activities and results to the DM and/or OGM on a periodic basis.

2.4 APR REVIEW COMMITTEE (APRRC)

The APRRC consists of members from each service line and generally represent their respective division. APRRC members are selected by the SLD, in coordination with the DM. The SLDs chair the APRRC and coordinate efforts through the CDO. Members of the APRRC assist in the implementation of the Quality Program by:

- Partnering with the DM, SLD and ASLD to monitor the APR program in their respective service line;
- Monitoring the sufficiency of the number of APRs to serve their division's needs;
- Identifying potential APR candidates and assisting/overseeing their mentorship through the APR selection process;
- Participating in the APR evaluation and project review process;



- Supporting APR training;
- Identifying and assisting in remediation of any division/service line quality issues; and
- Serving as participants on the “committee” for the service lines to help lead and support standards development and quality initiatives

2.5 SERVICE LINE DIRECTOR (SLD)

The SLD is the senior professional within Terracon appointed to supervise the policies, practices, activities and lead innovation of the individual service lines. SLDs have specific responsibility to ensure that the quality management processes are being followed within their service line in all aspects as set forth in this PQM. They lead their respective group of ASLDs and APRRC members to oversee the quality processes. The SLDs work with the CDO to oversee the program across the company and provide necessary quality leadership, monitor the performance of the quality management program and make necessary modifications to the program and processes as the company evolves and needs arise.

The SLD is assisted in the execution of their responsibilities by ASLDs who serve an operating group-level responsibility. The ASLDs work closely with the SLD, the OGM, DM and the APRRC to maintain a vibrant and effective quality program.

SLDs have specific responsibility to assist in reviewing and approving specialized SMEs, as well as supporting ASLDs and the DM in the identification and assignment of the Project EXEC at the earliest stage possible for TYPE II projects. SLD’s also may create specific practice guidelines, standards and quality management practices specific to the needs of their service line.

2.6 CHIEF DEVELOPMENT OFFICER (CDO)

The CDO reports directly to the President and is charged with monitoring the quality of our services, including the development and monitoring of the overall quality management processes. The CDO works with DMs, SLDs, and practitioners to continuously improve our quality of service to our clients and studies our current operations to explore and identify areas of necessary quality improvement as part of achieving our Strategic Plan vision, safety commitment, and prosperous growth imperative. The CDO co-chairs the ***Quality and Project Delivery Leadership Team (QPDLT),*** which is responsible for the implementation of project-level quality management and the quality processes that are defined herein to validate the performance of the quality program as well as identifying needed improvements.

2.7 OPERATIONS MANAGEMENT

Terracon incorporates several tiers of operations management into the project quality management processes as well as other significant functions related to project delivery and management responsibilities, including PM selection, PM development, project performance and other project success factors. The role descriptions listed below are only in relation to the quality aspects of their responsibilities.





2.7.1 Department Manager (DPM)

Department Managers have primary responsibility for the implementation, oversight, and success of the quality process within their department. DPMs from acquisitions should follow the acquisition quality integration process described in Appendix G, Section C. DPMs' specific responsibilities are:

- Recommending prospective Facilities and Materials DORs for approval by OM;
- Evaluating and approving qualified individuals in their department to be PMs in accordance with the Terracon PM Selection and Approval Guidelines;
- Selecting the appropriate PM and APR for projects at the proposal stage based on type and complexity of the project and making sure the PM and APR are registered on the project in the ProjectXchange System;
- Considering projects being identified as TYPE II at the proposal stage and elevating the conversations for designation to the OM, ASLD and/or DM;
- Working with the PM so appropriate/qualified and licensed staff are assigned to projects and that the APR concurs with staff assignments;
- Partnering with the APR to oversee PM's performance;
- Financial performance of projects in their department (actual WU/WD to plan, invoicing, AR, WIP etc.);
- Partnering with the PM and APR to identify when an SME is necessary on the project and assist with the selection of the SME with the SLD and their representatives;
- Performing periodic site check-ins during field activities on projects to engage staff on safety issues;
- Reviewing deliverables by spot auditing project files to document APR review compliance;
- Attending and actively participating in the office quality "brown bag" continuing education meetings described in Appendix J;
- Being accountable for the approval of project scopes and project budgets within their department; and
- Serving as a quality champion, role model, and mentor, engaging with employees to understand the value and importance of quality as part of our Strategic Plan, safety culture, and on-time project delivery

2.7.2 Office Manager (OM)

Office Managers (OMs) are responsible for the implementation, oversight, and success of the quality process for all service lines within their office. OMs from acquisitions should follow the acquisition quality integration process described in Appendix G, Section C. OMs' specific responsibilities are:

- Approving DORs and posting and maintaining the list of approved DORs on ***TerraNet*** https://terracon4.sharepoint.com/sites/Offices;
- Recommending projects as Type II to the ASLD and DM when a project is of sufficient nature to warrant assignment of a Project EXEC;
- Ensuring that appropriate staff participates in required continuing education as set out in Appendix J;





- Conducting an annual “brown bag” style meeting for their DPMs, PMs, and APRs on the quality processes and best practices, with standardized training materials provided to OMs by the QPDLT as described in Appendix G, Section C;
- Ensuring office participation in the annual ***PM/APR Survey*** and sharing results, findings and information as it applies to their operation by communicating management expectations, and
- Serving as a quality champion, role model, and mentor, engaging with employees to understand the value and importance of quality as part of our Strategic Plan, safety culture, and on-time project delivery

2.7.3 Division Manager (DM)

Division Managers (DM) are responsible for the implementation, oversight and success of the quality management processes in their division. DM reinforce the importance of quality deliverables and project reviews in management communications to the same degree as financial performance. Their specific responsibilities are:

- Working with APRRC members to know and understand APR capabilities within the division and reinforcing the quality process within the division so it is properly executed;
- Working with APRRC members to identify new APR candidates to meet business needs;
- Working with SLDs and CDO on approval of new APRs;
- Partnering with the ASLD to confirm the identification of a potential TYPE II project and work with the PM, ASLD, DPM and OM in the selection of the Project EXEC;
- Reviewing the Division’s ***PM/APR Survey*** with OMs and following up on results and findings as appropriate, with coaching, training, resources, etc. to ensure that improvements to the quality processes are being made;
- Serving as a quality champion, role model, and mentor, engaging with employees to understand the value and importance of quality as part of our Strategic Plan, safety culture, and on-time project delivery

2.7.4 Operating Group Manager (OGM)

Operating Group Managers (OGMs) are responsible for oversight of the DM’s implementation of the quality management processes through:

- Observing and monitoring performance of the quality processes and giving periodic real-time feedback as to the effectiveness of the processes within the divisions;
- Providing DM with quality process improvement goals as needed;
- Reviewing the OG’s ***PM/APR Survey*** with DMs and following up on results and findings as appropriate, with coaching, training, resources, etc. to ensure that improvements to quality processes are being made; and
- Serving as a quality champion, role model, and mentor, engaging with employees to understand the value and importance of quality as part of our Strategic Plan, safety culture, and on-time project delivery





2.7.5 All Practitioners

All employee-owners who touch our projects and clients bring their own expertise and curiosity to add value in our quality processes. From time to time, practitioners have the opportunity to review work (data, reports, etc.) that has been finalized for release in accordance with the provisions of the Project Quality Manual. A prominent example of such opportunity is in the case of National Account Managers.

In the course of their review, if the practitioner notes inconsistencies that, in the opinion of the practitioner, are of the level that require action, the practitioner should notify the APR of such inconsistencies. This notification should include the Assistant Service Line Director for the service line and region of responsibility.

3.0 PROJECT TYPES

This section explains the hierarchy of quality review based upon the project type and complexity. The common thread of all projects at Terracon is appropriate project oversight conducted by an APR.

More specifically, Terracon has two types of projects based on the required level of oversight – TYPE I and TYPE II. TYPE I projects are standard Terracon projects, requiring APR assignment and execution as described in Section 3.1 below. TYPE II projects are generally larger, have more strategic visibility or risk potential, and/or are more complex and, as such, require a higher level of oversight. For that reason, while TYPE II projects require the same APR assignment and execution discussed above for TYPE I projects, they also require additional oversight by a Project EXEC as described in Section 3.2 below.

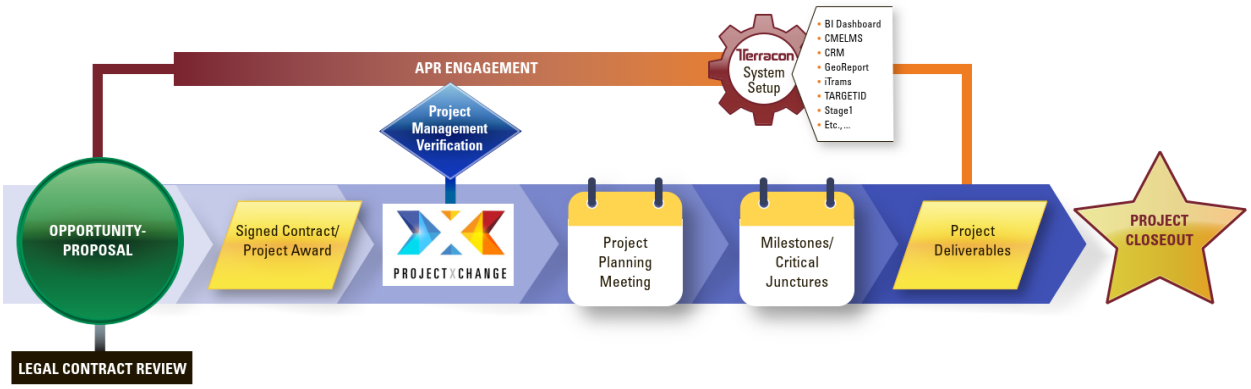
3.1 TYPE I PROJECTS

The quality process for Type I projects includes the full range of duties of the APR as described in Section 2.2 and execution requirements as set out in Section 4. The APR should be involved in the project from the proposal stage through completion of the project. Therefore, the PM shall notify the APR of their selection prior to registering the project to verify the APR's availability.

As stated, a TYPE I project is generally considered a "standard" Terracon project led by the PM with engagement and oversight by the APR. The TYPE I project process follows the quality expectations of this PQM as discussed in Section 4.



TYPE I PROJECT PROCESS



3.2 TYPE II PROJECTS

For TYPE II Projects, the quality process is consistent with TYPE I projects with APR engagement and oversight with an elevated level of management provided by the Project EXEC as independent oversight, which is performed in addition to the review and oversight provided by the APR. The Project EXEC oversight does not replace the APR or relieve them of their duties but serves to enhance the process. Specific activities of Project EXEC oversight are outlined in Appendix N.3.

TYPE II projects are generally those that are very large in magnitude and/or have high risk or high opportunity. Project factors that could trigger a TYPE II project designation and the Project EXEC quality process are listed below. This list is not intended to be an exhaustive representation of factors that could require TYPE II project designation.

- Financial Risk: May include total construction cost, revenue generating capabilities of the finished project, potential repair costs, large subcontractor fees, potential liquidated damages, or risk of non-payment of significant Terracon fees. Examples may include:
  - More than $100M total construction cost and Terracon has significant scope or scope involving high risk;
  - Large revenue generating facility with a potential for consequential damages and Terracon has a significant component of the scope for the facility
  - Contracted fees >$1M for Materials and >$500k for Environmental, Facilities & Geotechnical;
  - Combination of smaller projects under one contract with combined fees of $500,000 or more
- Project Staffing: May include multiple office and/or service line teams as well as long duration, unique qualifications and experience or significant staffing requirements.
- Technical Risk: The work performed may have technical aspects that are on the periphery of Terracon's experience of availability of appropriate technical staff to deliver the work.
- Client Value or Risk: May include clients that are high value or high opportunity, as well as high risk or litigious clients.
- Project Complexity: May include technical complexity, multiple phases, strict regulation or contractual compliance requirements, safety or political sensitivity concerns.
- Legal Risk: May include high/no limitations of liability, lack of waiver of consequential damages, litigious market reputation, particularly in comparison to the Financial Risks discussed above.



In addition to the assignment of a Project EXEC to a TYPE II project, there are expanded management expectations and processes that focus on communication, collaboration, planning and oversight. The TYPE II Project Process is expected to be initiated as early in the project stages as possible, including the pursuit stage. The TYPE II Process is expected to be followed by PMs who have the responsibility to lead the process with support from the ASLD, Project EXEC and DM.

The TYPE II Proposal and Project Processes are summarized and included in Appendix N.1.

4.0 PROJECT QUALITY PROCESSES

This section describes the quality processes for proposals and projects. Appendix D provides a graphical summary of the process.

4.1 PROJECT PROPOSALS

With the exception of projects in the Facilities and Materials service lines as noted in the paragraph below requiring Data-Only Deliverables, the APR should be assigned at the proposal stage, and proposals are to be reviewed by the APR. To the best extent practical, the same APR should be engaged from the proposal stage forward throughout the life of the project. Two signatures are required on all proposals to ensure review has taken place. One of those signatures must be an APR. By affixing their signature to the proposal, the APR attests that their responsibilities have been fulfilled.

For projects producing Data-Only Deliverables in the Facilities and Materials service lines, APR review is not required on proposals for projects not requiring professional opinions, conclusions or recommendations, unless fees exceed $10,000. For such projects, the proposal may be authored or reviewed by either an OM or DPM without an APR oversight.

For TYPE II Projects requiring Project EXEC oversight, the Project EXEC should provide an independent review of the proposal. Confirmation of Project EXEC document review must be signified on the cover page of the proposal, but actual signatures from Project EXECs are not required.

Additional signature requirements are set out in ***Risk Management Policy No. 8*** - **Authority to Sign Proposals and Contracts.**

The APR must review the proposal to consider the following aspects of the project.

- Scope and technical approach;
- Client expectations;
- Project risk and risk mitigation strategies;
- Anticipated need for, and availability of, SMEs;
- Working with the PM to consider project as TYPE II with verification and confirmation by the ASLD and DM;
- Ability to achieve the schedule for on-time delivery with sufficient consideration for quality;





- Budget review for work items, hours, contingency, pricing, and proper allocation to each budget/task category in PX, etc.;
- Scope definition to confirm clarity of Terracon's commitment;
- Assumptions associated with pricing and how the assumptions are stated within the proposal; and
- Precision of scope and that all exclusions are stated clearly

4.2 PROJECT EXECUTION

In the event the APR who reviewed the project proposal is unavailable to serve as APR for the project, the PM should consult with the DPM to select an alternate APR. The PM should notify the selected APR and confirm their availability to serve as APR for the remainder of the project before changing the assignment within PX.

The PM should establish that a contract is developed for the conduct of work consistent with Terracon's Risk Management Policies and the APR should confirm that such contract is in place.

The following sections outline the Project Execution requirements for all projects.

4.2.1 Project Kick-Off Meeting

The kick-off meeting is an important opportunity to engage with our clients, explore and understand their needs, and learn how we can create a great client experience and build these relationships.

Consistent with the commencement of the project, the PM shall schedule a project kick-off meeting with ample time and with appropriate parties, including the APR, to affect the initiation of a successful project. The APR has the responsibility to make sure the PM conducts the kick-off meeting and communicates clearly the elements that will result in project success, including safety, scope, schedule, quality, budget, risk and client satisfaction. If the APR is not physically present in the office where the kick-off meeting occurs, the APR should attend via video conferencing to allow the APRs full engagement. During the kick-off meeting, the APR and PM shall mutually agree on critical junctures and the desired level of engagement. The kick-off meeting shall also be used to establish the parameters that will bring about project success from safety, client satisfaction and financial perspectives. In the case of a need for an independent SME(s) or a Project EXEC to support the project, they shall also be included in the kick-off meeting.

For TYPE II projects, the Project Management Plan (PMP) should be completed, presented and discussed in detail with all Project Team Members in the Project Kickoff Meeting.

Separate, Client-Engaged Project Kick-Off Meetings are encouraged whenever possible. Such meetings should be initiated by the PM, and they should include the PM, the APR, the client and design team professionals.





4.2.2 Critical Junctures

Critical junctures create opportunities for the APR to monitor the project status, to verify the assumptions in the scope, schedule and budget, to consider the need for SMEs, and to validate with the PM that the project is progressing as planned. APR and PM interaction at each defined critical juncture is essential. If critical juncture meetings are not taking place, the APR, DPM and OM will develop a corrective action plan for the PM, which will include a client communication plan for any scope and/or budget adjustments requiring a signed change order before any extra work is begun.

Mandatory critical junctures include:

- Proposal submission,
- Project kick-off meeting,
- Preparation of change orders,
- Deliverable reviews, and
- Project closeout

Additional critical junctures may be deemed necessary by the APR based on criteria such as project risk, experience of the project team, client, and technical difficulty. In addition, the Project EXEC may elect to participate in certain critical junctures as set forth in the PMP. Other critical junctures may include, but are not limited to, the following:

- Project team meetings;
- Characterization and calculations;
- Preliminary findings, opinions, recommendations or conclusions;
- Preliminary document outlines formation;
- Client communication preparation, including verbal and e-mail and Client Portal submittals, which convey opinions, recommendations, and/or conclusions

Whenever possible, these critical junctures should include interim deliverables to the client and their design team professionals to facilitate collaboration. In addition to critical junctures established at the Project Proposal stage, certain events during the project execution may arise, which create critical junctures, not originally anticipated at the Project Planning stage. Examples of such unanticipated events include, but are not limited to:

- Safety-related incidents, including near-miss and actual incidents of any type;
- Unanticipated conditions related to project findings with potential to affect project scope, schedule and/or budget or client expectations;
- Unexpected delays of any type affecting project schedule;
- Client interaction changing work scope or schedule;
- Reassignment of PM, APR or other key staff

The APR must be involved at critical junctures during the course of the project for consultation, guidance, and coaching.

4.2.3 Document Review

As noted above, any and all client communication (documents, email, verbal), except data reports without conclusions, recommendations or opinions, constitute a critical juncture unless





the communication is clearly defined as preliminary and subject to modification. The APR must review and approve all final deliverables. APRs must examine the technical approach, validity of assumptions, verification of data and analysis and the overall compliance of the deliverables within Terracon standards (format, grammar, punctuation, consistency and alignment of deliverable contents with correct table of contents and other aspects of the 'written quality' of the deliverables) as well as confirming that the deliverables are aligned with the scope as defined in the proposal.

The APR and PM shall strive to schedule and coordinate the preparation of project deliverables to allow the APR and SME adequate time to perform the required functions. The APR expects sufficient lead time for reviewing the draft of the final deliverable. The PM is expected to provide the deliverables to the APR in a final form ready for client delivery. Likewise, the SME needs adequate time to be engaged in the project in such a way that they can provide input in a timely manner up through and including reviewing portions of the project deliverables related to their area of involvement.

The APR shall confirm that project deliverables:

- Provide appropriate opinions, recommendations, and/or conclusions that align with client needs and project risks and that all such opinions, recommendations and/or conclusions are supported by the data;
- Satisfy contractual obligations and client-specific requirements;
- Incorporate appropriate risk management elements;
- Satisfy pertinent statutory requirements;
- Correlate with information and findings contained in other Terracon services impacting the project site;
- Follow Terracon guidelines and formats for the particular services; and
- Satisfy project-specific QC plans

As a subset of the APR responsibilities, where an SME has been engaged, the APR must clearly define the areas of responsibility of the SME so that they can provide adequate support to the project.

The APR shall also verify the PM is effectively consulting with the client regarding project recommendations contained within the deliverables. The communications should occur in a manner in which the client clearly recognizes and understands the recommendations.

4.2.4 Data-Only Review

Certain deliverables in the Materials and Facilities service lines are "Data-Only", meaning that the deliverable contains field, laboratory, observation or test data only and does not contain an opinion, recommendation, or conclusion. In those instances, the DOR is a formal designation for individuals who are qualified and approved to review factual data. Offices maintain lists of qualified DORs for Facilities and Materials for reviewing ***Data-Only Deliverables***. The role of the APR on a data review will vary depending upon the complexity of the project. The APR may review some of the deliverables; however, at a minimum, the APR will provide coaching and technical oversight to the DOR and periodic review of representative deliverables. Specific data review activities are outlined in detail in Appendix E – Data-Only Review Project Checklist.





Further data review activities applying specifically to Materials and Facilities services are outlined in Appendix F.

4.2.5 Real-Time Data Delivery

In many instances, Terracon may establish means to share data collected in the conduct of a project with the client, design team professionals, and/or other project team stakeholders in real-time, or as the data is collected. The specific criterion that such data must meet to be delivered real-time is: Such data are representative of a condition at a point in time and cannot be modified subsequent to the collection of the data, with exception of location errors. When this criterion is met, the specific data to be delivered real-time must be developed using quality processes that anticipate the delivery of such data in real-time, including the knowledge and experience of any individual that may apply engineering judgement in the context of real-time delivery. The APR must confirm that such processes are in place before real-time data delivery can proceed. From time to time specific, routine opinions or engineering judgement related to the real-time data can be delivered in association with the actual data. In such cases, any opinions must be specifically identified as preliminary, and subject to change upon completion of Terracon's quality processes. In any case where specific and routine opinions are delivered in association with the real-time data, the APR must approve the specific process that is in place to deliver such opinions.

4.2.6 Signature Requirements

The PM and APR must co-sign any project deliverables containing opinions, recommendations, and/or conclusions, unless the deliverable is clearly identified as preliminary and subject to change. If there are licensing or certification requirements by a state, agency, or client that must be met, either one signer or the combination of the two signers must jointly satisfy all requirements, including sealing the documents with a professional seal. If the PM is an APR, any project deliverable must be reviewed and signed by a second person who is considered to be capable of rendering a competent, critical review consistent with the complexity of the project. The second reviewer shall be selected by the DPM. The second reviewer is not required but should be an APR, if at all possible, and should not be a subordinate to the PM on the project. In any event, the deliverable must be signed by an APR, either as author (first signature) or reviewer (second signature). Two signatures are required on all deliverables, unless the deliverable is specifically noted as preliminary and subject to revision based upon final review.

4.2.5.1 Hard-Copy Documents

Original signatures are preferred for hard-copy documents. Unless a statute or the client requires original signatures, APRs or authors may authorize another person to sign on their behalf. The procedure for proxy signatures for an APR shall be for the individual authorized to sign on behalf of the APR to sign their own name and add below "for [APR's NAME]" to refer to the APR.





4.2.5.2 Electronic Documents

Deliverables are generally issued in PDF format or delivered via our Client Portal Website, email or other document management system required by our clients. When delivering electronic documents outside the Client Portal, it is required that the deliverables utilize electronically affixed signatures that can be digitally verified if needed. This occurs through the use of Terracon's required secured digital signature program, ***TerraSign***, or Terracon's approved electronic signature platform, ***Adobe Sign***, in accordance with Terracon Risk Management Policy No. 12.

As an alternative, the deliverable can be signed with "wet ink" and scanned into PDF format for distribution to the client and followed by a hard copy to the client. The PM shall confirm that electronic deliverables follow Terracon policies and procedures for digital signatures and are consistent with state requirements for electronic reporting or digital signatures.

4.2.5.3 E-mail, Client Portal and Other Communications

E-mail, client portal and other communications containing opinions, recommendations, and/or conclusions must be reviewed consistent with this manual and must document an APR review. To document, include "Reviewed by [APR's NAME]" in the closing of the e-mail, and copy the APR on the e-mail.

The only exception to this requirement is related to specific electronic communications that are designated as preliminary and subject to subsequent revision.

4.3 PROJECT CLOSEOUT

Upon completion of the project, the APR shall meet with the PM and conduct a Project Closeout Meeting. If the project is identified as a TYPE II, the Project Closeout and Project Closeout Meeting should follow expectations of the PMP (Appendix N.4).

The Project Closeout Meeting is to review the parameters as established in the Kick-Off Meeting that defined safety, client satisfaction and financial success and to assess whether all parameters were met. The APR may require the DPM to attend the Project Closeout Meeting. When unusual experiences are noted, the APR and PM should use the opportunity to document any lessons learned for the continued development of the PM and to keep the DPM apprised of any pertinent items. Meetings focused on continuous improvement should include developing lessons learned, which may also be helpful in evaluating potential "systemic" issues within the safety, quality and project delivery processes.

Additionally, The PM should update their resume and prepare project capsules for future proposals that would benefit from the experience gained during the project.

Items to be discussed in the Project Closeout stage include the following:





4.3.1 Records Management

At Project Closeout, the PM shall properly close the project files and documents (email communications, photos, financial documents, etc.) according to Terracon's Records Management Policy, with confirmation by the APR. When applicable, the PM shall also collect underlying electronic files (i.e. CADD) from other offices that performed work on the project and place in appropriate project files.

4.3.2 Technical Success

The APR is encouraged to engage the PM in a conversation with the client and other project team members to gauge their opinions related to the success of the project. This offers an excellent opportunity for the APR to coach the PM to build client communication skills as well as to improve upon our ability to meet particular client needs. Upon completion of the client conversation, the APR and PM should consider ways to improve their processes as a part of the Continuous Improvement philosophy. In conclusion, the APR and PM shall update their resumes and write project capsules describing the project and its success for future client development opportunities.

4.3.3 Financial Success

The APR must review the success of the project from a financial perspective. They should consider whether the project met the budget, the planned WU/WD expectations and the client's expectations. If variations are discovered, the APR shall discuss the root causes of the unplanned WU/WDs, with the PM and document how to prevent such occurrences in the future as a part of the Continuous Improvement philosophy.

5.0 PROGRAM COMPLIANCE

Regular examination of the quality management processes is essential to ensure the processes are being implemented and executed consistent with this manual and its objectives.

The QPDLT will conduct an annual survey regarding the quality process and its implementation. Separate surveys will be sent to APRs and PMs to obtain numerical feedback ratings and open-ended question responses on the quality process and its implementation from the specific perspective of each audience. Survey participants will be invited to raise specific concerns and to suggest ideas for improvement.

The CDO or their designee will compile and present an annual report for the Executive Committee to provide a status report outlining the progress of Quality and Project Delivery efforts. The report will include:

- Information such as the number of APRs approved during the year for each division by service line and the estimate of how many are expected to go through the approval process the following year.
- Summary of the annual APR/PM Survey;
- APR training (what was taught and how many were trained) and training approach for the following year;





- Refinements made to any quality process;
- PX initiative accomplishments and what updates are expected the following year.
- Number of APRs evaluated and any significant modifications to the evaluation process or trends/results; and
- Progress made on any additional initiatives assigned by Executive Committee at the beginning of the year

6.0 DOCUMENT CHANGES

Continued development and improvement of quality processes and procedures are a critical part of a functioning and effective quality program. It is expected that some modifications to supporting documents, forms and templates, including clarification of defined processes and procedures may be needed from time to time. Therefore, changes to the PQM document may be defined as follows:

- **Major changes** – Changes to the PQM document, other than those defined as minor changes, are considered major changes and shall be reviewed by the **QPDLT** and approved by the **Executive Committee**.

- **Minor changes** – Minor changes to documents that do not impact the original intent, such as editorial corrections, clarifications, modifications to forms, tables, templates and other attachments shall not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval shall be authorized by the **CDO** and documented as a minor revision, accordingly, on the **Revision Record.**





Appendix A
Definitions

The following terms are bolded and italicized on first reference in this manual. Their definitions are:

AdobeSign is Terracon's electronic signature platform which may be used for signing contracts, proposals, offer letters, lien waivers and invoices, among other documents. Adobe Sign should not be used to sign documents which require a seal, reports, or when clients require digital signature use for uploading to their systems. In those instances, TerraSign should be utilized.

Annual Project Quality Report is compiled by the DQPD on an annual basis to provide review process compliance information to management personnel.

Acquisition APR is a senior professional who is a member of an acquired firm and has been identified by the DM and SLD as qualified to perform the quality functions for projects in accordance with the acquired firm's quality processes. The use of the term 'Acquisition APR' and person selected as the project quality manager can function in this role until the candidate has become an APR using Terracon's processes. Time limits of the use of the Acquisition APR for projects are to be agreed upon by the SLD, DM and senior members of the acquired firm, but not to exceed two years from the date of acquisition.

Authorized Project Reviewer (APR) is a senior professional within Terracon who has been recognized in their service line as capable and qualified to provide project oversight as set out in this manual.

APR Program Administrator (APRPA) reports directly to the Chief Legal Officer and is responsible for administering the APR application process from nomination through approval in addition to maintaining APR electronic files, updating the Quality page on TerraNet, and assisting APRs, Service Line Directors, ASLDs, APRRC, QPDLT members with any APR-related assignments, questions, or concerns.

APR Review Committee (APRRC) is a committee made up of senior APRs (representing each division and service line) appointed by Service Line Directors in conjunction with Division Managers. Their responsibilities are to identify potential APR candidates and mentor them through the APR selection process, participate in evaluating the performance of existing APRs, support and lead APR training at the division level, identify and assist in remediation of any division/service line quality issues, and serve as a "committee" for the service lines to help lead and support any quality initiatives that may occur.

Assistant Service Line Director (ASLD) supports the SLD to supervise the policies, practices, activities and lead innovation of the individual service lines. ASLDs serve at an operating group-level of responsibility. The ASLDs work closely with the SLD, the OGM, DM and the APRRC to work with operations to manage and maintain the quality program.

Chief Development Officer (CDO) reports directly to the President and is responsible for continually monitoring the quality of our services and is responsible for developing and monitoring the Quality Program and the review processes of this manual. The CDO may approve MINOR changes to the PQM for release to operations.

Client-Engaged Kick-Off Meetings – Project kickoff meeting that incudes the key client representatives to improve project execution, establish milestones important to the client, and unify the project team and include and introduction to the Client Portal. Topics to be discussed during the client kickoff meeting include site specific safety considerations, schedules and communication, project understanding, scope and change order management, and milestones/delivery preferences.

Contract Authority **-** Terracon has adopted authority levels for signing contracts and proposals defined in Risk Management Policy No. 8. With the grant of authority comes the requirement to independently assess the risks and rewards of the project to ensure that it is in the best interests of Terracon to perform the services under the scope and terms outlined in the contract prior to signing the proposal or contract.

Critical Junctures are clearly defined points in time in the life of the project when the APR and the PM meet to discuss project progress. Critical Junctures should be defined at the outset of each project.





Data-Only Deliverables are associated with a Type I project in either the Materials or Facilities service line, which do not include opinions, conclusions or recommendations.

Data-Only Reviewer (DOR) is an individual assigned to do a data review on any given project. For Materials Service Line projects, the Data-Reviewer is approved by the Office Manager and authorized to review project deliverables or tasks relating to field and laboratory observations and test data collection only that do not contain opinions, recommendations, or conclusions. A list of qualified Data Reviewers for each office is posted on TerraNet/Offices/[Office Name] for Materials Service Line projects only.

Kick-Off Meeting is a required meeting that takes place at the beginning of a project to establish the project goals and to confirm that the project team understands those goals, including project schedule, budget, safety plans, quality guidelines, communication plans, critical junctures, etc. The meeting should be run by the Project Manager with the APR and all project team members in attendance. If the APR is remote, they should attend via video conference to ensure engagement and consensus between the APR and PM.

Office Manager **(OM)** includes both Office Managers and Regional Managers with Office Manager responsibilities over a specific office.

PM/APR Survey is an annual survey of APRs and PMs on the execution and office culture associated with Terracon's quality processes.

Project Executive (Project EXEC) is a senior professional designated by the ASLD in collaboration with the Division Manager. Project EXEC has oversight responsibility on TYPE II projects in partnership with the APR.

Project Manager (PM) is a technical professional within Terracon who is responsible for overall quality, product delivery, and client service of projects they manage.

Project Management Plan (PMP) is a document prepared by the PM and approved by the Project EXEC for TYPE II Projects. The Project Management Plan lists all responsible parties within Terracon as well as other project partners, and the individual responsibility of each, includes a communication plan and a definition of project success.

ProjectXchange System (PX) is an electronic, company-wide enterprise data entry system for registering projects and specific project information; used in managing the project and providing overall data for wider analysis of common issues or trends.

Quality Control (QC) consists of the procedures and practices established for executing Terracon's services to achieve quality objectives. This means establishing those measurements (i.e., standards, specifications, or criteria) and then controlling, monitoring, or measuring the services performed through checks, tests, or confirmations so that quality objectives are met.

Quality Assurance (QA) is the assessment process of reviewing, monitoring, and auditing to verify that quality control procedures and practices are fully incorporated and are meeting quality objectives.

Quality Program summarizes Terracon's overall approach, policies, and procedures relating to quality and is formally documented in the Quality Program Manual.

Quality and Project Delivery Leadership Team (QPDLT) is a committee appointed by the Executive Committee to oversee Terracon's Quality and Project Delivery Program. The committee is co-chaired by the CDO and the CLO, and includes the President, Service Line Directors, CFO, CIO, Director of EDW, and representative members from the respective service lines and operating groups.

Quality Management System (QMS) is the organizational structure, staff, responsibilities, policies, standard operating procedures, processes, and records that assist in achieving its quality objectives of Terracon's field and laboratory testing services.

Risk Management Policies are the policies enacted by the Executive Committee to control and manage the risks and exposures related to our services.

Service Line Director (SLD) is the senior technical professional within Terracon administering the policies, practices, and activities and leading quality, consistency and innovation within the various service lines.





Subject Matter Expert (SME) is an individual, as determined by the Service Line Director, who possesses specific technical experience and expertise in a particular technical field associated with the execution of a project.

TerraNet is Terracon's electronic intranet, supplying valuable information, policies, and procedures to our employees in an easily accessible format and access to the service line and office sites.

TerraSign is Terracon's digital signature system allowing professionals to provide digital signatures and stamps to project deliverables.

TYPE I Projects are those projects that are assigned an APR without a Project EXEC.

TYPE II Projects are those that, as determined by the ASLD in collaboration with the Division Manager, carry significant investment by our clients, represent a unique challenge for Terracon or significant risk to (or opportunity for) Terracon and require a Project EXEC review. See Section 3.2 for general criteria for TYPE II Projects.





Appendix B
Project Quality Duties and Responsibilities

Role	Primary	Oversight
Perform project services consistent with company methods, practices, and core values.	All Staff	OM
Review Materials or Facilities projects deliverables or tasks relating to field and laboratory observations and test data collection that do not contain opinions, recommendations, or conclusions for projects of $10K or less. Confirm collection of field and laboratory data consistent with provisions set forth in Quality Management System for all projects.	Data-Only Reviewer	OM, DPM or APR
Project Success. Considering all safety, technical quality, product delivery, client service, employee engagement and financial aspects of project.	PM	DPM APR Project EXEC
APR assignment for projects containing deliverables with opinions, recommendations, or conclusions. Work with the PM to ensure that qualified staff is assigned to the project.	DPM	OM
Confirm proper technical oversight of PM, using SMEs when deemed necessary. Provide guidance, coaching and review of project execution including adherence to safety rules and practices, scope, schedule and budget. Provide documented review of final correspondence containing opinions, conclusions, or recommendations.	APR	APRRC Project EXEC
Define Type II Projects requiring Project Executive. Select Project Executive for Type II Projects.	ASLD	DM
Represent service lines and divisions to identify and mentor APR candidates and review standing APRs. Support/lead APR training at the division level. Serve as a “committee” for the service lines leading quality initiatives	APRRC	ASLD SLD
Implement corporate policies and systems necessary to achieve project quality at the office level	OM	DM
Promote and enforce PQM and all referenced policies and procedures. Maintain adequate APR staffing and confirm consistent training program. Assumes responsibility, authority, and accountability for quality of projects within Division.	DM	OGM
Develop and monitor Quality Program and recommends continuous improvements.	SLD	CDO
Set corporate philosophy regarding Quality and Project Delivery. Promotes attitudes, processes, and procedures necessary to achieve quality and project success.	QPDLT	EXCOM

This table summarizes Duties and Responsibilities of the various staff that will be engaged with a project. More details regarding the Levels of Quality Control are provided in Appendix C.





Appendix C
Quality Control Tiers

Quality Tier	
Project Type	Description and Documentation
DOR (Data-Only Reviewer)	**Assigned by DPM, Approved by OM**
Project deliverables for Materials or Facilities SL and tasks for all SLs providing field and laboratory observations and test data collection. Deliverables do not include opinions, recommendations, or conclusions.	(a) Data collection, calculation and reporting in conformance with QMS (b) Independent check of field and laboratory observations, data and calculations. (c) Documentation by initials and dates on deliverables.
APR (Authorized Project Reviewer)	**Assigned by DPM**
Projects where opinions, recommendations, or conclusions are provided.	Confirm data review responsibilities noted above, plus: (a) APR review of proposals, procedures, calculations and final submittals to assure data quality, data interpretation, analytical methods, calculations, results, opinions, recommendations, and conclusions. (b) Attends Project Kick-Off and Critical Juncture meetings to coach PMs on aspects of project including client relationship, safety, scope, schedule, budget and technical review of deliverables. (c) Based upon complexity of projects, assigns SMEs when deemed necessary by the APR. Document by signature of APR on project deliverables. (d) Assigns independent SMEs when deemed necessary. (e) Signs all final documentation and is copied on all electronic deliverables with appropriate documentation.





Project EXEC (Project Executive)	**Assigned by ASLD in Collaboration with DM**
TYPE II Projects. A TYPE II Project is confirmed by the ASLD in collaboration with the DM based upon their judgment of size, scope, risk or opportunity.	Confirm APR responsibilities noted above, plus: (a) Independent project review. (b) Review and approve Project Management Plan. (c) On unique technical projects, independent review of APR's selection of SMEs, confirming proper technical contribution from SMEs within or outside the company. (d) Oversees project execution including client relationship and risk management, meeting budget and schedule, staffing, and overall successful delivery of the project (e) Confirms proper signature/documentation of APR.





Appendix D
Project Review Process

	Data-Only Projects	All Others (including Type II Projects as defined in Appendix A)
Project Planning		
Proposal/Contract	One Signature Required DOR, APR, Dept. Mgr. or OM.	Two Signatures Required, APR must be one Type II Projects: include & acknowledge ***Project EXEC Oversight*** Additional signature requirements are set out in ***Risk Management Policy No. 8 – Authority to Sign Proposals and Contracts***
Project Execution & Document Delivery		
Project Kick-Off Meeting	Part of weekly staff meeting	Participants: APR/PM & Other Key Members (as designated by PM) TYPE II Projects should include ***Project EXEC*** Define Project Team, including PM, APR, SMEs, Project EXEC, Establish Parameters for Success, Critical Junctures, Scope, schedule, budget, quality, safety and client expectations
Critical Junctures	N/A	Critical Juncture (CJ) meetings held as specified in Kick-Off meeting APR/PM attend all CJ Meetings. SMEs attend as defined by APR. ***Project EXEC*** attend specified CJ Meetings for TYPE II Projects
Project Deliverables	One Signature Required DOR, APR, DPM. or OM	PM and APR Signature If PM is the project APR, add signature by independent reviewer Project EXEC Review for TYPE II Projects Project EXEC Oversight acknowledged on signature page
Project Closeout		
Records Management	PM verifies file maintenance consistent with Terracon's Records Retention Policy	
Technical Success	PM confirm client satisfaction	PM/APR review compliance with scope/schedule Include Project EXEC for TYPE II Projects Hold Continuous Improvement Meeting for unique projects
Financial Success	PM confirm Financial Parameters, Invoicing and Collection	PM confirm Financial Parameters, Invoicing and Collection APR confirm compliance with budget and WU/WD Projection Hold Continuous Improvement Meeting for unique projects

Note: TYPE II projects, shall be conducted under the direction of a Project Management Plan reviewed and approved by the Project EXEC.

Important Notes about Safety:

Safety is integral to everything that we do. APRs and PMs have unique and specific responsibilities related to project safety.





PMs are responsible for establishing safety protocols throughout the life of the project consistent with Terracon's Core Safety Rules and Practices and Life Safety Absolutes as well as any project specific safety requirements.

APRs are responsible to coach the project team to complete all phases of the project safely, consistent with Terracon's Core Safety Rules and Practices as well as any project specific safety requirements.

The scope of safety-related responsibilities is beyond the scope of this document. Project-Specific Safety planning and Safe and Right Procedure Certification requirements provide more details.





Appendix E
Data-Only Review Project Checklist

DATA-ONLY REVIEW PROJECT CHECKLIST

Following checklist is provided to assist the Data-Only Reviewer (DOR) during the project deliverable review process. Not all points are mandatory to follow; however, each should be appropriately considered based upon project requirements.

The DOR should review the project scope and ascertain whether they are familiar with the scope of services required for the project. If the scope of services for the project is outside the traditional experience of the DOR, the project should be directly reviewed by another DOR or an APR. Special projects, such as forensic studies and projects with high inherent risk should be directly reviewed by an APR. If significant issues arise or if opinions, recommendations, or conclusions are provided during the project, the DOR should immediately involve the APR.

Project Document and Data Review

- ☐ Are appropriate template formats used?
- ☐ Does deliverable adhere to proposal scope or signed contract?
- ☐ Are project specifications available for review?
- ☐ Are data and calculations being reviewed?
- ☐ Are data and calculations being reviewed by senior personnel or APR, if necessary?
- ☐ Is correct grammar and language being used?
- ☐ Are field data and results consistent with final deliverable?
- ☐ For Materials services, are deviation logs being maintained daily, and deviations communicated to client and other parties within 24 hours?
- ☐ Are deliverables being distributed to client in required time frame?
- ☐ Are opinions, recommendations, or conclusions provided? If yes, is an APR reviewing the deliverables?
- ☐ Is DOR discussing quality of deliverables with APR on a regular basis?





Appendix F
Project Quality Review Responsibilities For Materials Services

PROJECT QUALITY REVIEW RESPONSIBILITIES FOR MATERIALS SERVICES

The services that Terracon provides on a significant majority of our projects in the Materials Service Line involve performing field and laboratory observations, testing, and data collection. On many Materials projects, we may not be required or requested to provide opinions, recommendations, or conclusions at any point during the project. The PQM defines project deliverables or tasks related to providing field and laboratory observations and test data collection and not containing opinions, recommendations, or conclusions as a Data-Only Review process (see Section 4.2.4 of this manual). However, this does not remove the requirement of having an APR assigned and involved in each Materials project. The PQM requires that an APR be assigned to each project, regardless of complexity or services to be provided. Project personnel must have a clear understanding of the role of the APR on Materials projects. In the case that a project does not have opinions, recommendations or conclusions, but requires an APR, the APR is not required to have a Professional Engineer's license. Materials Service Line has provisions for the non-PE APR, as shown in the APR applications. In the event a project evolves to include recommendations and opinions, the non-PE APR shall seek review by an appropriately-skilled PE, preferably with APR status.

As discussed above, a DOR can be assigned to do the quality review on many of the deliverables on Materials projects. This is often more practical and efficient due to the volume of Materials projects and associated reports in an office. However, any project deliverable that contains opinions, recommendations, and/or conclusions must be reviewed by the APR prior to client submission. If the APR is not a licensed Professional Engineer in the state that the services were performed, the primary author needs to be a licensed Professional Engineer in the applicable state.

The following table provides additional guidance for review responsibilities for various types of project deliverables on Materials projects. This report is not an exhaustive listing of every type of Materials report. If questions arise on a Materials project as to the necessary level of review required, the PM should consult with the APR.





Reviewer Requirements for Various Materials Reports

Minimum Required Reviewer	Materials Report Type
DOR that meets client and local jurisdictional review and signature requirements Note: Expectations for report content and review need to be discussed, clarified and set in the kickoff meeting with the APR	■ Report of laboratory test results ■ Report of Field Observation, Inspection and/or Testing services that strictly reports test results and results of observations and inspections and state acceptability or compliance only (contain no opinions or recommendations), with exception of those noted below. The experience and qualifications/certifications of the field personnel performing the testing, observations, and inspections contained in the reports must be appropriate and current for the service being performed and reported.
DOR with either the author or reviewer having specific additional expertise and certification/license; meet client and local jurisdictional review and signature requirements Note: Expectations for report content and review need to be discussed, clarified and set in the kickoff meeting with the APR	■ Structural Steel Reports – DOR must be a CWI, ASNT LEVEL II, or a Professional Engineer ■ Roofing Observation Reports – DOR must be an RRO, RRC, or a Professional Engineer
APR with professional license, or Registered Professional Engineer that meets client and local jurisdictional review and signature requirements Note: Expectations for report content and review need to be discussed, clarified and set in the kickoff meeting with the APR	■ Certification/Verification/Confirmation Letters ■ Interim and Final Letters required by client or local jurisdiction for Certificates of Occupancy (COs) ■ Report of Field Observation, Inspection, and/or Testing that also includes opinions, recommendations, and conclusions (e.g., proof rolling, foundation bearing capacity, load tests, review of weld procedures, etc.). The experience and qualifications/certifications of the field personnel performing the testing, observations, and inspections contained in the reports must be appropriate and current for the service being performed and reported. ■ Review, Verification, or Design of Concrete/Grout/Asphalt Mixes ■ Verify that Materials QMS is being implemented ■ Consults regarding failing tests, trends, and problems, in addition to providing solutions and remedial actions, e.g., proof rolls that fail and Terracon recommends aeration, removal and replacement, chemical stabilization, or other remedies ■ Statistical analysis of test results to evaluate acceptability or compliance ■ Reports related to the investigation, evaluation, or forensic study of existing structures and or in-place materials





	■ Subcontracted services which contain engineering opinions, judgment, recommendations, or conclusions.





Appendix G
PM and APR Appointment and Review

PM AND APR APPOINTMENT AND REVIEW

The PM and the APR roles provide the foundation of our quality program, and it is critical that only experienced and qualified PMs and APRs be appointed. Terracon is continuing to build upon our PM training, appointment and review process. PMs are assessed for appointment as part of their hiring or promotion process by the hiring team.

A. PM SELECTION, TRAINING AND APPROVAL

Candidates to be PMs must have at least two years of professional experience in our industry and must complete designated training and demonstrate proficiency in the use of Terracon systems and tools, as well as exhibit competency in selected skills. PM candidates are required to complete the Terracon PM Selection process. Approval to the role of PM is made by the DPM or OM for personnel assigned to operations offices or the supervising Sector/Service Line/Operations Director for personnel assigned to operations development

Once an employee has met the requirements to become a PM and approved as such, it will remain the responsibility of the employee, their direct supervisor and the APRs they work with on their projects to continue development and training. The PMs supervisor should assign projects to PMs based on their experience, knowledge, abilities, and continued growth in varying complexities and size of projects.

The expectation of this role is continuous improvement, fundamental competence and eventual mastery in project management, and the ability to consistently meet project quality, safety, financial, and on-time delivery expectations and a successful client experience.

Only PMs that have met all the PM expectations and has consistently shown their ability to successfully manage a wider array of Type I projects of varying size and complexity and successfully completing tasks can the individual qualify to be assigned to the PM role on Type II projects. Type II projects are required to be managed by PMs that are accepted by the assigned Project EXEC.

B. REQUIRED STEPS FOR APR APPOINTMENT AND REVIEW

A fundamental aspect of maintaining quality is the process of identifying, appointing and reviewing APRs. APRs must possess a broad base of experience in their respective technical field and must also be well-versed in project management, quality and risk management matters. APRs must demonstrate excellence, integrity, and curiosity in technical, business and ‘interpersonal’ skills to be able to bring their influence and expertise to their assigned projects. APRs must be intimately familiar with, and supportive of, Terracon’s standards for project execution and project delivery.

APR candidates should have ten years of professional experience and five years of management or supervisory experience. Exceptions to the year’s requirement may be considered based on the SLDs evaluation of the candidate’s education, professional and project experience. Additionally, APRs must





be proven as competent PMs. All the specific criteria for APR approvals for each service line are included in Appendix H.

There are two APR application types; Standard and Tailored. The Standard APR Application applies to the typical professional who has developed their skills to a point of being eligible for APR status by experience, professional registration, completion of the PM Development course, and their self-study of Terracon policies and Geoprofessional Business Association (GBA) professional practice material. The Tailored APR Application is intended ONLY for senior staff with more than 20 years' experience who have joined Terracon as a recent hire or through a recent acquisition. Under special circumstances, a senior staff member of 15 to 20 years' experience will be considered for the Tailored APR application. The Tailored APR application is only applicable after six months of employment with Terracon, and eligibility closes after two years of employment at Terracon. If the applicant does not submit the application within their first two years of employment, then the Standard APR Application is to be used.

The following steps outline the process for APR appointment and review. The process of filling out the APR application and the subsequent approval steps below follow an electronic workflow process.

The following steps outline the process for APR appointment and review. The process of filling out the APR application and the subsequent approval steps below follow an electronic workflow process.

B.1 APR Candidate

Each APRRC member takes responsibility for the APR candidates within their technical, service line and typically within their geographic responsibility. APRRC members work with DPMs, OMs and DMs to identify candidates and to assess their potential as an APR. APR candidates are typically identified one to two years in advance of 'eligibility.' The APRRC member oversees the candidate's preparation and readiness for the application process. The APRRC member may assign a mentor to the candidate. If assigned, the mentor must be an APR within the same service line as the candidate. The APRRC member or mentor is expected to work with the candidate throughout the review process and for a period of time following the candidate's APR appointment to ensure that Terracon quality policies and procedures are being followed and expectations are being met.

The APR preparation process typically includes attendance in APR preparation classes led by ASLDs. Multiple APR candidates work together as a group to complete the requirements of the APR application and to collaborate and build relationships. Once a candidate successfully completes all modules, the application should be ready for submission.

The APR candidate must complete the appropriate application found in the APR Application Utility, checking off all required boxes before signing/submitting. The application can be saved and re-accessed at any time during the approval process to update progress on requirements until the SLD approves or denies the application.

When the mentor agrees that the APR candidate is thoroughly prepared, the APRRC member will discuss with the candidate their project experiences and together discuss and select at least three projects and deliverables for review. The APRRC member works with and interviews the candidate



to verify readiness to complete the approval process. When the APRRC member determines the candidate is ready, the application is finalized and electronically signed by the candidate, the APRRC member and is automatically sent to the appropriate DM for their approval.

Once the application has been signed by both the APRRC member and DM, the workflow process will send the application to the ***APR Program Administrator*** **(APRPA)** to initiate the review process.

B.2 APR Review Process

The APRPA will receive the signed application and contact the APRRC member to identify three reviewers to assign to review the three representative projects designated on the APR candidate's application. The review focuses on the proposals, project documentation, compliance with Terracon standards, financials, invoicing, deliverables, etc.

Following assignment of the projects, the review process is as follows:

- APRPA sets up the project review feedback call and interview.
- Once both meetings are scheduled, the APRPA marks the application as "interview scheduled," which forwards the application to the SLD for approval following the interview.
- Once complete, the peer review comments are compiled by the APRPA and distributed to the APR review team, consisting of the SLD, ASLD, DM, APRRC member and the peer reviewers, in preparation for the APR candidate project review feedback call and final interview.

If, during the APR candidate project review feedback call, the SLD determines that the APR candidate would benefit from additional, focused mentoring in one or more aspects of their APR responsibilities, the ASLD and APRRC will work with the SLD to develop a specific plan to address these responsibilities. The APR candidate will, under the direction of the ASLD and APRRC, execute this plan before the final interview is conducted. The APR candidate will proceed to final interview after the ASLD has determined that the candidate has addressed the needs that were identified in the project review feedback call.

B.3 APR Candidate Interview

When possible, the final interview is scheduled within one week of the project review feedback call. The APR review team will participate in a virtual interview. The interview addresses the APRs knowledge and confidence regarding the following topics:

- Project safety (particularly the role of the APR);
- Knowledge of this PQM, Quality Program Manual (QPM), QMS and Risk Management Policies;
- Knowledge of Terracon standards and processes;
- Awareness of APR responsibilities and limitations;
- Project management strengths;
- Attitude toward standards and quality; and
- Other topics as determined by the peer review team based upon the prior review process and the interview discussion.





B.4 APR Approval Decision

Following the interview, the interview team determines whether the APR candidate meets the requirements of an APR.

- If the APR is approved, the SLD and the CDO will approve the application.
- Once approved by the CDO, the APR candidate is notified by email of the approval and the practice areas for which they are approved.
- If the APR is not approved, the APR candidate is notified by the APRRC member and/or the ASLD. The reasons for non-approval will be reviewed, and a strategic improvement plan will be agreed upon with a deadline for completion by the candidate. At the end of said time period, the candidate will be re-evaluated, and a second interview may be required.

The APR Approval Process is illustrated/summarized as follows:



Terracon

APR Approval Process

Candidates can be identified 3 months to 2 Years prior to entering the process



APR Candidate identified – The APRRC, ASLD and Division Manager along with the local Office and Department Managers work together to identify APR candidates and to determine readiness.

The APR Candidate Class lasts from 12 to 18 weeks, depending on the service line and number of sessions (5 or 6). Attendance is expected to move forward.



Concurrently with the classes:

- Candidate is consistently completing the application requirements, including the 3 independent projects (standard only), and updating the application.
- APRRC and Local Mentor review the 5 deliverables to prep for the mock interview.
- Final interviews are pre-scheduled, if requested. Interviews will be cancelled or rescheduled if Candidate is not ready to progress.

After the final class, ASLD and/or APRRC holds mock interview with Candidate to verify readiness.

Digital Signature

APR Candidate signs the application and initial approvals by the APRRC and Division Manager prompt the next step.

Standard Applicants
(3 to 4 Weeks)

- Project reviewers assigned for 3 independent projects.
- APRPA sets up Project Feedback Call and Interview.

1-hour Project Feedback Call (candidate does not attend)

2-hour APR Candidate Interview

OR

Tailored Applicants
(Generally, within 1 week)

- APRPA sets up Project Interview.

1.5-hour APR Candidate Interview

Service Line Director Approval

Chief Development Officer Approval

APPROVED APR



Once approved, APRs are expected to routinely visit the Quality and Project Delivery (QPD) pages on TerraNet. The main QPD page has a social feed, which gives both APRs and PMs a platform to share ideas, challenges, best practices, success stories and questions and answers about project delivery. We also use social to communicate important information, such as training opportunities, tools, updates to processes and systems, manuals and general correspondence regarding quality and project delivery.

C. ACQUISITION QUALITY INTEGRATION AND APR APPOINTMENT PROCESS

With approval of the DM and the appropriate SLD, a company acquired by Terracon is allowed to continue to operate using its prior quality management system for an interim period if it contains similar project review practices using senior staff. The DM and SLD will develop an integration schedule for any acquisition company to become trained and compliant with Terracon's Corporate Quality Program. The acquired company will adopt and use the Terracon system at the earliest practical time, but in no case should this transition time exceed two years. The DM, with input from the senior leaders of the acquired company, will determine the integration schedule.

SLDs will coordinate with the DM to develop the timeline, training and APR selection. During this interim period, projects from the acquired company and new projects may be registered within PX using the designation of "Acquisition APR." After the integration schedule has been exceeded, the Acquisition APR selection will no longer be available for new project registration. After six months of employment with Terracon, satisfactory APR candidates from the acquired company may use the Tailored APR Application approval process as set out in Appendix I. After two years, any new APR candidates from the acquired company will be required to use the Standard APR Application approval process also set out in Appendix I.





Appendix H
APR Approval Criteria

The APR Application Utility is an electronic workflow designed to give APR candidates a checklist of requirements to meet prior to submittal as well as a way to administer the subsequent approvals in a timely manner.

There are two types of APR applications:

1) **Standard:** This application is the most common. It is intended for employees with 10+ years of overall experience and those who have been at Terracon for more than three years.
2) **Tailored:** This application is intended for employees with 20+ years of experience who have joined Terracon within the last two years either as a new hire or through an acquisition. If application is received after the two-year eligibility date, a standard application must be submitted.

Note: On a case-by-case basis, a Service Line Director may make exceptions in the years of experience based on job performance as a Project Manager and technical expertise.

Requirements to become an APR are listed in the table below, which mirrors the APR application:

REQUIREMENTS	STANDARD	TAILORED
PRACTICE AREAS		
Candidate will check off at least one practice area for which they want to be approved as an APR. *Note: If the Candidate checks off more than one practice area, and the Review Team decides not to approve the Candidate for all of them, the application will be modified and approved for only the approved areas of practice.*	X	X
PROJECTS (FOR INDEPENDENT REVIEW)		
Candidate must upload 3 Projects to be independently reviewed by APRRC members or senior APRs (other than 5 deliverables mentioned below)	X	N/A
FORMAL EDUCATION		
Note: Each service line has its own requirements regarding formal education and professional licensure or certifications. A candidate should discuss these requirements with his/her ASLD prior to submitting an APR application. Candidates must meet all requirements for the service line in this category.	X	X
EXPERIENCE AND ABILITY		
Minimum years of overall experience practicing in a professional position	10 Years*	20 Years
Minimum years of experience as staff supervisor, department manager, or comparable position with increasing responsibility for the performance and review of work of other professional staff	5 Years	10 Years
In the case of an acquisition, approval by the acquired firm's senior management for tailored APR responsibilities.	N/A	X
Submitted to APRRC Mentor at least five deliverables (different projects than the three listed on the application) prepared by APR applicant	X	X





Participate in an interview (preparatory) with the assigned APRRC member	X	X
CONTINUING EDUCATION		
I have completed all five modules of Terracon's PM Development course or am actively working with my office manager to complete the modules.	X	X
I have read, understand, and agree to comply with Terracon's Project Quality Manual (PQM) and Quality Program Manual (QPM).	X	X
I commit to use Terracon's systems for Project Delivery.	X	X
I have read, understand, and agree to comply with the Records Management Policy, including file organization and retention requirements.	X	X
I have read, understand, and agree to comply with Terracon's Risk Management Policies.	X	X
I have read, understand, and agree to prioritize use of Terracon's contract forms (standard contract form and residential form).	X	X
I understand the serious nature of the APR responsibilities, and I am committed to providing the necessary time and energy to maintaining the standards of the program.	X	X
I understand the importance of timely APR services and will prioritize the time needed to serve as an APR.	X	X
I agree to complete annual continuing education requirements as training is developed and rolled out to stay in compliance with the Project Quality Manual (PQM).	X	X
I agree to actively participate in surveys, programs, committees and forums to improve Terracon's Quality Program.	X	X
I am knowledgeable of the resources available from GBA and have access to relevant GBA publications and documents (electronic and hard copy publications can be ordered free from GBA at https://www.geoprofessional.org).	X	X
I have completed the GBA Fundamentals of Professional Practice course (or similar loss prevention seminar) OR have been a presenter of at least five local internal risk management seminars using topics available from GBA Material.	X	X
I have listened to the GBA Project Management Fundamentals, Volumes 1 and 2 Recordings (Recordings are accessible on the Quality/For APR Applicants/GBA Information and Materials page of TerraNet.)	X	X
I have read the GBA publication entitled 'In House Review of Reports.'	X	X
I have read ten relevant GBA case histories and discussed with my APRRC representative.	X	X





RESUMES		
Candidate must upload a current resume to the system in order to submit the application.	X	X

* - Exceptions to the year's requirement may be considered based on SLDs evaluation of the candidate's education, professional and project experience.

For approval workflow process information, please see Appendix G, Section B.4.





Appendix I
PM and APR Evaluations

Our quality management process includes the continuing evaluation of PMs and APRs. Continuing evaluation is integral to our process of constant quality improvement.

A. PM Evaluations

Project Managers are evaluated for quality as part of our employee annual review processes given that is one of their primary job responsibilities. In addition, PMs must meet the requirements of the Managing Projects at Terracon - PM Training, Development, Selection and Approval Requirements, which is posted on the Quality and Project Delivery/PM page on TerraNet.

B. APR Evaluations

The final APR candidate review process consists of the review of three projects in which the candidate served as the PM. The APRRC will work with the APR candidate to select three representative projects that include the various APRs that typically serve as the APR for the candidate. This final project review process also allows the opportunity for the review team to evaluate the performance of each project APR. The review team's comments and observations will be documented on the APR Candidate Project File Peer Review form and provided to the APRRA. If the review team identifies quality concerns with the existing APRs work, this will be discussed with the APRRC, DM and SLD. The APPRC, DM and SLD will be responsible for determining corrective measures.

Additionally, APR Needs Assessments are performed on selected Divisions and Service Lines on an annual basis. The intent of the Assessment is to evaluate strengths and challenges that exist within the APR network with the end goal of this process to identify potential areas of improvement and whether the current APR resources appear appropriate to fit needs. The APR Needs Assessment evaluates the APR network within a Division and the performance of individual APRs is considered and evaluated based on their workload.





Appendix J
APR Continuing Education

As senior members of Terracon's professional service lines, APRs are expected to lead our efforts to continually improve our quality processes and to identify innovations and/or lead in the implementation of innovative processes. Each APR is expected to coach PMs and other staff as those individuals aspire to achieve APR status in the future.

Effective continuing education is an important part of the professional growth of the APR and the continuous improvement of Terracon's quality processes. This section outlines the specific requirements of our continuing education program.

Six hours of continuing education relating directly to the duties of an APR are required for all APRs each year. APR continuing education takes the form of in-person training, as well as virtual training activities. Subject matter shall include regular reminder education as to the quality and project delivery processes, and the specific duties of the PM, APR and Project EXEC to provide a solid foundation of knowledge of the Company's expectations relating to quality deliverables. It is also essential that APRs are made aware of any compliance issues regarding the review process and any current practice-related matters.

Notifications for APR continuing education opportunities is generally provided by email notification or on the Quality and Project Delivery TerraNet page.

The components of continuing education regarding the APR process shall focus on:

- Review of Annual Project Quality Report information;
- Updates to Terracon's Quality Management Program;
- Quality process as outlined in this PQM;
- Competencies required for APRs;
- Best practices;
- Terracon standard templates, formats and processes for consistency of our deliverables;
- Lessons learned, both positive and negative, of APR involvement in specific projects;
- Terracon's Risk Management Policies; and
- Emerging trends affecting our practice.

OFFICE PROJECT QUALITY "BROWN BAG" SESSION

The OM shall conduct an annual "brown bag" style meeting for their DPMs, PMs, DORs and APRs. Other topics will include best practices, Annual Project Quality Report information for the office, as well as standardized training materials provided to OMs by the QPDLT.

VIRTUAL CLASSROOM CONTINUING EDUCATION FOR APRS

APRs are required to participate annually in service-line-specific virtual training sessions focusing on APR-specific issues. The content of these presentations will be prepared by the SLD with input from the QPDLT. PMs will be invited and encouraged to participate in all APR virtual continuing education opportunities.





These presentations may be conducted via virtual conferencing, conference calls or by other various internet technology systems.





Appendix K
APR Project Review Checklist

The following checklist is provided to assist APRs during project review. The APR must be involved from the proposal stage through completion of project. It is not mandatory to strictly follow each step, but all should be appropriately considered based upon project requirements.

Proposal Review

- ☐ Is the scope of services appropriate to satisfy client objectives and well defined?
- ☐ Are the fees appropriate for the scope of services and contract terms?
- ☐ Is total Terracon fee larger than $10,000 for Materials service lines? (If so, an APR must review the proposal.) For other service lines, APRs are to review all proposals.
- ☐ Is the project schedule achievable?
- ☐ Is the proposal using standard risk management language?
- ☐ Is an appropriate limitation of liability included in contract?
- ☐ Is a reasonable indemnification provision included in contract?
- ☐ Is the correct proposal template and format being used?
- ☐ Are Terracon Risk Management Policies being followed?
- ☐ Does the proposal have provisions for safety including equipment, labor, and planning, and have safety hazards and safety concerns been considered and discussed?
- ☐ Is the project designated a TYPE II project requiring a Project EXEC?
    - If yes, has Project EXEC been engaged in proposal process?

Project Execution and Critical Junctures

- ☐ Are performed services adhering to proposal scope?
- ☐ Are safety practices and project safety requirements being adhered to?
- ☐ Have any unanticipated safety conditions arisen, and have they been properly addressed?
- ☐ Is the project designated a TYPE II Project requiring a Project EXEC?
    - If yes, has a Project Management Plan been established?
- ☐ Does the project entail non-routine calculations or require expertise of Subject Matter Experts (SMEs)?
    - If yes, consult with SMEs and PM to secure proper expertise
- ☐ Did PM encounter unanticipated conditions, deviations, or problems during data collection?
- ☐ Is a change in scope of services required?
- ☐ Is a change order necessary or an increase in fee?
- ☐ Is PM discussing findings and recommendations with APR?
- ☐ Is APR checking in with PM on project objectives, including scope, schedule and budget compliance?
- ☐ Are recommendations appropriate considering client and project risks?
- ☐ Are design data and calculations documented and checked, including any calculation spreadsheets?
- ☐ Are the parameters and assumptions used in the analyses supported by appropriate laboratory or field testing data?
- ☐ Is PM aware of correct templates to use in final report?
- ☐ Is PM providing final draft deliverables to APR well in advance of client due date?
- ☐ Is APR discussing and mentoring PM regarding comments and changes?
- ☐ Is PM proactively serving as a “consultant” and “advisor” to client?

Review of Deliverables

- ☐ Is deliverable adhering to proposal scope?
- ☐ Does report and all exhibits professionally displayed and consistent with Terracon Standards?
- ☐ Are recommendations clearly presented and logical?





- ☐ Is deliverable addressing client and project risks?
- ☐ If multiple design alternatives/options are provided, are the risks associated with each discussed?
- ☐ Is data in deliverable correct, complete, and internally consistent with Appendix?
- ☐ Is deliverable reflecting any change orders?
- ☐ Is standard risk management language used?
- ☐ Have other Terracon service lines or offices provided deliverables on the same project site? (If yes, has PM confirmed, coordinated, and reviewed any findings with other service line's PM?)
- ☐ Is deliverable using correct grammar and language?
- ☐ Is deliverable issued to the proper parties and client?
- ☐ Have APR changes been made to final deliverable?





Appendix L
Data-Only Reviewer Approval

DATA-ONLY REVIEWER APPROVAL

(Send to Office Manager – All Items Must Be Checked)

PROPOSED QUALITY CONTROL REVIEWER NAME:_____

SERVICE LINE: _____

- ☐ Registration as an EIT or PE, or certification as a NICET Level II, ICC Special Inspector, AWS Certified Welding Inspector, or equivalent DOT certifications or other recognized national qualifications-based registration or certification.
- ☐ For Materials services, current Terracon job classification title is Technician III or higher (excluding Field Professional) or Staff Professional I or higher. For all other services, current Terracon job title is Project Professional I or higher.
- ☐ Clear understanding of the requirements and responsibilities of Data-Only Reviewer.
- ☐ Experience in the preparation of deliverables and written documents to be reviewed.
- ☐ Proven ability as author and reviewer of the type of reports to be reviewed. In addition, Office Manager or a designated Authorized Project Reviewer has reviewed at least five reports that have been completed by the proposed Data-Only Reviewer.
- ☐ Read and adhere to Terracon's Risk Management Policies.
- ☐ Read and adhere to Terracon's Quality Program and Project Quality Review Program Manuals.
- ☐ Read the GBA publication: *In-house Review of Reports.*
- ☐ Familiar with pertinent GBA publications and documents (these publications can be ordered free from GBA at www.geoprofessional.org).
- ☐ Judged to have appropriate attitude toward the serious nature of the responsibilities assumed by a Data Reviewer.
- ☐ Demonstrates a willingness to honestly assess personal qualifications and seek advice and opinions from other senior staff and APRs as appropriate.
- ☐ Judged to have appropriate ability to proofread and edit text so it is clear and unambiguous from a client perspective.
- ☐ Signed by:

_____		_____	
Proposed Data-Only Reviewer	Date	DPM	Date
_____		_____	
Authorized Project Reviewer (If DPM or Office Manager is not an APR)	Date	Office Manager	Date

THIS APPOINTMENT AND FORM SHALL BE POSTED TO THE OFFICE'S TERRANET SITE.





Appendix M
Data-Only Reviewer Appointment Process

DATA-ONLY REVIEWER APPOINTMENT PROCESS

DORs are appointed for the Materials and Facilities Service Line by the OM with input from the Materials or Facilities DPMs. The approved appointment lists and form for each office will be posted to the office's TerraNet site. See https://terracon4.sharepoint.com/sites/Offices.

The DOR Approval Form, attached as Appendix I, sets forth the guidelines for qualification as a Materials or Facilities DOR.

In this instance, the reference to Data-Only Review is only relevant to the deliverables in Facilities and Materials that do not contain opinions and does not relate to the more over-arching process of data review that occurs on any deliverable containing data.





Appendix N
Type II Project Delivery

TYPE II projects are a major contributor to our vision for being dominant in our markets and are important to our financial success and we continue to grow them. How we support, collaborate, work and learn together impacts how we successfully deliver them.

TYPE II Project Processes were developed to deliver a consistent project experience to identify and manage enterprise risk and to achieve professional development utilizing the experience and knowledge of our resources to promote project ownership, on-time delivery and client experience success. Type II Projects and Programs are challenging and complicated in a variety of ways.

Objectives of the TYPE II Project Process are to:

- Improve communication within Operations and Operations Development on TYPE II project opportunities,
- Define expectations of the project team, including project management execution and accountability,
- Understand and define project risks,
- Build on and utilize systems and tools we have in place to support project management,
- Adopt PM development practices,
- Focus on financial management planning during proposal and project pricing, and
- Enhance communication of project staffing selection, including PM/APR/SME/Project EXEC.

Keys to TYPE II Project success include:

- Communicating and collaborating effectively during the early stages of an opportunity, whether that is a pursuit, proposal or project,
- Selecting the right team members to lead the project, and
- Implementing project structure to manage project risks through setup and planning.

The TYPE II Project Process is expected to be initiated as early in the project stages as possible, including the pursuit stage. From a project tracking and management planning standpoint, the TYPE II Project Process is formalized when a proposal is entered into PX. The TYPE II Process is expected to be followed by PMs who have the responsibility to lead the process with support from the ASLD, Project EXEC and DM.

TYPE II Projects will vary in size, scope and risk, and thus, may require and need varied approaches and engagement by supporting project team members.

The intent of the TYPE II Project Process is to enforce the expectation of communication and partnership between operations, operational finance, operations development, service line and senior leadership resulting in on-time project delivery and client experience success.





Appendix N.1
TYPE II Proposal Process

During the proposal stage for a TYPE II Project, or when a project proposal is identified as TYPE II, the PM will lead the project team through the following tasks:

- **Proposal Planning Meeting** – The purpose of the Proposal Planning Meeting is to have a high-level focused discussion regarding Terracon's ability to perform the project, the project organization, staffing and pricing approach, financial expectations, proposed project leadership, and initial understanding of project risks. The Proposal Planning Meeting should include final Go/No-Go discussions. Attendees should include, as necessary or required:
  - Contract Signing Authority (See Risk Management Policy No. 8),
  - Proposal Champion/Manager,
  - OM, DPM, APR, DM, ASLD, and SME,
  - Legal,
  - Representative of Operational Finance,
  - Sector Leader/Representative,
  - National Account Manager (NAM).
- **Project Exchange Entry** - Proposal entered/set-up in PX with complete and accurate project information included.
- **Legal Contract Review** – Contract has been sent to Legal Department (contracts@terracon.com) for review, if available.
- **Proposal Kickoff Meeting** – Comprehensive discussion of proposal approach, i.e., scope, pricing, finance, staff, schedule, contract, risks, safety, selection of the proposed PM and Team. Participants should include selected Senior Leadership from Operations, Operations Development, Operational Finance, Sector, Legal and HR, as necessary/required. The intent of this meeting is to obtain consensus and agreement of proposed approach and pricing structure amongst the Team and Operational Leadership.
- **Enter Costing in Pricing Tool Application** – Complete pricing and budget estimates by Task with estimated WU/WD forecasts.
- **Pricing Approval Meeting** – Discussion of scope, schedule, and Pricing Tool budget with Project Team/Senior Leadership. Operational Finance completes and presents financial analysis for approval. Attendees must include Contract Authority.
- **Proposal Submittal**





TYPE II PROPOSAL PROCESS



Proposal Planning Meeting
- Include Contract Authority and Operational Finance
- Can we do the project?
- Outline Project Organization
- Define Pricing Approach
- Final Go/No-Go

Proposal Kickoff Meeting
Comprehensive discussion of proposal approach with Senior Leaders from Operations, Legal, Finance, Operations Development, Sector, and HR, as required.

Pricing Approval Meeting
Discuss scope and schedule with Senior Leaders and Contract Authority. Operational Finance completes and presents financial analysis for approval.

Defining success, together, by communicating and engaging across the Type II proposal process and delivering client success.





Appendix N.2
TYPE II Project Process

During the project set-up stage for a TYPE II project, the PM will lead the project team through the following tasks:

- **Pre-Project Setup Meeting** - Meeting/discussion to announce/update Project Team on proposal/contract acceptance with Operational Leadership, including Contract Authority approval to proceed.
- **Project Registration in PX** - Project entered/set-up in PX with complete and accurate information and validated by the PM.
- **Legal Contract Review** – Contract has been sent to Legal Department (contracts@terracon.com) for review and comment. The PM should have deliberate discussions with legal reviewer to discuss contract and project delivery risks. Risks should be discussed directly with the Contract Signing Authority.
- **Complete Project Setup in Terracon Apps/Systems** – CMELMS, GeoReport, iTRAMS, TARGETID, etc.
- **Develop Project Management Plan** – The PMP includes applicable project approach aspects for on-time project delivery, assigns responsibilities, project organization and levels of accountability, financial expectations and management approach, and establishes the agenda for the Project EXEC Review Calls.
- **Project Planning Meeting** – Comprehensive discussion of project approach and execution, (i.e., scope, pricing, financial approach and expectations, staffing, schedule, contract, risks, safety. The draft PMP should be presented at this meeting for discussion/comment. Attendees should include, as necessary or required:
    - Contract Signing Authority (See Risk Management Policy No. 8),
    - OM, DPM, APR, DM, ASLD, and SME,
    - Representative of Operational Finance,
    - Sector Leader/Representative,
    - Legal,
    - National Account Manager (NAM),
    - Representative from HR.
- **Project Kickoff Meeting** – Comprehensive project discussion focused around the presentation of the final Project Management Plan and project approach to the active project team members, including discussion of project risks and financial management approach and expectations. Project organization and roles should be clearly defined in this meeting. A separate Client-engaged Kickoff Meeting is also suggested.
- **Project EXEC Calls/Project Reviews** – The Project EXEC/Project Review calls are critical to the success of a TYPE II project. The frequency, participants and agenda items for these calls are included in the PMP. Primary agenda items should always include safety, quality and risks, financial performance, staffing, schedule and the client experience/management. The attendees should always include the DM and OGM.
- **Closeout Process –** In addition to the required project closeout summarized in Section 4.3, the TYPE II project closeout process should include a discussion, presentation and/or documentation of “lessons learned”, project successes, project challenges.





TYPE II PROJECT PROCESS



Defining success, together, by communicating and engaging across the Type II proposal process and delivering client success.





Appendix N.3
Project EXEC Oversight Checklist

The following checklist has been prepared to assist the Project EXEC during project oversight. A Project EXEC is responsible for identifying the business need, problem, or opportunity and ensures the project benefits and results are realized, while supporting the PM with resolution of any issues that arise during a project. Project EXEC oversight does not replace the APR, nor does it relieve them of the responsibilities for checking and reviewing the project from proposal to closeout. Some of the objectives of Project EXEC oversight are as follows, but are not all inclusive:

- Engage in the pursuit process providing oversight to the PM and APR, including proposal preparation, to provide input and direction, as needed;
- Assure that the APR and PM have the qualifications, skills and experience appropriate for the project, and that they work together to fulfill the duties of the project in a timely manner;
- Confirm that, when necessary, appropriate SMEs have been engaged and are serving the roles on the project as designated by the APR;
- Ensure that the Contract has been reviewed by Legal as early in the process as possible, ideally at the proposal stage to review and discuss project delivery and contract risks with the PM, APR and Project EXEC.
- Provide an independent oversight of the project to ensure that all the criteria of project success are considered, including safety, budget, financial performance, risk, client expectations, schedule, and quality perspectives. Facilitate the development of recovery plans, as necessary.
- Ensure that the PM and APR understand the TYPE II Proposal and Project Processes and confirm that the processes are followed and completed as necessary.
- Work with the PM to develop the Project Management Plan to include items that are critical to project delivery success.
- Ensure that the PM periodic Project EXEC/Project Review calls on a periodic basis in accordance with the Project Management Plan to provide project status and progress to the DM and OGM. Participate and be engaged in the Review Calls. The Project EXEC, in some cases, may lead the Review Calls.
- Ensure that the project budget and financial performance is being managed appropriately. Provide support to the PM with change management as necessary.
- Assist the PM with client contacts and attend selected meetings, especially related to financial, risk, and/or contractual matters as necessary.
- Ensure the final close-out of the project to include external and internal lessons learned, client satisfaction, financial completion, and identification of additional client project opportunities.

Actual activities and level of effort required to achieve the objectives stated above should be determined by the Project EXEC based on the complexity of the project and the apparent care, skill and quality of the services provided by the PM and the APR. The Project EXEC should be involved from the early stages of the project, including proposal preparation, to provide input and direction as needed.

For all TYPE II projects, the development of a PMP is required. The PMP template should be used to develop an overall project approach to ensure the efficient execution and on-time delivery of the project. The Project EXEC along with the PM and APR should determine the appropriate level of detail needed for an effective PMP based on the complexity of the project.





Depending upon complexity of the project, some or all of the following items should be considered as part of the Project EXEC oversight:

Administrative Oversight

- ☐ Has a PMP been established and followed for overall direction on the project?
- ☐ Have the Project EXEC and APR discussed and defined their responsibilities and schedules with one another?
- ☐ Are project reviews being held consistent with the PMP and are all required team members attending?
- ☐ Have lines and procedures for communication with the client been established and used to discuss needs and progress of the project?
- ☐ Has the PMP been discussed so all key project members are aware of and fully understand the project's budget, scope, schedule, client expectations, client interaction/relationships and established goals for project success?
- ☐ Is the project safety plan and approach included in the PMP and been discussed with all project members, including the plan and frequency of site safety check-ins?
- ☐ Does the PMP include periodically updating the DM and/or OGM on the status of the project, including quality, safety and financial management, staffing, schedule and on-time project delivery?

Technical Oversight

- ☐ Have the APR and PM been assigned to the project and are their experience and expertise appropriate for the project?
- ☐ Have required and sufficient SMEs been retained and properly utilized to achieve the desired results?

Financial Oversight

- ☐ Has a financial analyst been designated for the project?
- ☐ Has the project budget been entered into PX by Task?
- ☐ Does the project have an estimated WU/WD and is it entered into PX accordingly?
- ☐ Is the PM tracking project costs and labor hours to meet budget?
- ☐ Is the PM holding meetings with accounting staff and key staff to review budget status and ability to complete project within budget?
- ☐ Is the PM forecasting Estimate to Complete or Earned Value to monitor financial success of the project?
- ☐ Is the PM managing project change requests and change orders timely and prior to initiating new scope items?
- ☐ Is the PM communicating with the client periodically regarding budget management and soliciting change orders when task budgets are exceeded?

Risk Oversight

- ☐ Are the PM and the APR cognizant of the project risks?
- ☐ Are steps being taken to monitor, manage and mitigate risks?
- ☐ Are the PM and APR evaluating new risks that may occur during the project life cycle, and preparing a plan to monitor, manage and mitigate risks?
- ☐ Are milestone specific risk reviews being performed?





Schedule Oversight

- ☐ Are the PM, APR and project team meeting on a regular basis to review project status and to determine LOE to complete the project on schedule and on budget?
- ☐ Does the PM have the resources available to keep the project on schedule? If not, is the APR assisting in locating resources to meet schedule?

Client Relationship Oversight

- ☐ Is there evidence of a positive client relationship with the PM/project team?
- ☐ Does the PM hold regular meetings with the client to keep them appraised of project status, scope, schedule, and/or budget issues?
- ☐ Has the PM kept the client informed on preliminary findings or other factors that would be beneficial for the client to have knowledge of during the project, prior to its completion?
- ☐ Is an effort being made to maintain a client relationship to verify that the project team is meeting client expectations?
- ☐ Has a client development plan been completed to identify other opportunities to do work for the client?

Project Close-out Oversight

- ☐ Share critical concerns or comments regarding the performance of the APR with the Service Line Director.
- ☐ Has the project been closed to charging upon completion?
- ☐ Has all WIP been removed and A/R collected?
- ☐ Has an internal and external lessons learned document been developed and shared with the project team and other interested parties?





Appendix N.4
Project Management Plan Template

Link to PQM Library of Updated Templates and Example Plans





[Project Name]

[Project Number]

Project Management Plan

The Terracon Project Management Plan (PMP) is an integral component to consistently deliver successful TYPE II Projects. The PMP defines the approach and expectations to assist our Project Managers, APRs, Project Executives and other integral project team members execute their responsibilities for managing and delivering safe, quality, technically excellent, financially strong projects on-time and in turn providing a successful client experience that sets us apart from our competitors.

The [Project Name] project is identified and confirmed as a TYPE II Project. Terracon's Project Quality Manual (PQM) outlines the requirements for a TYPE II project and requires a Project Management Plan. The PMP provides applicable project approach aspects for on-time project delivery, assigns responsibilities, project organization and levels of accountability, financial expectations and management approach, and establishes the agenda for the Project EXEC Review Calls.

1.0 PROJECT INFORMATION AND OVERVIEW

The project includes [Describe the project scope of work.]

If project is Design-Build, additional sections may be needed to discuss the Design-Build Client Team, Project Background, Benefits, Goals, etc.

2.0 CONTRACT TERMS AND DETAILS

Client:

Date Executed:

Contract Value:

Contract End Date:

Terracon Contract Authority:

Contract Type: - Standard Agreement or Short Form Agreement?
- Master Service Agreement
- Modified Terracon Agreement
- Client-Provided Agreement
- Other

Client Contract Number/Purchase Order No.:





The contract review and Risk Analysis was performed by [Legal Contact/Reviewer] and was completed on [Date]. The Risk Analysis Form is attached to this document for reference. The contract review identified the following contract terms of specific note and risk:

- Limitation of Liability
- Indemnification
- Standard of Care/Warranty
- Waiver of Consequential Damages
- Payment Terms

Additional contract delivery risks were identified as follows:

- Change Order Approval Process
- Invoice Delivery/Submittal

At this point, the contract has already been reviewed and executed. It is critical that the Project Manager and Project Team has read the contract and is fully-aware of the terms, requirements and risks. Additional contract details and discussion may include:

- Invoicing Schedule and requirements (what is best schedule to manage cash flow, and AR. Likely not Terracon internal invoicing schedule)
- Payment Terms - Retainage
- Client Deliverables and Expectations of Delivery
- Penalties
- Savings back to owner (either based on payment terms or contract language)
- Who is defined as responsible party in contract?
- Who can execute Change Orders for Terracon and Client
- Other key items identified by Team in review of contract

Subcontractor Agreement Details

If Terracon is subcontracting any work as part of this project, include subcontract details and discussion, including scope of subcontractor, agreement, rates, schedule, etc. Attach subcontract agreement to the PMP.

3.0 TERRACON PROJECT TEAM AND RESPONSIBILTIES

- Contract Authority:
- Senior Project Manager:
- Project Executive:
- APR:
- SME:
- Division Manager:
- Assistant Project Manager:
- Financial Analyst:
- ASLD:





- Project Coordinator:
- Design Quality Manager
- Field Manager

Project Team will be the participants in the Project Review Calls.

If there are additional responsibilities due to specific project requirements, include below. [If there is an organization chart for this project, please attach it to the PMP. Modify this list as best fits your project. Include subcontractors, if applicable, and list their projected significant contributions to this project.]

Project Executive (Project Exec) – Name
The Project Executive will provide overall project leadership and independent review of project delivery, including client relationships, financial oversight and risk management. The Project Executive is also responsible for approving and ensuring the implementation of the Project Management Plan and supporting the Project Review Meetings. The Project Exec is encouraged to use Appendix K of the PQM (Project Exec Oversight Checklist) to ensure that his/her responsibilities are being fully executed.

Assistant Service Line Director (ASLD) – Name
The ASLD will work under the general direction of the Service Line Director and the Operating Group Manager to promote the safety, quality, profitability, and growth of the service line. To this end, the ASLD will assist and support TYPE II project as needed. The ASLD may or may not have an expanded role in the project and be a part of the project team.
A TYPE II Project is confirmed by the ASLD in collaboration with the DM based upon their judgment of size, scope, risk or opportunity.

Project Manager/Senior Project Manager – Name
The Project Manager leads the project and is responsible for managing all aspects of the project, including but not limited to financial, safety, quality and the client experience.

Assistant Project Manager – Name

Authorized Project Reviewer (APR)/Quality Assurance Manager – Name

Subject Matter Expert (Area of expertise for this project) – Name

Financial Analyst and/or Project Accountant – Name
The project accountant may assist the project manager with billings and required paperwork, preparing administrative and financial reports preparing invoices for the PM's review. They may support the project by setting up the budget, verifying weekly bookings and support budget tracking.

Project Coordinator(s) – Names
The project coordinator will serve as the document control manager and will assist the project manager with preparing and submitting project deliverables.





Division Manager

Office Manager

Department Manager

Subconsultants - Define the subconsultants/subcontractors and their scope and role.

Laboratory Services

Field Staff

Drilling Services

Project Executive Committee Identify the members of the Committee, frequency and agenda of meeting and scope of the Project Executive Committee's role on this project.

4.0 PROJECT STAFFING PLAN

The project staffing plan will align with the project budget and manpower estimates. If applicable and necessary, include discussion on staffing needs and management plan.

Should include any specific experience or certification requirements and hiring plans/needs.

5.0 FINANCIAL MANAGEMENT

Project Budget and Tracking

List the financial targets for this project as agreed upon in the pricing phase. Use Budget by Task.

Include WU/WD Plan from Pricing vs Project Award Analysis – How does the WU/WD plan align with project WU/WD analysis – what changes may occur and how does that impact original plan?

Change Management – Discussion may include tracking changes in scope. Work should not be performed on any change order work without authorization. Change order work should be tracked using additional tasks to keep it separate for billing and tracking purposes. Monthly discussions regarding changes/change management should be conducted with owner and subcontractors on cost issues for timely resolution. Any specific changes to contract should be priced and tracked separately with pricing reviewed by Project Executive before submittal to owner.

Subcontractors - How do we manage the labor, equipment, expenses and subcontractors? A detailed task list should be developed by the project manager based on the detailed estimate to track costs. What are the contract terms (unit fee, cost plus, or lump sum), mark-up added to subcontractor invoices, payment terms and invoicing schedule?

Other Direct Costs and Considerations – Staff compensation/per diem, burdened costs, equipment.





Billing Strategy and Invoicing Procedures - List specific plans/requirements for invoicing, including any client-provided specifications.

Portfolio Project Parameters and Expectations

Financial Forecasting – Work with Financial Analyst and Project Executive to manage burn rate and allow forecasting based on actual work performed and remaining. Should be completed on a monthly basis to evaluate performance vs WU/WD.

Financial Reporting – As part of the monthly Project Executive Committee, a financial summary shall be provided. It should include, projected WU/WD, forecast of all labor, expenses, equipment, and subcontractors. What are expectations for client financial reporting?

Financial Goals

Financial targets will be achievable and agreed upon by all senior staff. List the financial targets for this project. How do we achieve the targeted goals? What are project book rates to manage to?

6.0 INTERNAL COMMUNCATIONS

Integral to successful delivery of a Type II project is the need to develop a communication plan for the internal team.

It is important that the PM and Project Executive engage in discussions about the project and develop a schedule for their coordination. In addition, a Project Executive Committee should be defined so the PM and Project Executive can present the project progress and receive input from other key internal stake holders. Project Executive Committee calls shall be based on the attached Agenda (modified accordingly to meet the project needs).

Subcontractors should be treated as an extension of Terracon. To be successful, subcontractors should be included in all project planning meetings, so they understand importance of this project to Terracon. Depending on the size and scope of the contract their involvement in the Project Executive Committee calls may be warranted. What is our communication and plan to actively manage the subcontractors (i.e. – weekly meetings, cost issue review meetings, subcontractor change orders, pricing into any owner changes).

Present a communication matrix and plan.

Meetings to be conducted (Agenda, simple, minutes, and commitments)

- Kick-off Meeting(s)
- Daily (Pretask Planning, Schedule, Staff Planning, Subcontractor coordination)
- Weekly (Tool Box Talks, Check-Ins, Schedule, Staff Planning, Subcontractor Coordination)
- PM and Field Staff – What challenges do we have?
- PM and Project Executive – Project status – labor issues, change management, etc.





- Monthly (Schedule, Staff Planning, Subcontractor Coordination – invoice review and change management, Project Executive Committee, Billing review and Discussion, Financial Forecasting Discussions)

7.0 EXTERNAL COMMUNCATIONS

This section pertains to project-specific communications, primarily based on the desires of the client. It may contain information regarding scope creep; notifications of budgets reaching 50%; financial reporting on the project and the frequency of such reporting, including to whom the reporting will be conveyed; and plans to realign activities should the project run into problems that affect the budget.

Define who is managing the client. What does success look like for our client? How do we manage the project to ensure their success? What are the client's goals and expectations for the project? Who is called and notified when there is an issue that needs resolution.

This will be project specific and will be fluid as the project progresses.

Define in this section who is to receive Terracon deliverables and schedule/frequency.

The following meetings may be appropriate or required the client (or any other external partners)

- Daily (safety, project requirements, quality, deviations, results and findings)
- Weekly (safety, project requirements, deviations – open and resolved)
- Attend owner, architect, contractor meetings
- Monthly (Schedule, Budget/Change Management, Invoice Review)

8.0 SCHEDULING

[Insert project scheduling information here, including milestones and estimated project completion date.]

Considerations - In this section define who is responsible for Terracon's schedule. Is the schedule owned and developed by Terracon or other entity? Software used?

How do we communicate schedule with owner and team members and subcontractors? Are we reacting to contractor schedule?

Schedule ties very closely to budget – burn rates on labor need to be considered

How often is schedule reviewed and compared to project budget?

Staffing to the project schedule.





9.0 SAFETY AND IIF

Terracon is an I*ncident and Injury Free* (*IIF*) company, and that core value will be evident on this project. Terracon's core rules and practices will be followed, and all team members will be empowered to stop work for any potential safety hazard until the issue has been addressed to the satisfaction of the team member and PM.

- Violations of Terracon's or the project specific safety standards will result in removal from the project at the PM's discretion.
- The PM will visit the site [frequency – bi-weekly, monthly, etc.] with the intent of having safety conversations with the lead technician and other technicians working at the site.

Describe project-specific safety issues that are currently known and what the plan is to address the issue(s).

Is there a Project Safety Plan, either internally or client/contractor provided? If so, reference and include a Team review process.

What are the client and contractual safety (external) requirements? What are the general contractor requirements and training? For example, orientations, drug screening, pre-task planning reporting, tool box talks reporting, near miss reporting.

How do you report a recordable incident on the project site?

Define list of known project specific safety risks that will need to be addressed on the project and how those will be addressed. For example – confined space, exposure to contaminated soils, fall protection, excavation safety, ladder use age, etc.

Define site check-in schedule to discuss safety with on-site team members.

10.0 PROJECT RISKS AND MANAGEMENT

Key factors, conditions, or circumstances associated with the project, including project, contract and client risks, if not properly accounted for, could have a significant negative impact on the project.

Project Risks – Internal to Terracon

- Contract Risks
- Project Delivery Risks

Project Risks – External to Terracon

[For each risk, identify mitigation measures to be implemented to limit Terracon's risk and/or risk to the client. List any factors, conditions, or circumstances viewed as favorable or positive in performance of the project.]

Risks are fluid on a project and change from week to week, month to month. How do we manage them?





Planned/known risks accounted for from the proposal stage should be identified here so they can be managed properly.

11.0 QUALITY PROGRAMS AND COMPLIANCE

Terracon's commitment to quality requires that all our employees and subconsultants be familiar with and trained in implementation of the Terracon and project specific QA/QC programs. Each member of our project team participates in assuring that all steps in project QA/QC are thoroughly completed and documented in a timely manner. Continued commitment to quality is essential to Terracon's success in serving both our clients and the public.

The QA/QC program is mandatory for all staff levels and includes checking calculations and following the Terracon Quality Program, as well as complying with the project plans and specifications. Not following the Terracon or the project specific QA/QC programs will be grounds for dismissal from the project.

Modify accordingly and describe specifically how quality will be implemented and verified on this project – identified critical junctures, calculation checks, drawing checks, APR reviews, etc.

Describe, reference and discuss project-specific quality plans or programs and how they will be managed.

Are separate accreditations or licenses required to support/deliver the project?

Define project-specific quality requirements from the plans and specs for sharing with team.

Subcontractor quality management discussion.





Appendix N.5
TYPE II Project Process Meeting Agenda

Included herein are suggested agenda items for the critical meetings included in the TYPE II Proposal and TYOE II Project Processes. The suggested agenda provided should be considered all-inclusive and should be discussed with the PM, APR and Project EXEC to develop appropriate meeting agenda to meet the specific project needs and requirements.

Proposal Planning Meeting
The meeting focus should be a high-level discussion that should include the following topics:

- Terracon's ability to deliver the project
- Staffing expectations/requirements and approach (availability, experience, certifications/licenses).
- HR concerns
- Project schedule
- Discuss project leadership and organization - Senior Project Managers, Project EXEC, APR, SME.
- Define and discuss potential pricing approaches and financial performance expectations. Assign Operational Finance Reviewer/Representative to work with Project Team
- Initial understanding of risks
- Contract availability for review
- Proposal submittal schedule and time to prepare proposal and cost estimate
- Final Go/No-Go discussion/decision

Attendees should include, as necessary and required:

- Contract Signing Authority (See Risk Management Policy No. 8)
- Proposal Champion/Manager
- OM, DPM, APR, DM, ASLD, Project EXEC and SME
- Legal
- Representative of Operational Finance
- Sector Leader/Representative
- National Account Manager (NAM)

If the consensus is to pursue the opportunity and prepare a proposal, the meeting should close with a focus on assigning responsibilities and establishing action item schedules and commitments. Confirm responsible party for completing the proposal, cost estimate, PX entry, and scheduling additional meetings. If more than one office will be involved, define the "controlling" office or cost center.

Proposal Kickoff Meeting(s)
The meeting(s) is a comprehensive discussion of proposed approach to project delivery and the effort of preparation of the proposal/submittal to the client. These meetings could be held as one single meeting, or separately.

Proposed Work Approach

- Project Overview and Client Discussion
- Scope of work
- Pricing and finances
- Staffing and project leadership





- Schedule
- Contract Review/Risk Analysis
- Safety Considerations

Proposal/Submittal Presentation

- Proposal/Submittal response requirements
- Support needed
- Assign responsibilities and establish dates for review
- Presentation

Attendees should include, as necessary and required:

- Proposal Champion/Manager,
- DPM, APR, SME, Project EXEC,
- DM, ASLD and OGM
- Legal
- Representative of Operational Finance
- Sector Leader/Representative
- National Account Manager (NAM)
- Corporate Marketing
- HR

Pricing Approval Meeting

- Presentation of Budget/Cost Estimate/Pricing Model
- Booking Rates
- WU/WD Analysis
- Discussion of Rates, Expenses, Subcontracts
- Burdened Costs
- Laboratory Services/Mobile Laboratory
- Per Diem
- Financial Expectations and Risks

Attendees should include, as necessary and required:

- Contract Authority (Required)
- DPM, Project EXEC, OM, DM, ASLD and OGM
- Representative of Operational Finance
- Sector Leader/Representative
- National Account Manager (NAM)

Pre-Project Setup Meeting

The objective of the Pre-Project Setup Meting is to announce and update the project team on the contract award and status. The discussion should focus on any changes to the proposal, costs and/or approach made during contract award negotiation, if any, including an update on the status of contract review and risk analysis. The meeting attendees should include at a minimum the APR, DPM, OM, Project EXEC, DM and Contract Authority.





Project Planning Meeting

- Presentation of draft Project Management Plan with discussion of:
  - Planned project approach and execution
  - Scope of Work
  - Pricing, financial approach and expectations
  - Staffing plan and schedule
  - Discussion of Contract, Status and Risks
  - Safety Plan and Considerations

Attendees should include, as necessary or required:

- Contract Signing Authority and/or DM
- OM, DPM, APR, ASLD, and SME
- Key Project Personnel
- Representative of Operational Finance
- Sector Leader/Representative
- Legal
- National Account Manager (NAM)
- Representative from HR

Critical information and expectations were established in the Proposal Kickoff Meeting. This information should be updated/presented in the Project Planning Meeting.

Project Kickoff Meeting

- Presentation and comprehensive discussion of finalized PMP
- Project Roles and Responsibilities
- Project Overview
  - Client
  - Critical Milestones
  - Scope
  - Organization Chart
  - Communication Plan
- Contract Status and Discussion
- Change Order Management
  - Approach, tracking and client notification/submittal process
- Staffing
  - Final staffing model
  - Hiring plan, training, certification
- Safety Approach and Plan
  - Site Safety Requirements/Training/Orientation
- Budget Management and Tracking
  - Financial Management Plan
  - WU/WD
  - Invoicing Procedures

Project Executive/Project Review Meetings

- IIF Moment
- Project Safety





A. Identified hazards or changed conditions
B. Site Conditions
   i. Site specific conditions
   ii. Site safety check-ins (Frequency, observations, who is performing)
   iii. Site specific requirements (changes/updates/status)
   iv. Staff Safety – Shift work, travel, fatigue, weather

- Project Performance
- Staffing / Schedule
  A. Staffing plan - update
  B. Staffing Needs
- Financial Management
  A. Contract
  B. Change Orders
  C. Burn rates
  D. Estimate to Complete
  E. Current WU/WD
  F. Accounting adjustments
  G. Overall financial performance
  H. Invoicing, WIP and AR
- Technical Issues
- Quality Issues
- Project Communications
  A. Reporting
  B. Client
- Technology
- Project Communications
- Additional Topics/Open Discussion/Questions

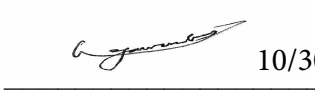


APPENDIX C

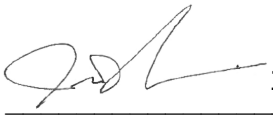
Analytical Laboratory Documents

QUALITY SYSTEMS MANUAL
VOLUME II, REVISION 18

EFFECTIVE DATE: 11/04/2025



10/30/2025 **Dr Kesavalu Bagawandoss**
TECHNICAL MANAGER/GENERAL MANAGER



10/30/2025 **Jamie Sampson**
QUALITY ASSURANCE OFFICER

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INTRODUCTION

The SGS North America Inc. Laboratories Quality Assurance System, detailed in this plan, has been designed to meet the quality program requirements of TNI 2016, ISO/IEC 17025:2017, 40 CFR Part 136, and any other applicable environmental testing requirements or regulations. The plan establishes the framework for documenting the requirements of the quality processes regularly practiced by the Laboratory. The Quality Assurance Director is responsible for changes to the Quality Assurance Program, which is appended to the Quality System Manual (QSM) during the annual program review. The plan is also reviewed annually for compliance purposes by the Company President and Laboratory Director and edited if necessary. Changes that are incorporated into the plan are itemized in a summary of changes following the introduction. Plan changes are communicated to the general staff in a meeting conducted by the Director of Quality Assurance following the plan's approval.

The SGS North America Inc. – Scott (SGS – Scott, SGS) plan is supported by standard operating procedures (SOPs), which provide specific operational instructions on the execution of each quality element and assure that compliance with the requirements of the plan are achieved. SGS -Scott employees are responsible for knowing the requirements of the SOPs and applying them in the daily execution of their duties. These documents are updated as changes occur, and the staff are trained to apply the changes.

At SGS North America Inc. – Scott, we believe that satisfying client requirements and providing a product that meets or exceeds the standards of the industry is the key to a good business relationship. However, client satisfaction cannot be guaranteed unless there is a system that assures the product consistently meets its design requirements and is adequately documented to assure that all procedural steps are executed, properly documented and traceable.

This plan has been designed to assure that this goal is consistently achieved and the SGS - Scott -. product withstands the rigors of scrutiny that are routinely applied to analytical data and the processes that support its generation.

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SUMMARY OF CHANGES

SGS North America Inc. Laboratories Quality System Manual

SECTION	DATE	DESCRIPTION
All		Rebranded to SGS North America Inc. standard format
Title Page		Remove Mitesh Koirala, Metals Manager and added Brandy Broussard, Metals Supervisor
Table of Contents		Updated to reflect accurate location for sections.
1.3		Added The NELAC Institute (TNI). Changed NELAC to TNI throughout the section.
2.3		Removed Benoist Lasserre as Vice President of SGS North America and added Marcus Maguire to the position. Added Mike Earp, Vice President Operations Conventional Chemistry Lab Services. Removed Mitesh Koirala, Metals Manager and added Brandy Broussard, Metals Supervisor.
2.4		Changed 15 to 35 and added the phrase “and the Louisiana Department of Health Certification Program to the last sentence in the section. The sentence now reads “Should this absence exceed thirty-five (35) consecutive days, the Louisiana Department of Environmental Quality, Laboratory Accreditation Program and the Louisiana Department of Health Certification Program shall be notified in writing. Added the current SGS North America Inc. – Scott organizational Chart and the current SGS North America Inc. Organizational chart.
3.1		Added the Vice president Operations Conventional Chemistry Lab Services.
4.1		Added the Vice President Operations Conventional Chemistry Lab Services. Removed Louisiana from the name of the Scott facility and removed Gulf Coast. Changed the title Client Services Director to Project Manager. Removed the first of two Organic Preparation Managers. Removed Client Services/Report Generation Manager and requirements.
5.2		Corrected Sub-section numbering.
		Signature and Initials Log subsection – removed “but annotated with their date of termination."
6.1		In Subsection “Controlled Documents,” changed Louisiana to Scott.

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SECTION	DATE	DESCRIPTION
6.4		Last paragraph, first sentence removed “as paper or scanned documents” and inserted “in AccuLims . . . “
6.8		Training was revised to read “Training records for individuals employed by the company are retained in the file cabinets for a period of approximately six months following their termination of employment. The last sentence was added: “After that time, training records for these employees are removed from the file cabinet and placed into storage boxed for archiving on site or off site. The archived employee training files are held for a minimum of 10 years.
6.9		“For each new employee” was removed from the end of the first sentence.
8.6		The following verbiage was added to the subsection: “MDLs must be prepared in at least three batches on three separate calendar days. For areas with multiple instruments, then the sample analysis must be distributed across all of the instruments. At least once every 13 months the MDL will be recalculated using quarterly spike values using at least seven spiked samples and seven method blanks for the annual verification. MDLs will be calculated for the spiked samples as well as for the last 50 method blanks. If the MDL for the method blanks is higher than the spiked MDL, then the new MDL will be the method blank MDL.
8.10		The following verbiage was added to Limit of Quantitation (LOQ): “or lower limit of quantitation (LLOQ) however named”.
9.7		Changed “work order” to job number to be consistent with AccuLims. Added the following to the second paragraph: “The first letter, “L” stands for Louisiana and the second letter, “A” currently”, is a sequential letter for starting the next 100,000 samples. For example: “LA” then “LB” followed by “LC” then “LD” etc.
9.8		In subsection “Subcontracted Analysis,” the following was added to the first paragraph: “Subcontracted laboratories must be TNI certified for any analytical results that will be used for regulatory purposes or the laboratory must be certified by the appropriate accrediting body for non-TNI states. Subcontracted laboratories for drinking water analysis must be certified through the Louisiana Department of Health.”
9.11		Sample Retrieval for Analysis – deleted the second sentence of the first paragraph and deleted the last half of the sentence in the second paragraph: “and completes the custody transfer from the department of the transfer back to sample management or sample storage.”
11.1		Non-Routine Maintenance – revised the last two sentences of the subsection to read as follows: “The service technician is responsible for documenting all details to the occurrence and repair. Instruments that are outside requirements must be shown to be back in control before analyses restart.

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SECTION	DATE	DESCRIPTION
12.2		Subsection Laboratory Control Samples – Spiked Blank was changed to Blank Spike (BS). "A2LA" accredited vendor was changed to "TNI" accredited Vendor.
		Third paragraph the following verbiage was added: "A copy of this summary shall be submitted to the TNI primary Accrediting Authority, Louisiana Environmental Laboratory Accreditation Program or the Louisiana Department of Health or any other state accrediting authority for review if required".
12.8		Subsection Data Package Review – removed Report Generation Review from this subsection. Subsection Project Management/Quality Control Review added the following. "The project managers review final reports to verify that the report meets the client's specification." The following sentence was deleted: "Spot check data package reviews are performed by the project management staff.
13.2		Subsection Documentation and Communications – second paragraph the last sentence was added "The corrective action is assigned to the responsible party at the time the corrective action is initiated. Corrective action due dates are set for 14 calendar days from initiation. The following verbiage was added to the third paragraph of this subsection: "Any time a corrective action is initiated QA will notify the responsible party, the appropriate department supervisor, the laboratory director, and the QA Director that a corrective action has been initiated. The e-mail should include the due date. The QA department will review the corrective action database twice a week. An e-mail will be sent to the responsible party any time a corrective action due date is about to expire. Once a week the QA department will hold a corrective action meeting with the appropriate department supervisors, managers, and laboratory director to discuss the status of any open corrective actions. If there aren't any open corrective actions, then the meeting will be cancelled.
15.2		Added the following verbiage: "The Project Manager that initiated the client complaint will send an e-mail to the QA department, lab manager, and the responsible party notifying them that a client complaint was initiated and the due date for resolution of the complaint.
19.3		Added the following verbiage to the Safety Committee: "The safety committee is comprised of department managers, supervisors, and the QA officer(s). The safety committee acts as safety champions within the laboratory.
Appendix II		Updated SOP Directory
Appendix III		Updated Analytical Capabilities
Appendix IV		Updated Laboratory Equipment
Title Page	2/9/2021	Removed Larry Gwinn and Jenney Babin. Added Roger Paul Johnson, Organic Supervisor

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SECTION	DATE	DESCRIPTION
SUMMARY OF CHANGES	1/14/2021	Added the “DATE Column”
2.2	1/14/2021	Removed Quality Assurance Director (QA Director) and added Quality Assurance Supervisor, Gulf Coast
2.2	1/14/2021	Quality Assurance Officer – added “ensuring that the Quality System Manual is current and for” and removed QA Director and added QA Supervisor, Gulf Coast.
2.3	2/9/2021	Removed: Larry Gwinn, Organic Manager; Jason Savoie, Corporate Technical Project Manager and Semi-Volatile Supervisor; Jenney Babin, Quality Assurance Officer and Charles Hartke, QA Director, Corporate Quality Assurance. Added Paul Johnson, Organic Supervisor and Svetlana Izosimova, Quality Assurance Supervisor, Gulf Coast.
2.4	2/9/2021	Added current Org. Chart+
3.1	1/14/2021	Changed Quality Assurance Director to Quality Assurance Supervisor, Gulf Coast. Changed Quality Assurance Officers/Managers to Quality Assurance Officers. Added “reviewing and revising the QSM as necessary. Responsible for . . .
4.1	1/14/2021	Added; “Laboratory Technical Manager for inorganic chemistry must have an associate degree in chemical, physical or environmental sciences or two years of experience in the environmental analysis of representative inorganic and organic analytes with a minimum of 16 college semester hours in chemistry. Laboratory Technical Managers for chemical analysis must have a bachelor’s degree in chemical, environmental, biological sciences, physical sciences or engineering with at least 24 college semester credit hours in Chemistry. Laboratory Technical Manager for Micro must have a bachelor’s degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering with a minim of 16 college semester credit hours in general biology and microbiology.” Added requirements for Technical Inorganic Manager and Technical Micro Manager. Changed Quality Assurance Director to Quality Assurance Supervisor. Removed EHS SGS North America Inc. and added Operations Conventional Chemistry Lab Services. Removed “Establishes the company quality agenda, develops quality assurance procedures.” Technical Organics Manager Academic Training has been revised to include “with at least twenty-four (24) college semester credit hours in chemistry
5.1	1/14/2021	Removed Quality Assurance Director
8.0	1/14/2021	Removed Quality Assurance Director
8.13	1/14/2021	Replaced Quality Assurance Director with Quality Assurance Officer
10.4	3/26/2021	Added discussion on Relative Error

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SECTION	DATE	DESCRIPTION
12.4	1/14/2021	Replaced Quality Assurance Director with Quality Assurance Officer
13.2	1/14/2021	Replaced Quality Assurance Director with Quality Assurance Officer
15.2	1/14/2021	Replaced Quality Assurance Director with Quality Assurance Officer
16.0	1/14/2021	Replaced Quality Assurance Director with Quality Assurance Officer.
ALL	1/14/2021	Corrected grammar and spelling throughout the document
APPENDIX IV	3/26/2021	Added the new ICPMS to the equipment list. Listed the old ICPMS as out of Service
4.1	9/30/2021	Job descriptions for the Laboratory Director, Technical Inorganic Manager, Technical Organics Manager, and Quality Assurance Officer were revised to require their approval prior to any major modification being allowed by the laboratory.
8.3	9/30/2021	The following language was added to paragraph 3 of this section: Method modification must be approved by the laboratory director/technical director and Quality Assurance Department. Four spiked reference samples will be analyzed, and the data compared to the method precision and accuracy criteria. If the results meet or exceed the criteria established in the reference method, then a justification memo will be written and signed by the laboratory director/technical director and the QA Department. The justification memo and the analytical results will be maintained in the QA directory on the server. Conducted annual review of QSM.
All Sections Reviewed	3/1/2022	Corrected grammar and spelling throughout the document
Title page	3/1/2022	Removed Karen Rodrigue Varnado. Added Rebecca Theriot as Quality Assurance Officer.
9.3	3/1/2022	Removed; “A bar-coding and scanning system electronically tracks sample custody transfers between individuals within the laboratory.” And “A documented, chronological record of each sample transfer identifying everyone having possession of the sample is created in a custody program linked to the laboratory information management system, which can be printed and included in data reports to demonstrate continuous custody.
Appendix II	3/1/2022	Added SOPs
Appendix IV	3/1/2022	Updated equipment list.
Appendix V	3/1/2022	Added Appendix V: Certification Summary.
14.3	3/11/2022	Added: “SGS maintains a record of all certification parameters on the quality assurance directory and displays the current certificates for each state that is accredited in the front lobby of the laboratory
2.3	3/11/2022	Removed Paul Johnson, organic supervisor. Removed Karen Rodrigue-Varnado, and replaced with Rebecca Theriot, Quality Assurance Officer.

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SECTION	DATE	DESCRIPTION
Appendix II	3/23/2022	Added revision date column.
Title Page Appendix II Section 2.4	7/9/2022	Updated Management Signatures, Updated SOP Revisions, Updated Organizational Chart
Sections 9.7, 9.3, 9.8, 12.0, 2.4, 7.1, 7.2 and Appendix II	12/14/2022	Added: The sample management department affixes waterproof with indelible blank or blue ink, permanent labels with these sample identification numbers to each sample bottle before they are stored for analysis by the labs. Added: Time record of sample received. Added information for subcontracted sample analysis results received by SGS for clients. “Can be received by SGS either electronically or hard copy.” Added: The most stringent quality control requirements are used, where needed the Code of Federal Regulations (40 CFR) supersedes methods for quality control parameters, followed by the State-specific regulations, then EPA methods. When a method or regulation is unclear, SGS North America Inc. – Scott seeks guidance. Updated SOP revisions, updated organizational chart, updated NIST Thermometer calibration to every 5 years, updated NIST weights calibration to every 5 years
Sections 8.2, 2.4, and Appendix II	01/26/2023	Changed annually to every 2 years, updated SOP revisions, and updated organizational chart.
Throughout	3/24/23	Added ISO/IEC 17025:2017 references.
Section 2.4, 7.0, 7.5, 10.8, 15.4, 17.0, 18.1, 18.8, Appendix II, III, IV, V	5/10/23	Corrections for ISO 17025 Assessment/Compliance Organizational Chart
Section 2.4	10/31/2023	Organizational Chart updated to current structure and position names
Section 2.3	10/31/23	Removed Rebecca Theriot as QAO, added Jamie Sampson as QAO, removed Ron Benjamin as Lab Director, and added Richard Clinkscales as Lab Director.
Appendix II	10/31/23	Removed list table from QSM and directed to Master list form F-LQA001 current revision for SOP list.
Appendix III	10/31/23	Added EPA 8082A to list for non-potable water, solid chemical material, and oils
Appendix V	10/31/23	Updated list to current accreditation.
Appendix V Section 2.4	3/26/24	Reviewed and updated list to match current certifications. Updated organizational chart.

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SECTION	DATE	DESCRIPTION
Section 2.3 Appendix III		Update Chain of Command Added new Analytical Capabilities to the list.
Section 15.1 & 15.2 Section 2.4 Appendix V	8/8/2024	Added language to address the validation of complaint via an investigation (ISO 17025 Audit-2024 CA-Scott-080824-169.1 Updated Organizational Chart Updated certification listing to current status
Appendix III & IV	9/19/24	Updated Appendix III for methods. Updated Appendix IV for equipment
Section 8.3 Section 10.7	12/31/24	Corrected wording to meet TNI 2016 requirements (LDEQ 2024 Audit) (CA-Scott-123124-235) Update to current TNI requirements of section V1M2 5.5.13.1 e iii and V1M2 5.5.13.1 e iv (CA-Scott-123124-235.10)
Section 1.0 Section 2.0 Section 4.0 Appendix II Appendix IV Whole Document	10/30/2025	Update to current policy w signature Removed names for Org Chart and notes list maintained by QA Update Key staff to match the current SGS-Scott structure Removed full list of SOP and reference Master List form Removed full list and reference Master Equipment Log form Corrected header with page numbering

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1.0 MISSION AND QUALITY POLICY

1.1 SGS NORTH AMERICA INC. MISSION:

SGS North America Inc. provides analytical services to commercial and government clients in support of environmental monitoring and remedial activities as requested. SGS North America Inc.'s mission is dedicated to providing accurate and reliable data that satisfies client requirements as explained in the following:

"Deliver value to our clients by providing easy access to accurate and timely analytical information which meets or exceeds their expectations."

These services are provided impartially and are not influenced by undue commercial or financial pressures which might impact the staff's technical judgment. SGS North America Inc. does not engage in activities that endanger the trust in our independent judgment and integrity in relation to the testing activities performed.

1.2 QUALITY POLICY AND PROFESSIONALISM STATEMENT:

Quality and Professionalism are integral parts of SGS' Business Principles and are a cornerstone of ensuring high levels of customer satisfaction. By maintaining operational excellence, we ensure the long-term sustainability of our business.

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Quality and Professionalism are integral parts of SGS's operations and the cornerstones for ensuring high levels of customer satisfaction. Through mutually beneficial partnerships and continued operational excellence we ensure the long-term sustainability of our business.

IT IS OUR AIM TO

- Deliver world-class services that meet our customers' needs
- Build strong customer relationships based on trust, mutual respect and the prioritization of the needs of the customer
- Be known and recognized for our superior knowledge, reliability, accuracy and consistency
- Nurture and encourage a culture of quality within SGS with the full support of management and engagement of all employees

IT IS THEREFORE OUR COMMITMENT TO

- Place customers at the heart of everything we do, engaging proactively with their needs
- Maintain flexibility, listening to industry and customer needs and expectations and actively evolving our quality statement to meet them
- Continuously challenge ourselves to improve our quality management system by setting and reviewing our objectives, risks, KPIs, results and customer satisfaction levels
- Develop and maintain the processes we need to deliver high quality, optimized and coherent services
- Continuously measure, maintain and increase SGS's knowledge base through a sustainable processes of talent recruitment and training
- Respect client confidentiality and individual privacy while remaining transparent in all other aspects of our work
- Protect SGS's intellectual property and know-how
- Embody the SGS brand and its independence in all that we do

Delivering quality and professionalism is an individual responsibility for all of us, at every level within our organization.
These commitments apply to all SGS employees and contractors.
Management is responsible for ensuring full compliance with SGS policies.



GÉRALDINE PICAUD
Chief Executive Officer

This version cancels and replaces all previous Quality policy statements.

The English version of this document constitutes the binding version.

When you need to be sure

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The following is implied in this policy:

- Commitment to comply with the latest requirements of The NELAC Institute 2016 and ISO/IEC 17025:2017
- Commitment to continually improve the effectiveness of the Quality Management System
- Commitment to good professional practices
- Commitment to the quality of our services
- Commitment that testing will be carried out to stated methods and client requirement
- All personnel must familiarize themselves with the Quality Policy, Quality System Manual and implement all policies and procedures related to their jobs.

Management must ensure that this quality policy is communicated and understood with SGS North America Inc. and reviewed for continued suitability.

The management system of SGS has been designed in accordance with The NELAC Institute 2016, and ISO/IEC 17025:2017 “General Requirements for the Competence of Testing and Calibration Laboratories”.

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1.3 ADVERTISING POLICY

Where "The NELAC Institute" (TNI) name and/or logo are used on general literature such as letterhead and advertisement, it must always be accompanied by the word “accredited”.

While there are no restrictions on the size and color of the TNI accredited logo reproduction, the logo must maintain its form.

The TNI-accredited logos must be generated electronically provided that the prescribed formats and forms are retained.

When promoting or providing proof of accreditation, accredited laboratories must use the scope(s) of accreditation, as this document details the specific tests which are accredited. The certificate must be used for display purposes and must also accompany the scope.

When the TNI-accredited logo is used in conjunction with laboratory test results, it must always be accompanied by the TNI accreditation number(s). The logo should be used in a manner as not to imply endorsement by the accrediting authority.

When the TNI accredited logo is used for advertising or on a business solicitation document such as a proposal or quotation form, the laboratory has the responsibility to distinguish between those proposed tests that fall within the laboratory’s scope of accreditation and those that do not. This is done by attaching a copy of the TNI Scope of Accreditation sheet and Supplement to the Scope, if appropriate, or by noting which tests or calibration is non-accredited.

Upon suspension or termination of accreditation, a laboratory must immediately cease to issue test reports displaying the logo and must cease publishing documents containing the logo.

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2.0 ORGANIZATION

2.1 ORGANIZATIONAL ENTITY

SGS North America Inc. is part of the SGS organization with headquarters in Geneva, Switzerland. Satellite laboratories are maintained in Dayton, New Jersey; Orlando, Florida; Houston, Texas; Wheat Ridge, Colorado; and Scott, Louisiana.

2.2 MANAGEMENT RESPONSIBILITIES

Requirement - Each laboratory facility has an established chain of command. The duties and responsibilities of the management staff are linked to the Vice President of SGS North America Inc. who establishes the agenda for all company activities.

Vice President EHS SGS North America Inc. – Primarily responsible for all operations and business activities. Delegates authority to laboratory directors, general managers, and the quality assurance staff to conduct day to day operations and execute quality assurance duties at all EHS SGS North America Inc. facilities; this includes the five operational environmental laboratories located in New Jersey, Florida, Texas, Colorado, and Louisiana.

Quality Assurance Director, – Primarily responsible for oversight and facilitation of all quality systems elements as identified in the Quality program. The Quality Assurance Supervisor reports directly to Vice President of Operations – Conventional Lab Services, US.

Laboratory Director/General Manager/ Technical Manager – Executes day to day responsibility for laboratory operations including technical aspects of production activities and associated logistical procedures. Reports directly to the Vice President of EHS SGS North America Inc.

Quality Assurance Officer (QAO) – Responsible for ensuring that the Quality Assurance Manual is current and for the implementation and execution of the day-to-day Quality Program with regards to the laboratory. This includes but is not limited to method audits, personnel training, maintaining training records, document control and state accreditations. The QAO reports directly to the QA Director,.

Technical Managers (Organics/General Chemistry/Microbiology) – Responsible for day-to-day technical activities of the individual laboratory including implementation of technical requirements. The Technical Managers meet the requirements of Section 4.1.7.2 of the 2009 TNI Standards. Reports directly to the Department Manager or Laboratory Director.

Department Managers – Executes day to day responsibility for specific laboratory areas including technical aspects of production activities and associated logistical procedures. Department managers report directly to the Laboratory Director.

Section Supervisors/Team Leads – Executes day to day responsibility for specific laboratory units including technical aspects of production activities and associated logistical procedures. Section supervisors report directly to the Department Manager.

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Corporate Technical Project Manager – Responsible for developing and implementing corporate level projects. Reports 60% of the time to the Laboratory Director and 40% of the time to corporate office.

2.3 Chain of Command

The responsibility for managing all aspects of the Company's operation is delegated to specific individuals, who have been assigned the authority to act in the absence of the senior staff. These individuals are identified in the following Chain of Command for the Louisiana Facility:

Géraldine Picaud, Chief Executive Officer, SGS North America Inc.
Marcus Maguire, Vice President of SGS North America Inc., Environment, Health, and Safety.
David Chastain, Vice President Operations Conventional Chemistry Lab Services
Lionel Thomas, Operations Manager – Scott
Kesavalu Bagawandoss, Technical Manager - Scott
Jamie Sampson, Quality Assurance Manager(Scott) / Regional QA Manager (Mid West)

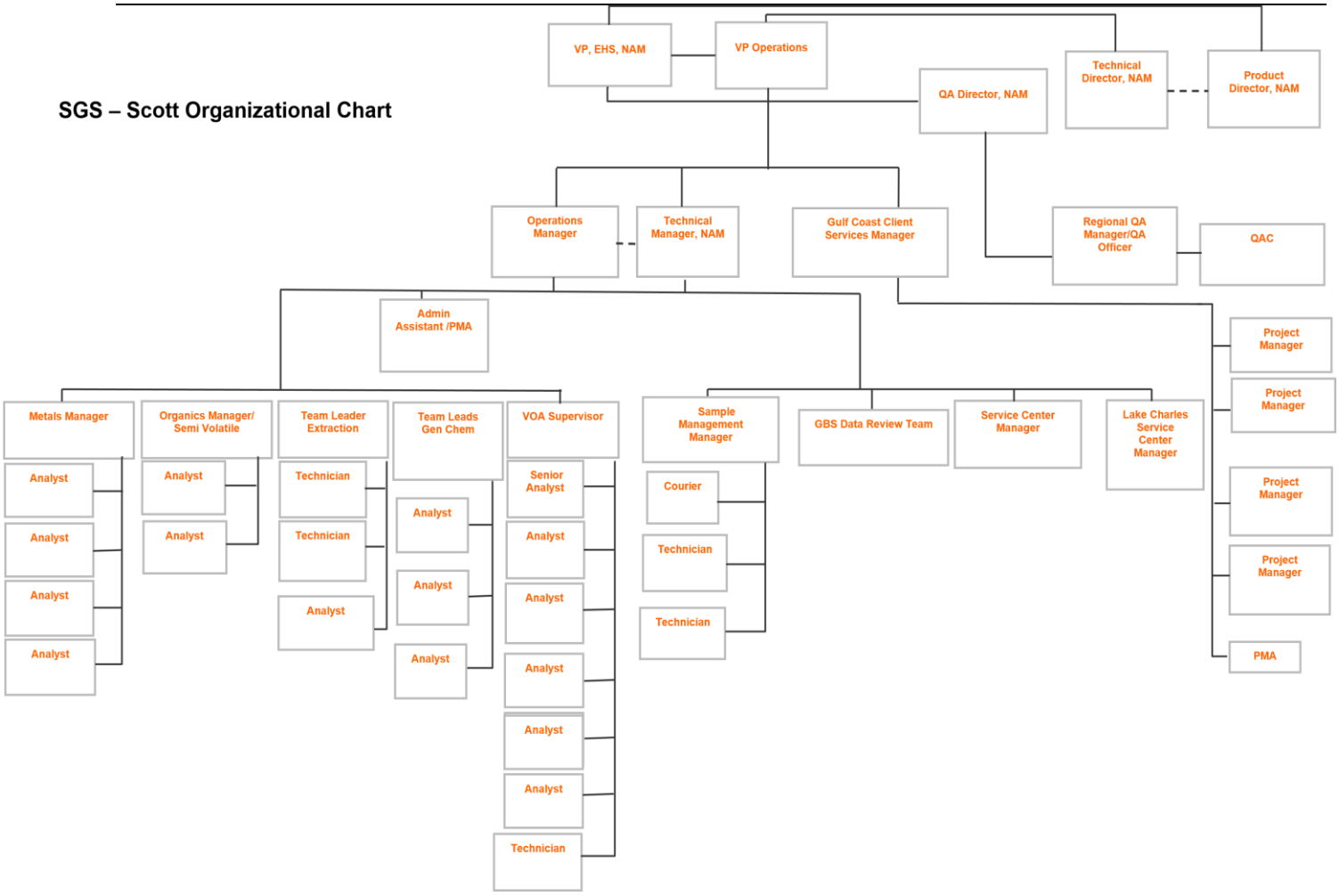
2.4 Organization Chart

The hierarchy of the Company's operational control and oversight is illustrated in the SGS North America Inc. Laboratories Organization Chart. Employees listed with an asterisk are considered to be the appointed deputy in the event that the Technical Manager or Quality Assurance Officer are absent from their respective position for a period of time exceeding fifteen (15) consecutive calendar days.

Should this absence exceed thirty-five (35) consecutive calendar days, the Louisiana Department of Environmental Quality, Laboratory Accreditation Program, and the Louisiana Department of Health Certification Program shall be notified in writing.

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SGS – Scott Organizational Chart



QA Department maintains an organization chart with names for persons in each position
See F-LQA323 current

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3.0 QUALITY RESPONSIBILITIES OF THE MANAGEMENT TEAM

3.1 REQUIREMENT - Each member of the management team has a defined responsibility for the Quality System. System implementation and operation is designated as an operational management responsibility. System design and implementation is designated as a Quality Assurance Responsibility.

VICE PRESIDENT EHS SGS NORTH AMERICA INC. – Primarily responsible for process improvements to all business aspects of the company.

VICE PRESIDENT OPERATIONS CONVENTIONAL CHEMISTRY LAB SERVICES - Primarily responsible for process improvements to business aspects of the conventional chemistry division of EHS.

QUALITY ASSURANCE SUPERVISOR, GULF COAST – Responsible for design, implementation support, training, and monitoring of the quality system. The QA Supervisor identifies product, process, or operational defects using statistical monitoring tools and process audits for elimination via corrective action. The QA Supervisor is empowered with the authority to halt production if quality issues warrant immediate action. The QA Supervisor monitors implemented corrective actions for compliance.

LABORATORY DIRECTOR/GENERAL MANAGER – Responsible for overseeing the technical aspects of the quality assurance system as they are integrated into method applications and employed to assess analytical control on a daily basis. The laboratory directors review and acknowledge the technical feasibility of proposed QA systems involving technical applications of applied methodology. The technical directors meet the requirements of section 4.1.7.2 of the 2009 TNI standards.

DEPARTMENT MANAGERS – Responsible for applying the requirements of the Quality System in their section and assuring subordinate supervisors and staff apply all system requirements. Initiates, designs, documents, and implements corrective action for quality deficiencies.

SECTION SUPERVISORS & TEAM LEADERS – Responsible for applying the requirements of the Quality System to their operation and assuring the staff applies all system requirements. Initiates, designs, documents, and implements corrective action for quality deficiencies.

QUALITY ASSURANCE OFFICERS – Responsible for reviewing and revising the QSM as necessary. Responsible for design support, implementation support, training, and monitoring support for the quality system. Conducts audits and product reviews to identify product, process, or operational defects using statistical monitoring tools and processes audits for elimination via corrective action. Provides monitors support for implemented corrective actions for compliance.

BENCH ANALYSTS – Responsible for applying the requirements of the Quality System to the analyses they perform, evaluating QC data and initiating corrective action for quality control deficiencies within their control. Implements global corrective action as directed by superiors.

3.2 PROGRAM AUTHORITY – Authority for program implementation originates with the Vice President EHS SGS North America Inc. who bears the ultimate responsibility for system design,

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implementation, and enforcement of requirements. This authority and responsibility is delegated to the of Quality Assurance Officers who performs quality functions independently without the encumbrances or biases associated with operational or production responsibilities to ensure an honest, independent assessment of quality issues.

3.3 DATA INTEGRITY POLICY – The SGS North America Inc. Data Integrity Policy reflects a comprehensive, systematic approach for assuring that data produced by the laboratory accurately reflects the outcome of the tests performed on field samples and has been produced in a bias free environment by ethical professionals. The policy includes a commitment to technical ethics, staff training in ethics and data integrity, an individual attestation to data integrity and procedures for evaluating data integrity. Senior management assumes the responsibility for assuring compliance with all technical ethics elements and operation of all data integrity procedures. The staff is responsible for compliance with the ethical code of conduct and for practicing data integrity procedures.

The SGS North America Inc. Inc. Data Integrity Policy is as follows:

"SGS North America Inc. Laboratories are committed to producing data that meets the data integrity requirements of the environmental regulatory community. This commitment is demonstrated through the application of a comprehensive data integrity program that includes ethics and data integrity training, data integrity evaluation procedures, staff participation and management oversight. Adherence to the specifications of the program assures that data provided to our clients is of the highest possible integrity and can be used for decision making processes with high confidence."

DATA INTEGRITY RESPONSIBILITIES

MANAGEMENT – Senior management retains oversight responsibility for the data integrity program and retains ultimate responsibility for execution of the data integrity program elements. Senior management is responsible for providing the resources required to conduct ethics training and operate data integrity evaluation procedures. They also include responsibility for creating an environment of trust among the staff and being the lead advocate for promoting the data integrity policy and the importance of technical ethics. The Vice President of EHS NAM is the designated ethics officer for the Company.

STAFF – The staff is responsible for adhering to the company ethics policy as they perform their duties and responsibilities associated with sample analysis and reporting. By executing this responsibility, data produced by SGS North America Inc. Laboratories retains its high integrity characteristics and withstands the rigors of all data integrity checks.
The staff is also responsible for adhering to all laboratory requirements pertaining to manual data edits, data transcription and data traceability. These include the application of approved manual peak integration and documentation procedures. It also includes establishing traceability for all manual results calculations and data edits.

ETHICS STATEMENT

The SGS North America Inc. ethics statement reflects the standards that are expected for businesses that provide environmental services to regulated entities and regulatory agencies on a commercial basis. The Ethics Policy is comprised of key elements that are essential to

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organizations that perform chemical analysis for a fee. As such, it focuses on elements related to personal, technical and business activities.

SGS North America Inc. Laboratories provides analytical chemistry services on environmental matters to the regulated community. The data the company produces provides the foundation for determining the risk presented by a chemical pollutant to human health and the environment. The environmental industry is dependent upon the accurate portrayal of environmental chemistry data. This process is reliant upon a high level of scientific and personal ethics. It is essential to the Company that each employee understands the ethical and quality standards required to work in this industry. Accordingly, SGS North America Inc. has adopted a code of ethics, which each employee is expected to adhere to as follows:

- Perform chemical and microbiological analysis using accepted scientific practices and principles.
- Perform tasks in an honest, principled, and incorruptible manner inspiring peers and subordinates.
- Maintain professional integrity as an individual.
- Provide services in a confidential, honest, and forthright manner.
- Produce results that are accurate and defensible.
- Report data without any considerations of self-interest.
- Comply with all pertinent laws and regulations associated with assigned tasks and responsibilities.

DATA INTEGRITY PROCEDURES – Four key elements comprise the SGS North America Inc. data integrity system. Procedures have been implemented for conducting data integrity training and for documenting that employees conform to the SGS North America Inc. Data Integrity and Ethics policy.

The data integrity program consists of routine data integrity evaluation and documentation procedures to periodically monitor and document data integrity. These procedures are documented as SOPs. SOPs are approved and reviewed annually following the procedures employed for all SGS North America Inc. SOPs. Documentation associated with data integrity evaluations is maintained on file and is available for review.

DATA INTEGRITY TRAINING – SGS North America Inc. employees receive technical ethics training during new employee orientation. Employees are also required to refresh their ethical conduct agreement annually, which verifies their understanding of SGS North America Inc.'s ethics policy and their ethical responsibilities. A brochure summarizing the details of the SGS North America Inc. Data Integrity Policy is distributed to all employees with the Ethical Code of Conduct Agreement. The refreshed agreement is appended to each individual's training file.

The training focuses on the reasons for technical ethics training, explains the impact of data fraud on human health and the environment, and illustrates the consequences of criminal fraud on businesses and individual's careers. SGS North America Inc.'s ethics policy and code of ethics are reviewed and explained for each new employee.

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Training on data integrity procedures are conducted by individual departments for groups involved in data operations. These include procedures for manual chromatographic peak integration, traceability for manual calculations and data transcription.

DATA INTEGRITY TRAINING DOCUMENTATION – Records of all data integrity training are maintained in individual training folders. Attendance at all training sessions is documented and maintained in the training archive.

SGS NORTH AMERICA INC. DATA INTEGRITY AND ETHICAL CONDUCT AGREEMENT – All employees are required to sign a Data Integrity and Ethical Conduct Agreement annually. This document is archived in individual training files, which are retained for duration of employment.

The Data Integrity and Ethical Conduct Agreement is as follows:

I. *I understand the high ethical standards required of me with regard to the duties I perform and the data I report in connection with my employment at SGS North America Inc. Laboratories.*

II. *I have received formal instruction on the code of ethics that has been adapted by SGS North America Inc. Laboratories during my orientation and agree to comply with these requirements.*

III. *I have received formal instruction on the elements of SGS North America Inc. Laboratories' Data Integrity Policy and have been informed of the following specific procedures:*

   a. *Formal procedures for the confidential reporting of data integrity issues are available, which can be used by an employee.*

   b. *A data integrity investigation is conducted when data issues are identified that may negatively impact data integrity.*

   c. *Routine data integrity monitoring is conducted on sample data, which may include an evaluation of the data I produce.*

IV. *I have read the brochure detailing SGS North America Inc. Laboratories Data Integrity and Ethics Program as required.*

V. *I am aware that data fraud is a punishable crime that may include fines and/or imprisonment upon conviction.*

VI. *I also agree to the following:*

   a. *I shall not intentionally report data values, which are not the actual values observed or measured.*

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b. *I shall not intentionally modify data values unless the modification can be technically justified through a measurable analytical process.*
c. *I shall not intentionally report dates and times of data analysis that are not true and actual times the data analysis was conducted.*
d. *I shall not condone any accidental or intentional reporting of inauthentic data by other employees and immediately report its occurrence to my superiors.*
e. *I shall immediately report any accidental reporting of inauthentic data by myself to my superiors.*

DATA INTEGRITY MONITORING – Documented procedures are employed for performing data integrity monitoring. These include regular data review procedures by supervisory and management staff (Section 12.8), supervisory review and approval of manual integrations and periodic reviews or GALP audit trails from the LIMS and all computer-controlled analysis.

DATA REVIEW – All data produced by the laboratory undergoes at least two levels of review, the final must be performed by a manager, supervisor, or designated reviewer. Detected data anomalies that appear to be related to data integrity issues are isolated for further investigation. The investigation is conducted following the procedures described in this section.

MANUAL PEAK INTEGRATION REVIEW AND APPROVAL – Routine data review procedures for all chromatographic processes includes a review of all manual chromatographic peak integrations. This review is performed by the management staff and consists of a review of the machine integration compared to the manual integration. Manual integrations, which have been performed in accordance with SGS North America Inc.'s manual peak integration procedures, are approved for further processing and release. Identification of samples and analytes in which manual integration had been necessary may be recorded in a report case narrative specific to a particular client and project requirement. Manual integrations which are not performed to SGS North America Inc.'s specifications are set aside for corrective action, which may include analyst retraining or further investigation as necessary.

DATA INTEGRITY REVIEW – Data integrity audits are comprehensive data package audits that include a review of raw data, process logbooks, processed data reports and GALP audit trails from individual instruments and LIMS. GALP audit trails, which record all electronic data activities, are available for the majority of computerized methodology and the laboratory information management system (LIMS). These audit trails are periodically reviewed to determine if interventions performed by technical staff constitute an appropriate action. The review is performed on a recently completed job and may include interviews with the staff who performed the analysis. Findings indicative of inappropriate interventions or data integrity issues are investigated to determine the cause and the extent of the anomaly.

CONFIDENTIAL REPORTING OF DATA INTEGRITY ISSUES – Data integrity concerns may be raised by any individual to their supervisor. Employees with data integrity concerns should always discuss those concerns with their immediate supervisors as a first step unless the employee is concern with the confidentiality of disclosing data integrity issues or is uncomfortable discussing the issue with their immediate supervisors. The supervisor makes an initial assessment of the situation to determine if the concern is related to a data integrity

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violation. Those issues that appear to be violations are documented by the supervisor and referred to the Quality Assurance Manager for investigation.

Documented procedures for the confidential reporting of data integrity issues in the laboratory are part of the data integrity policy. These procedures assure that laboratory staff can privately discuss ethical issues or report items of ethical concern without fears of repercussions with senior staff.

Employees with data integrity concerns that they consider to be confidential are directed to the Corporate Human Resources Manager in Dayton, New Jersey or Corporate Human Resources employee in Houston, TX. The HR Manager acts as a conduit to arrange a private discussion between the employee and the QA representative.

During the employee – QA discussion, the QA representative evaluates the situation presented by the employee to determine if the issue is a data integrity concern or legitimate practice. If the practice is legitimate, the QA representative clarifies the process for the employee to assure understanding. If the situation appears to be a data integrity concern, the QA representative initiates a Data Integrity Investigation following the procedures specified in SOP LQA036.

DATA INTEGRITY INVESTIGATIONS – Follow-up investigations are conducted for all reported instances of ethical concern related to data integrity. Investigations are performed in a confidential manner by senior management according to a documented procedure. The outcome of the investigation is documented and reported to the company president who has the ultimate responsibility for determining the final course of action in the matter. Investigation documentation includes corrective action records, client notification information and disciplinary action outcomes, which is archived for a period of ten years.
The investigations are conducted by the senior staff and supervisory personnel from the affected area. The investigations team includes the Laboratory Director and the Quality Assurance Officer. Investigations are conducted in a confidential manner until it is completed and resolved.

The investigation includes a review of the primary information in question by the investigation team. The team performs a review of associated data and similar historical data to determine if patterns exist. Interviews are conducted with key staff to determine the reasons for the observed practices.

Following data compilation, the investigations team reviews all information to formulate consensus conclusions. The investigation results are documented along with the recommended course of action.

CORRECTIVE ACTION, CLIENT NOTIFICATION & DISCIPLINE – Investigations that reveal systematic data integrity issues will be referred for corrective action, resolution, and disposition (Section 13). If the investigation indicates that an impact to data has occurred and the defective data has been released to clients, client notification procedures will be initiated following the steps in Section 13.1.

In all cases of data integrity violations, some level of disciplinary action will be conducted on the responsible individual. The level of discipline will be consistent with the violation and may range from retraining and/or verbal reprimand to termination. A zero-tolerance policy is in effect for unethical actions.

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4.0 JOB DESCRIPTIONS OF KEY STAFF

4.1 REQUIREMENT - Descriptions of key positions within the organization are defined to ensure that clients and staff understand duties and the responsibilities of the management staff and the reporting relationships between positions. Laboratory Technical Manager for inorganic chemistry must have an associate degree in chemical, physical or environmental sciences or two years of experience in the environmental analysis of representative inorganic and organic analytes with a minimum of 16 college semester hours in chemistry. Laboratory Technical Managers for chemical analysis must have a bachelor's degree in chemical, environmental, biological sciences, physical sciences, or engineering with at least 24 college semester credit hours in Chemistry. Laboratory Technical Manager for Micro must have a bachelor's degree in microbiology, biology, chemistry, environmental sciences, physical sciences, or engineering with a minim of 16 college semester credit hours in general biology and microbiology and at least 2 years of experience in the environmental analysis.

VICE PRESIDENT EHS NORTH AMERICA INC. – Responsible for all laboratory operations and business activities. The Vice President of EHS SGS North America Inc. establishes the company mission and process improvements for business needs. Is responsible for Quality Assurance, IT Development, and Health and Safety.

VICE PRESIDENT OPERATIONS CONVENTIONAL CHEMISTRY LAB SERVICES – Primarily responsible for process improvements to business aspects of the conventional chemistry division of EHS.

LABORATORY DIRECTOR (DIRECTOR) – For SGS North America Inc. Scott, the Laboratory Director reports directly to the Vice President. The Director establishes laboratory operational strategies. At the SGS North America Inc. Laboratories Scott Louisiana, the Director supervises client services, organic chemistry manager, inorganic chemistry manager, field services, and sample management. The laboratory director approves any major method modification after reviewing the required data and may draft the justification memo for said major modification. The Laboratory Director maintains operational responsibility for the designated regional laboratories as defined in the SGS North America Inc. Laboratories Organization Chart.

ACADEMIC TRAINING: The laboratory director must have a bachelor's degree in chemical, environmental, biological sciences, physical sciences or engineering science or a minimum of four years equivalent experience in a related field. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

EXPERIENCE: The laboratory director must have a minimum of two years of experience in the area of environmental analysis.

QUALITY ASSURANCE DIRECTOR – Reports to the Vice President of EHS NAM and functions independently from laboratory operations. Establishes, provides assistance to operations on quality procedure implementation, coordinates all quality control activities, monitors the quality system, provides quality system feedback to management to be used for process improvement and oversees health and safety.

ACADEMIC TRAINING: The quality assurance supervisor must have a bachelor's degree in chemical, environmental, biological sciences, physical sciences or engineering science and a

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minimum of four years equivalent experience in a related field. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

EXPERIENCE: The quality assurance director must have a minimum of two years of experience in the area of environmental analysis.

PROJECT MANAGER(CLIENT SERVICES) – Reports to the Laboratory Director. Establishes and maintains communications between clients and laboratory pertaining to client requirements which are related to sample analysis and data deliverables. Initiates client orders and supervises sample login operations.

METALS MANAGER – Reports to the laboratory director. Directs the operations of the metal's laboratories. Establishes daily work schedule. Supervises method implementation, application, and data production. Responsible for following Quality System requirements. Maintains laboratory instrumentation in an operable condition.

ACADEMIC TRAINING: The Metals Manager must have a bachelor's degree in chemical, environmental, biological sciences, physical sciences or engineering science or a minimum of four years equivalent experience in a related field. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

EXPERIENCE: The Metals Manager must have a minimum of two years of experience in the area of environmental analysis.

ORGANICS MANAGER – Reports to the laboratory director. Directs the operations of the organics group, consisting of organics preparation, semi-volatile and volatiles analysis. Establishes daily work schedule. Supervises method development, implementation, application, and data production. Responsible for following Quality System requirements. Maintains laboratory instrumentation in an operable condition. Manages laboratory waste management program.

ACADEMIC TRAINING: The Organic Manager must have a bachelor's degree in chemical, environmental, biological sciences, physical sciences or engineering science or a minimum of four years equivalent experience in a related field. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

EXPERIENCE: The Organic Manager must have a minimum of two years of experience in the area of environmental analysis.

SAMPLE MANAGEMENT MANAGER – Reports to the laboratory director. Develops, maintains, and executes all procedures required for receipt of samples, verification of preservation, and chain of custody documentation. Responsible for maintaining and documenting secure storage, delivery of samples to laboratory units on request, and courier services.

ENVIRONMENTAL HEALTH AND SAFETY DIRECTOR – Reports to the Vice President EHS SGS North America Inc. Responsible for developing company safety program and chemical hygiene plan. These plans are reviewed and updated - annually. Responsible for employee training on relevant health and safety topics. Documents employee training. Manages laboratory waste management program.

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HEALTH & SAFETY OFFICER – Reports to the corporate Director, Environmental Health, and Safety. Responsible for developing company safety program and chemical hygiene plan. These plans are reviewed and updated. Responsible for employee training on relevant health and safety topics. Documents employee training. Helps manage the laboratory waste management program with the Organic Manager.

PROJECT MANAGERS – Report to the laboratory director. Develops, maintains, and executes all client sample projects from initial to final analysis. Responsible for maintaining client services, client reports, maintains and executes all client sample projects from initial to final analysis.

TECHNICAL INORGANICS MANAGER – Reports to the laboratory director. Oversees all instrument maintenance and new equipment installation. Conducts method development and implementation tasks. May approve any major method modifications after reviewing required data package and drafts the justification memo for said modification. Reviews data.

ACADEMIC TRAINING: The Technical Inorganics Manager must have a bachelor's degree in chemical, environmental, biological sciences, physical sciences, or engineering science with at least twenty-four (24) college semester credit hours in chemistry or a minimum of four years equivalent experience in a related field. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

EXPERIENCE: The Technical Inorganics Manager must have a minimum of two years of experience in the area of environmental analysis.

TECHNICAL MICROBIOLOGY MANAGER – Reports to the laboratory director. Oversees all microbiological analyses. Conducts method development and implementation tasks. Reviews data.

ACADEMIC TRAINING: The Technical Micro Manager must have a bachelor's degree in chemical, environmental, biological sciences, physical sciences, or engineering science with at least sixteen (16) college semester credit hours in general microbiology and biology. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

EXPERIENCE: The Technical Micro Manager must have a minimum of two years of experience in the area of environmental analysis.

GENERAL CHEMISTRY SUPERVISOR – Reports to the Laboratory Director. Executes daily analysis schedule. Supervised the analysis of samples for wet chemistry parameters using valid, documented methodology. Maintains instrumentation in an operable condition. Reviews data for compliance to quality and methodological requirements.

ACADEMIC TRAINING: The General Chemistry Supervisor must have a bachelor's degree in chemical, environmental, biological sciences, physical sciences or engineering science or a minimum of four years equivalent experience in a related field. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

EXPERIENCE: The Supervisor must have a minimum of one year of experience in the area to be supervised, preferably with a minimum of six months supervisory experience.

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METALS SUPERVISOR – Reports to the Metals manager. Executes daily analysis schedule. Supervises the analysis of samples for metallic elements using valid, documented methodology. Documents all procedures and data production activities. Maintains instrumentation in an operable condition. Reviews data for compliance to quality and methodological requirements. Assumes the responsibilities of the Metals Manager in his absence.

ACADEMIC TRAINING: The Metals Supervisor must have a bachelor's degree in chemical, environmental, biological sciences, physical sciences or engineering science or a minimum of four years equivalent experience in a related field. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

EXPERIENCE: The Supervisor must have a minimum of one year of experience in the area to be supervised, preferably with a minimum of six months supervisory experience.

ORGANIC PREPARATION MANAGER – Reports to the organic manager. Executes the daily sample preparation schedule. Performs the extraction of multi-media samples for organic constituents using valid documented methodology. Prepares documentation for extracted samples. Assumes custody until transfer for analysis.

ACADEMIC TRAINING: The Organic Preparation Manager must have a bachelor's degree in chemical, environmental, biological sciences, physical sciences or engineering science or a minimum of four years equivalent experience in a related field. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

EXPERIENCE: The manager must have a minimum of one year of experience in the area to be supervised, preferably with a minimum of six months supervisory experience.

TECHNICAL ORGANICS MANAGER – Reports to the organic manager. Oversees all instrument maintenance and new equipment installation. Conducts method development and implementation task. May approve any major method modifications after reviewing required data package and drafts the justification memo for said modification. Reviews data and prints Level IV Organic data packages.

ACADEMIC TRAINING: The Technical Organics Manager must have a bachelor's degree in chemical, environmental, biological sciences, physical sciences, or engineering science with at least twenty-four (24) college semester credit hours in chemistry or a minimum of four years equivalent experience in a related field. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

EXPERIENCE: The Technical Organics Manager must have a minimum of two years of experience in the area of environmental analysis.

QUALITY ASSURANCE OFFICER/MANAGER – Reports to the Quality Assurance Director. Performs quality control data review for trend monitoring purposes. Conducts internal audits and prepares reports for management review. Maintains training records for laboratory personnel. Oversees proficiency testing program and process quality control data for statistical purposes. The QAO or their supervisor approves any major method modification after reviewing the required data and may draft the justification memo for said major modification. The QAO will ensure that the data package and justification memo or stored in the QA directory on the server.

ACADEMIC TRAINING: The quality assurance officer must have a bachelor's degree in chemical, environmental, biological sciences, physical sciences or engineering science or a

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minimum of four years equivalent experience in a related field. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

EXPERIENCE: The quality assurance officer must have a minimum of two years of experience in the area of environmental analysis.

4.2 EMPLOYEE SCREENING, ORIENTATION, AND TRAINING

All potential laboratory employees are screened and interviewed by human resources and technical staff prior to their hire. The pre-screen process includes a review of their qualifications including education, training, and work experience to verify that they have adequate skills to perform the tasks for the job.

Newly hired employees receive orientation training beginning the first day of employment by the Company. Orientation training consists of initial health and safety training including general laboratory safety, personal protection and building evacuation. Orientation also includes quality assurance program training, data integrity training, and an overview of the Company's goals, objectives, mission, and vision.

All technical staff receives training to develop and demonstrate proficiency for the methods they perform and the instruments they operate. New analysts work under supervision until the supervisory staff is satisfied that a thorough understanding of the method is apparent and method proficiency has been demonstrated, through a precision and accuracy study that has been documented, reviewed, and approved by the QA Staff. Data from the study is compared to method acceptance limits. If the data is unacceptable, additional training is required. The analyst may also demonstrate proficiency by producing acceptable data through the analysis of an independently prepared proficiency sample. When staff member produces acceptable data, they are then authorized to operate independently with regards to the equipment and methodology for which they were trained.

Individual proficiency is demonstrated annually for each method performed. Data from initial and continuing proficiency demonstrations are archived in the individual's training folder.

4.3 TRAINING DOCUMENTATION

The Quality Assurance Department prepares a training file for every new employee. All information related to qualifications, experience, external training courses, and education are placed into the file. Verification documentation for orientation, health & safety, quality assurance, and ethics training is also included in the file.

Additional training documentation is added to the file as it is developed. This includes documentation of SOP understanding, data for initial and continuing demonstration of proficiency, performance evaluation study data and notes and attendance list from group training sessions. Employees are required to sign a SOP Compliance Statement form any time a new SOP is created, or an old SOP is revised. The forms are filed in the employee's training records.

The Quality Assurance Department maintains the employee training database. This database is comprehensive inventory of training documentation for each individual employee. The database enables supervisors to obtain current status information on training data for individual employees on a job specific basis. It also enables the management staff to identify training documentation in need of completion.

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Employee specific database records are created by human resources on the date of hire. Data base fields for job specific requirements such as SOP documentation of understanding and annual demonstration of analytical capability are automatically generated when the supervisor assigns a job responsibility. Employees acknowledge that their SOP responsibilities have been satisfied using a secure electronic process which updated the database record. Reports are produced which summarize the qualifications of individual employees or departments.

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5.0 SIGNATORY APPROVALS

REQUIREMENTS – Procedures have been developed for establishing the traceability of data and documents. The procedure consists of a signature hierarchy, indicating levels of authorization for signature approvals of data and information within the organization. Signature authority is granted for approval of specific actions based on positional hierarchy within the organization and knowledge of the operation that requires signature approval. A log of signatures and initials of all employees is maintained by the QA Staff for cross-referencing purposes.

5.1 SIGNATURE HIERARCHY

The following briefly describes the signature authority at the SGS North America Inc.

VICE PRESIDENT EHS SGS NORTH AMERICA INC. – Approval of quality assurance policy in lieu of the Quality Assurance Supervisor.

LABORATORY DIRECTOR – Approval of final reports. Approval of site-specific Quality Systems Manual (QSM), project specific QAPPs, data review and approval in lieu of technical managers. Establishes and implements technical policy. Approval and acceptance of incoming work and client services policy.

VICE PRESIDENT, CHIEF INFORMATION OFFICER – department specific supply purchase. MIS policy.

QUALITY OFFICERS – Approval of SOPs, site specific QSM, project specific QAPPs, data review and approval in lieu of technical managers as described in SOP LQA002, current revision.

MANAGERS, TECHNICAL DEPARTMENT – Methodology and department specific QAPs. Data review and approval, department specific supplies purchase. Technical approval of SOPs. Approval of final reports as described in SOP LQA002, current revision.

PROJECT MANAGERS – Approval of final reports, departmental SOPs, and project specific QAPs as described in SOP LQA002, current revision.

SUPERVISOR, SAMPLE MANAGEMENT – Initiation of laboratory sample custody and acceptance of all samples. Approval of department policies and procedures. Purchase of department specific supplies.

DIRECTOR, ENVIRONMENTAL HEALTH & SAFETY – Approval of health and safety policy in the absence of the President, approval of health and safety SOPs, waste manifesting and approval as described in SOP LQA002.

SUPERVISORS, TECHNICAL DEPARTMENTS – Data review approval, purchasing of expendable supplies as described in SOP LQA002.

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5.2 SIGNATURE REQUIREMENTS – All laboratory activities related to sample custody and generation, or release of data must be approved using either initials, signatures or electronic, password protected procedures. The individual, who applies his signature initial or password to an activity or document, is authorized to do so within the limits assigned to them by their supervisor. All written signatures and initials must be applied in a readable format that can be cross-referenced to the signatures and initials log if necessary.

5.3 SIGNATURE AND INITIALS LOG- The Quality Assurance Department maintains a signature and initials log. New employee signatures and initials are appended to the log on the first day of employment. Signature of individuals no longer employed by the company are retained.

5.4 ELECTRONIC SIGNATURE LOG - Key technical staff will sign a liability document for their signatures designating the use of their electronic signatures on an annual basis.

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6.0 DOCUMENTATION & DOCUMENT CONTROL

REQUIREMENT – Document control policies have been established which specify that any document used as an information source or for recording analytical or quality control information must be managed using defined document control procedures. Accordingly, policies and procedures required for the control, protection, and storage of any information related to the production of analytical data and the operation of the quality system to assure its integrity and traceability have been established and implemented in the laboratory. The system contains sufficient controls for managing, archiving and reconstructing all process steps which contributed to the generation of an analytical test result. Using this system, an audit trail for reported data can be produced, establishing complete traceability for the result.

6.1 ADMINISTRATIVE RECORDS – Administrative (non-analytical) records are managed by the quality assurance department. These records consist of electronic documents which are retained in a limited access electronic directory or paper documents, which are released to the technical staff upon specific request.

FORM GENERATION, MODIFICATION & CONTROL – The quality assurance group approves and manages all forms used either stand-alone documents or in logbooks to ensure their traceability. Forms are generated as computer files only and are maintained in a limited access master directory. The QA staff also manages and approves modifications to existing forms. Obsolete editions of modified forms are retained for a minimum of seven years and up to ten years if required by state or regulatory agency.

Approved forms are assigned a 5-character alphanumeric code. The first two alpha characters designate the department that uses the form; the next three digits are sequentially assigned number.

New forms must include the name SGS North America Inc. Laboratories and appropriate spaces for signatures of approval and dates. Further design specifications are the responsibility of the originating department.
The technical staff is required to complete all forms to the maximum extent possible. If information for a specific item is unavailable, the analyst is required to “Z” the information block. The staff is also required to “Z” the uncompleted portions of a logbook or logbook form if the day’s analysis does not fill the entire page of the form.

LOGBOOK CONTROL - All laboratory logbooks are controlled documents that are comprised of approved forms used to document specific processes. New logs are numbered and issued to a specific individual who is assigned responsibility for the log. Old logs are returned to QA for entry into the document archive system where they are retained for ten (10) years. Laboratory staff may hold a maximum of two consecutively dated logbooks of the same type in the laboratory including the most recently issued book to simplify review of recently completed analysis.

CONTROLLED DOCUMENTS – Key laboratory documents that are distributed internally and externally are numbered for tracking purposes. Individuals receiving documents, who must be informed when changes occur, receive controlled copies of these documents. Control is maintained through a document numbering procedure and document control logbook which identifies the individual receiving the controlled document and the date of receipt. Key

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documents are also distributed as uncontrolled documents if the recipient does not require update copies when changes occur. Key documents in uncontrolled status are marked as uncontrolled documents and numbered.

For SGS North America Inc. – Scott, the approval date or concurrence date is the effective date on the Quality Systems Manual and standard operating procedures. Controlled copies are printed on green paper.

QUALITY SYSTEMS MANUAL (QSM) – All QSMs are assigned a number prior to distribution. The number, date of distribution, and identity of the individual receiving the document are recorded in the document control logbook. The numbering system is restarted with each new volume, which corresponds to the annual revision of the QSM. Electronic versions are distributed as read only files that are password protected.

STANDARD OPERATING PROCEDURES (SOPS) – SOPs are maintained by pre-designating the numbers of official copies of documents that are placed into circulation within the laboratory. Official documents are copied to green paper and placed into the appropriate laboratory section as follows:

Administrative: One master copy for the quality assurance file.

Sample Management: One controlled copy for the sample management file.

Organic Laboratories: One controlled copy, for each division.

Inorganic Laboratories: One controlled copy, for each division.

The original, signed copy of the SOP is maintained in the master SOP binder by the QA staff. The QA staff collects outdated versions of SOPs as they are replaced and archived for a period of ten (10) years in the QA archives. Electronic versions of outdated SOPs are moved from the active SOP directory to the inactive directory.

6.2 TECHNICAL RECORDS – All records related to the analysis of samples and the production of an analytical result are archived in secure document storage or on electronic media and contain sufficient detail to produce an audit trail which re-creates the analytical result. These records include information related to the original client request, bottle order, sample login and custody, storage, sample preparation, analysis, data review and data reporting.
Each department involved in this process maintains controlled documents which enable them to maintain records of critical information relevant to their department's process.

6.3 QUALITY CONTROL SUPPORT DATA & RECORDS – All information and data related to the quality system is stored in restricted access directories on the network server. Information on these directories is backed-up daily. Users of the quality assurance information and data have "read-only" access to the files contained in the directory. The QA staff and the laboratory director have write capability in this directory.

This directory contains all current and archived quality system manuals, SOPs, control limits, MDL studies, precision and accuracy data, official forms, internal audit reports, proficiency test scores and metrics calibration information.

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The following information is retained in the directory:

Quality System Manual
Standard Operating Procedures
ASTM & NIST Methods
Bottle ware & Preservative QC Data
Certification Documentation
Change Management Data
External Audit Reports
Internal Audit Reports
Corrective Action Database
Laboratory Forms Directory
Health and Safety Manuals
Inactive Standard Operating Procedures
Method Detection Limit Data
Metrics Inventory & Calibration Data
Performance Limits
Proficiency Test Scores & Statistics
Project Specific Analytical Requirements
QC Report Reviews
Regulatory Agency Quality Documents
Staff Bios and Job Descriptions
State Specific Methods

6.4 ANALYTICAL RECORDS – All data related to the analysis of field samples are retained as either paper or electronic records that can be retrieved to compile a traceable audit trail for any reported result. All information is linked to the client job and sample number, which serves as a reference for all sample related information tracking.

Critical times in the life of the sample from collection through analysis to disposal are documented. This includes date and time of collection, receipt by the laboratory, preparation times and dates, analysis times and dates and data reporting information. Analysis times are calculated in hours for methods where holding time is specified in hours (≤72 hours). Sample preparation information is recorded in a separate controlled logbook. It includes sample identification numbers, types of analysis, preparation and cleanup methods, sample weights and volumes, reagent lot numbers and volumes and any other information pertinent to the preparation procedure.

Information related to the identification of the instrument used for analysis is permanently attached to the electronic record. The record indicates an electronic data file that indicates all instrument conditions employed for the analysis, including the type of analysis conducted. The analyst's identification is electronically attached to the record. The instrument tuning and calibration data is electronically linked to the sample or linked through paper logs which were used in the documentation of the analysis. Quality control and performance criteria are permanently linked to the paper archive or electronic file.

Paper records for the identity, receipt, preparation and evaluation of all standards and reagents used in the analysis are documented in prepared records and maintained in controlled documents or files. Lot number information linking these materials to the analysis performed is recorded in the logbooks associated with the samples in which they were used.

Manual calculations or peak integrations that were performed during the data review are retained in AccuLims and included as part of the electronic archive. Signatures for data review are retained on paper or as scanned versions of the paper record for the permanent electronic file.

6.5 CONFIDENTIAL BUSINESS INFORMATION (CBI) – Operational documents including SOPs, Quality Manuals, personnel information, internal operations statistics, and laboratory audit

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reports are considered confidential business information. Strict controls are placed on the release of this information to outside parties.

Release of CBI to outside parties or organizations may be authorized upon execution of a confidentiality agreement between SGS North America Inc. and the receiving organization or individual. CBI information release is authorized for third party auditors and commercial clients in electronic mode as Adobe Acrobat .PDF format only.

6.6 SOFTWARE CHANGE DOCUMENTATION & CONTROL – Changes to software are documented as text within the code of the program undergoing change. Documentation includes a description of the change, reason for change and the date the change was placed into effect. Documentation indicating the adequacy of the change is prepared following the evaluation by the user who requested the change.

6.7 REPORT AND DATA ARCHIVING – SGS North America Inc. laboratories produces digital files of all raw and processed data which is maintained for a minimum of seven (7) years. The archived files consist of all raw data files and source documents associated with the analysis of field samples and proficiency test samples. Data files and source documents associated with method calibration and project and method quality control are also archived. After seven years, the files may be discarded unless contractual arrangements exist which dictate different requirements. Client or regulatory agency specific data retention practices are employed for several government organizations such as the Louisiana Department of Environmental Quality, that require a retention period of ten (10) years for specific commercial clients in response to contractual requirements.

Either complete date and time stamped PDF reports or dated hardcopy reports are generated automatically from the laboratory information management system (LIMS) using the source documents archived on the document server. These source documents are maintained on a document server and archived to primary and clone tapes. The primary tapes remain on premises while the clone tapes are taken to a secure offsite location for permanent storage. Both the primary and clone tapes remain in storage for the remainder of the archive period.

6.8 TRAINING – The company maintains a training record for all employees that documents that they have received instruction on administrative and technical tasks that are required for the job they perform. Training record for individuals employed by the company are retained in the file cabinets for a period of approximately six months following their termination of employment. After that time, training records for these employees are removed from the file cabinet and placed into storage boxes for archiving on site or off site. The archived employee training files are held for a minimum of 10 years.

TRAINING FILE ORIGINATION – The Human Resources Group (HR) initiates training files. The QA staff, through the Quality Assurance officer, retains the responsibility for the maintenance and tracking of all site-specific training related documentation in the file. The file is begun on the first day of employment. Information required for the file includes a copy of the individual's most current resume, detailing work experience and a copy of any college diplomas and transcript(s) as applicable. Information collected during the first day includes a signed data integrity training and ethical conduct agreement. Additional documentation of health and safety training and quality assurance training must be included during the first month.

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Training documentation, training requirements, analyst proficiency information and other related support documentation is tracked using a customized database application (Section 4.3). Database extracts provide an itemized listing of specific training requirements by job function. Training status summaries for individual analysts portray dates of completion for job specific training requirements.

6.9 TECHNICAL TRAINING – The supervisor of each new employee is responsible for developing a training plan. The supervisor evaluates the employees training progress at regular frequencies. Supporting documentation, including demonstration of capability and precision and accuracy studies, which demonstrate an analyst's proficiency for a specific test, are added to the training file as completed. Employees and supervisors verify documentation of understanding (DOU) for all assigned standard operating procedures in the training database. Certificates or diplomas for any off-site training are also added to the file.

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7.0 REFERENCE STANDARD TRACEABILITY

REQUIREMENT – Documented procedures, which establish traceability between any measured value and a national reference standard, are established by the laboratory as required. All metric measurements are traceable to NIST reference weights or thermometers that are calibrated on a regular schedule. All chemicals used for calibration of a quantitative process are traceable to an NIST reference that is documented by the vendor using a certificate of traceability. The laboratory maintains a documentation system that establishes the traceability links. The procedures for verifying and documenting traceability are documented in standard operating procedures.

ISO/IEC 17025: 2017 REQUIREMENT – All vendors and suppliers used for ISO 17025:2017 testing must be ISO accredited. In addition, externally provided services and supplies used for ISO 170125: 2017 testing must be evaluated on an ongoing basis. Providers of CRMs must have ISO 17034 accreditation.

The laboratory shall have a procedure and retain records for:
a) defining, reviewing, and approving the laboratory's requirements for externally provided products and services.
b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers.
c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of ISO 17025:2017, before they are used or directly provided to the customer.
d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

7.1 TRACEABILITY OF METRIC MEASUREMENTS – THERMOMETERS – SGS North America Inc. uses NIST traceable thermometers to calibrate commercially purchased thermometers prior to their use in the laboratory and annually thereafter for liquid in glass thermometers or quarterly for electronic temperature measuring devices. The QA department maintains a spreadsheet that identifies all thermometers in use in the laboratory. The spreadsheet contains the schedule for calibration of each thermometer in use in the laboratory, date of calibration, expiration date for the calibration, correction factor is necessary. Thermometer calibrations are documented in the appropriate logbook. If necessary, thermometers are assigned correction factors that are determined during their calibration using an NIST thermometer as the standard. The correction factor is applied to temperature measurements before recording the measurement in the temperature log. Calibration of each thermometer is verified and documented on a regular schedule. The NIST thermometer is checked for accuracy by an ISO 17025 approved vendor every 5 years following the specifications for NIST thermometer calibration verification detailed in the United States Environmental Protection Agency's "Manual for the Certification of Laboratories Analyzing Drinking Water", Fifth Edition.

7.2 TRACEABILITY OF METRIC MEASUREMENTS-CALIBRATION WEIGHTS – SGS North America Inc. uses calibrated weights, which are traceable to NIST standard weights to calibrate all balances used in the laboratory. Balances are calibrated to specific tolerances within the intended use range of the balance. Calibration checks are required on each day of use. If the tolerance criteria are not achieved, corrective action specified in the balance calibration SOP is

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applied before the balance can be used for laboratory measurements. Recalibration of all calibration weights is conducted and documented every 5 years.

7.3 TRACEABILITY OF CHEMICAL STANDARDS – All chemicals, with the exception of bulk dry chemicals and acids, purchased as reference standards for use in method calibration must establish traceability to NIST referenced material through a traceability certificate. Process links are established that enable a calibration standard solution to be traced to its NIST reference certificate.

Chemical standards used for analysis must meet the purity specifications of the method. These specifications must be stated in the reagents section of the method SOP. Standards must have label containing the chemical name and expiration date. Chemical standards may not be used beyond the expiration date unless recertified by supplier/manufacturer.

7.4 ASSIGNMENT OF REAGENT, BULK CHEMICAL AND STANDARD EXPIRATION DATES – Expiration date information for all purchased standards, prepared standard solutions and selected reagents is provided to SGS North America Inc. by the vendor as a condition of purchase. Neat materials, bulk chemicals including solvents, acids and inorganic reagents are not required to be purchased with expiration dates. An expiration date of five (5) years from the date of receipt shall be established. Prepared solutions are labeled with the expiration date provided by the manufacturer. In-house prepared solutions are assigned expiration dates that are consistent with the method that employs their use unless documented experience indicates that an alternate date can be applied. If alternate expiration dates are employed, their use is documented in the method SOP. Expiration dates for prepared inorganic reagents, which have not exhibited instability, are established at two years from the date of preparation for tracking purposes. Bulk chemicals and standards must not be used beyond the expiration date.

The earliest expiration date has been established as the limiting date for assigned expiration dates to prepared solutions. The assignment of expiration dates that are later than the expiration date of any derivative solution or material is prohibited.

7.5 DOCUMENTATION OF TRACEABILITY – Traceability information is documented in individual logbooks designated for specific measurement processes. The quality assurance group maintains calibration documentation for metric references in separate logbooks.

Balance calibration verification is documented in logbooks that are assigned to each balance. The individual conducting the calibration is required to initial and date all calibration activities. Any defects that occur during calibrations are also documented along with the corrective action applied and a demonstration of return to control. Annual service reports and certificates are retained on file by the QA staff.

Temperature control is documented in logbooks covering a 12-month period assigned to the equipment being monitored. A calibrated thermometer is assigned to each individual team. Uncorrected and corrected measurements are recorded every single day of use along with date and initials of the individual conducting the measurement. For days when no one is present at the lab, but the equipment is in use (such as weekends) a min-max thermometer is used. Both minimum and maximum readings are recorded and must be in control for the time frame when no one was present.

Corrective action must be documented if temperatures are not within control limits. Return to control is also documented.

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Initial traceability of chemical standards is documented via a vendor-supplied certificate (not available for bulk dry chemicals and acids) that includes lot numbers, expiration date and certified concentration information. Solutions prepared using the vendor supplied chemical standards are documented in logbooks assigned to specific analytical processes. Alternatively, documentation may be entered into the electronic standards and reagents tracking log. The documentation includes links to the vendor's lot number, and internal lot number, dates of preparation, expiration date, and the preparer's initials.

SGS North America Inc. employs commercially prepared standard solutions whose traceability can be demonstrated through a vendor supplied certificate of analysis that includes an experimental verification of the standard's true concentration. The test value for the verification analysis must agree within 1% of the vendor's true value before it can be employed for calibration purposes. If the test value differs from the nominal value by more than 1%, then the test value is used as the true value in laboratory calibrations and calculations. Purchased standards which do not have a certificate of analysis cannot be used for calibration or calibration verification purposes and are rejected or returned to the vendor.

Supervisors conduct regular reviews of logbooks, which are verified using a signature and date.

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8.0 TEST PROCEDURES, METHOD REFERENCES, AND REGULATORY PROGRAMS REQUIREMENTS –

The laboratory employs client specified or regulatory agency approved methods for the analysis of environmental standards. A list of active methods is maintained, which specifies the type of analyses performed and cross-references the methods to applicable environmental regulations. Routine procedures used by the laboratory for the execution of a method are documented in standard operating procedures. Method performance and sensitivity are demonstrated annually where required. Defined procedures for the use of method sensitivity limits for data reporting purposes are established by the Quality Assurance Officer and Corporate Technical Director and are used consistently for all data reporting purposes.

8.1 METHOD SELECTION & APPLICATION – SGS North America Inc. employs methods for environmental sample analysis that are consistent with the client's application, which are appropriate and applicable to the project objectives. SGS North America Inc. informs the client if the method proposed is inappropriate or outdated and suggests alternative approaches. SGS North America Inc. employs documented, validated regulatory methods in the absence of a client specification and informs the client of the method selected. These methods are available to the client and other parties as determined by the client. Documented and validated in-house methods may be applied if they are appropriate to the project. The client is informed of the method selection.

8.2 STANDARD OPERATING PROCEDURES – Standard Operating Procedures (SOP) are prepared for routine methods executed by the laboratory, processes related to laboratory operations and sample or data handling. All SOPs are formatted to meet the specifications established by TNI, which are detailed in Quality Systems of the established Standards. The procedures described the process steps in sufficient detail to enable an individual, who is unfamiliar with the procedure to execute it successfully.

SOPs are evaluated annually and edited if necessary. SOPs that do not require modification are indicated as such by a reviewer signature next to the SOP ID on the Annual Review summary form indicating that an evaluation was conducted, and modifications were not needed. SOPs can be edited on a more frequent basis if changes are required for any reason. These may include a change to the methodology, elimination of systematic errors that dictate a need for process changes or modifications to incorporate a new version of the method promulgated by the originating regulatory agency. Procedural modifications are indicted using a revision number. SOPs are available for client review upon request.

The complete list of the laboratory's SOPs is available as of the date of publication of this QSM version are detailed in AppendixII.

8.3 METHOD VALIDATION – Standard methods from regulatory sources are primarily used for all analysis. Standard methods, Non-standard methods, and in-house methods are validated prior to use. Validation is also performed for standard methods applied outside their intended scope of use. Validation is dependent upon the method application and may include analysis of quality control samples to develop precision and accuracy information for the intended use. A final method validation report is generated, which includes all data in the validation study. A statement of adequacy and/or equivalency is included in the report. A copy of the report is archived in the quality assurance directory of the company server.

Non-standard methods are validated prior to use. This includes the validation of modified standard methods to demonstrate comparability with existing methods. Demonstration and

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validations are performed and documented prior to incorporating technological enhancements and non-standard methods into existing laboratory methods used for general applications. The demonstration includes method specific requirements for assuring that significant performance differences do not occur when the enhancement is incorporated into the method. Validation is dependent upon method application and may include the analysis of quality control samples to develop precision and accuracy information for intended use.

The study procedures and specifications for demonstrating validation include comparable method sensitivity, calibration response, method precision, method accuracy and field sample consistency for several classes of analytical methods are detailed in this document. Method modification must be approved by the laboratory director/technical director and Quality Assurance Department. Four spiked reference samples will be analyzed, and the data compared to the method precision and accuracy criteria. If the results meet or exceed the criteria established in the reference method, then a justification memo will be written and signed by the laboratory director/technical director and the QA Department. The justification memo and the analytical results will be maintained in the QA directory on the server. These procedures and specifications may vary depending upon the method and the modification.

8.4 ESTIMATED UNCERTAINTY – A statement of the estimated uncertainty of an analytical measurement accompanies the test result when required. Estimated uncertainty is derived from the performance limits established for spiked samples of similar matrices. The degree of uncertainty is derived from the negative or positive bias for spiked samples accompanying a specific parameter. When the uncertainty estimate is applied to a measured value, the possible quantitative range for that specific parameter at that measured concentration is defined. Well recognized regulatory methods that specify values for the major sources of uncertainty and specify the data reporting format do not require a further estimate of uncertainty.

8.5 DEMONSTRATION OF CAPABILITY – Confirmation testing is conducted to demonstrate that the laboratory is capable of performing the method before its application to the analysis of environmental samples. The results of the demonstration tests are compared to the quality control specifications of the method to determine if the performance is acceptable.

Capability demonstrations are conducted initially for every analyst on each method performed and annually on a method specific basis thereafter. Acceptable demonstrations are documented for individual training files and retained by the QA staff. New analytes, which are added to the list of analytes for an accredited method, are evaluated for applicability through a demonstration of capability similar to those performed for accredited analytes. Ongoing demonstration of capabilities may include one of the following: 1) acceptable performance of a blind sample (single blind to the analyst); 2) Successful analysis of a blind performance sample on a similar method using the same technology (e.g., GC/MS volatiles by purge and trap for methods 624 or 5030/8260) requires documentation for one of the test; 3) another initial DOC (4 consecutive BS meeting acceptance criteria for the method. DOCs will be required anytime there is significant change in the method or a change in instrument type, or a change in personnel. DOC records must identify, matrix, test method, analyst, analytes or organism, SOP used for analysis (including revision number); date(s) of analysis; summary of analysis (results, acceptance criteria, pass/fail).

8.6 METHOD DETECTION LIMIT DETERMINATION – Annual method detection limit (MDL) studies are performed as appropriate for routine methods used in the laboratory. MDL studies are also

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performed when there is a change to the method that affects how the method is performed or when an instrumentation change that impacts sensitivity occurs. The procedure used for determining MDLs is described in 40 CFR, Part 136; Appendix B. Studies are performed for each method on water, soil, and air matrices for every instrument that is used to perform the method. MDLs are established at the instrument level. The highest MDL of the pooled instrument data is used to establish a laboratory MDL. MDLs are experimentally verified through the analysis of spiked quality control samples at 1-4 times the concentration of the experimental MDL. MDLs must be prepared in at least three batches on three separate calendar days. For areas with multiple instruments, then the sample analysis must be distributed across all of the instruments. At least once every 13 months the MDL will be recalculated using quarterly spike values using at least seven spiked samples and seven method blanks for the annual verification. MDL will be calculated for the spiked sample as well as for method blanks. If the MDL for the method blank is higher than the spiked MDL, then the new MDL will be the method blank MDL.

8.7 LIMIT OF DETECTION (LOD) – The limit of detection (LOD) for each method and target analyte of concern is established for each instrument that is used to perform the method. The LOD is established by spiking a water and/or soil matrix at approximately two to three times the calculated MDL (for a single-analyte standard) or two to four times the calculated MDL (for a multi-analyte standard). The LOD undergoes all sample processing steps and is validated by qualitative identification of the analytes of interest. The spike concentration establishes the LOD and must be verified quarterly for the DoD ELAP program and otherwise annually. Texas TRPP program requires quarterly LODs. The LOD is determined by spiking a water and/or soil sample matrix at approximately 1-3 times the calculated MDL. The Texas TRPP sample may be used for the TNI required LOD.

8.8 INSTRUMENT DETECTION LIMIT DETERMINATION – Instrument detection limits (IDLs) are determined for all inductively coupled argon plasma emission spectrophotometers and mass spectrometers. The IDL is determined for the wavelength (emission) of each element and the ion (mass spectrometry) of each element used for sample analysis. The IDL data is used to estimate instrument sensitivity in the absence of the sample matrix. IDL determinations are conducted at the frequency specified in the appropriate SOPs' for ICP and ICP/MS analysis.

8.9 METHOD REPORTING LIMIT – The method reporting limit for organic methods is determined by the concentration of the lowest calibration standard in the calibration curve. This value is adjusted based on several sample preparation factors including sample volume, moisture content (soils), digestion, distillation or dilution. The low calibration standard is selected by department managers as the lowest concentration standard that can be used for calibration while continuing to meet the calibration linearity criteria of the method being used. The validity of the method reporting limits are confirmed through the analysis of a spiked quality control sample at the method reporting limit concentration. By definition, detected analytes at concentrations below the low calibration standard cannot be accurately quantitated and are qualified as estimated values.

The reporting limits for inorganics methods are defined as the concentration which is greater than the MDL where method quality control criteria have been achieved. The reporting limit for general chemistry methods employing multiple point calibrations must be greater than or equal to the concentration of the lowest standard of the calibration range.

The reporting limit established for both organic and inorganic analysis is above the calculated method detection limit where applicable.

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8.10 LIMIT OF QUANTITATION (LOQ) – The limit of quantitation (LOQ) or lower limit of quantitation (LLOQ) however named must be determined for each analyte of concern. The LOQ is set within the range of calibration and is greater than the established LOD. Precision and bias criteria for the LOQ are established to meet client requirements and are verified quarterly for the DoD ELAP program and otherwise annually.

8.11 REPORTING OF QUANTITATIVE DATA – Analytical data for all methods is reported without qualification to the reporting limit established for each method. Data, for organic methods may be reported to the established method detection limit depending upon the client's requirements provided that all qualitative identification criteria for the detected parameter have been satisfied. All parameters reported at concentrations between the reporting limit and method detection limit are qualified as estimated.

Data for inorganic methods are reported to the established method reporting limits. Inorganic data for specific methods may also be reported to the established method detection limit at client request. However, this data is always qualified as estimated.

Measured concentrations of detected analytes that exceed the upper limit of calibration range are either diluted into the range and reanalyzed or qualified as an estimated value. The only exception to this applies to ICP and ICP/MS analysis, which can be reported to the upper limit of the experimentally determined linear range without qualification.

8.12 PRECISION AND ACCURACY STUDIES – Annual precision and accuracy (P&A) studies, which demonstrate the laboratories ability to generate acceptable data, are performed for all routine methods used in the laboratory. The procedure used for generating organic P&A data is referenced in the majority of the regulatory methodology in use. The procedure requires quadruplicate analysis of a sample spiked with target analytes at a concentration in the working range of the method. This data may be compiled from a series of existing blank spikes or laboratory control samples. Accuracy (percent recovery) of the replicate analysis is averaged and compared to established method performance limits. Values within method limits indicate an acceptable performance demonstration. Precision and accuracy data is also used to annually demonstrate analytical capability for individual analysts. Annual demonstration of capability data is archived in individual training files.

8.13 METHOD SOURCES & REFERENCES – The Quality Assurance Staff maintains a list of active methods used for the analysis of samples. This list includes valid method references from sources such as state specified methods, USEPA, ASTM or Standard Methods designation and the current version and version date.

Updated versions of approved reference methodology are placed into use as changes occur. The Quality Assurance Officer informs operations management of changes in method versions as they occur. The operations management staff selects an implementation date. The operations staff is responsible for completing all method use requirements prior to the implementation date. This includes modification of SOPs, completion of MDL and precision and accuracy studies and staff training. Documentation of these activities is provided to the QA staff who retains this information on file. The updated method is placed into service on the implementation date and the old version is de-activated.

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Multiple versions if selected methods may remain in use to satisfy client specific needs. In these situations, the default method version becomes the most recent version. Client specific needs are communicated to the laboratory staff using method specific analytical method codes, which clearly depict the version to be used. The old method version is maintained as an active method until the specified client no longer requires the use of the older version.

SGS North America Inc. will not use methodology that represents significant departures from the reference method unless specifically directed by the client. If clients direct the laboratory to use a method modification that represents a significant departure from the reference method, the request will be documented in the project file.

8.14 ANALYTICAL CAPABILITIES – Appendix III provides a detailed listing of the methodology employed for the analysis of test samples.

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9.0 SAMPLING, SAMPLE MANAGEMENT, LOGIN, CUSTODY, STORAGE AND DISPOSAL

REQUIREMENT – The laboratory must employ a system which ensures that client supplied product or supplied product (the sample) is adequately evaluated, acknowledged, and secured upon delivery to the laboratory. The system also assures that product chain of custody is maintained, and that sample receipt conditions and preservation status are documented and communicated to the client and internal staff. The login procedure assigns, documents, and maps the specifications for the analysis of each unique sample to assure that the requested analysis is performed on the correct sample and enables the sample to be tracked throughout the laboratory analytical cycle. They system includes procedures for reconciling defects in sample condition or client provided data, which are identified at sample arrival. The system specifies the procedures for proper sample storage, transfer to the laboratory, and disposal after analysis. The system is also documented in standard operating procedures.

9.1 ORDER RECEIPT AND ENTRY – New orders are initiated and processed by the client services group (See Chapter 14, Procedures for Executing Client Specifications). The new order procedure includes mechanisms for providing bottles to clients, which meet the size, cleanliness, and preservation specifications for the analysis to be performed.

For new orders, the project manager prepares a bottle request form, which is submitted to sample management. This form provides critical project details to the sample management staff, which are used to prepare and assemble the sample bottles for shipment to the client prior to sampling.

The bottle order is assembled using bottles that meet USEPA specifications for contaminant free sample containers, SGS North America Inc. uses a combination of commercially supplied pre-cleaned bottles and bottles that have been tested for residual contamination and verified to meet USEPA specifications prior to use. Sterile bottles for microbiological samples were purchased from commercial sources.

Bottles, which are not purchased pre-cleaned, are checked to assure that they are free of contamination from targeted analytes before being released for use. Sterile bottles are checked for contamination with each lot. The QA staff retains a copy of the documentation of in-house contamination and sterility checks and maintains the responsibility for approving and releasing bottle lots for use following a review of the check data.

Preservative solutions that are specified for the analysis requested are dispensed into the sample bottle prior to shipment. All preservative solutions are prepared in the laboratory or purchased from commercial suppliers. Each solution is checked to assure that it is free of contamination from the compounds being analyzed before being released for use.

Reagent water for trip and field blanks is poured into appropriately labeled containers. All bottles are packed into ice chests with blank chain of custody forms and the original bottle order form. Completed bottle orders are delivered to clients using SGS North America Inc. couriers or commercial carriers for use in field sample collection.

9.2 SAMPLING - Documented procedures are employed by the field staff for field sample collection and are accessible during sample collection activities. Field activities are documented in controlled notebooks which detail relevant field conditions, site data and the results of field measurements. Appropriate custody procedures for collected samples are initiated by the field

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staff at the time of sample collection. Samples are documented, labeled and preserved according to the specifications of the method and/or regulatory program prior to being shipped to the laboratory.

9.3 SAMPLE RECEIPT AND CUSTODY – Samples are delivered to the laboratory using a variety of mechanisms including SGS North America Inc. couriers, commercial shippers, and client self-delivery. Documented procedures are followed for arriving samples to assure that custody and integrity are maintained, and handling/preservation requirements are documented and maintained.

Sample custody documentation is initiated when the individual collecting the sample, collects the field samples. Custody documentation includes all information necessary to provide an unambiguous record of sample collection, sample identification, and sample collection chronology. Initial custody documentation employs either SGS North America Inc. or client generated custody forms.

SGS North America Inc. generates a chain of custody in situations where the individuals who collected the sample did not generate custody documentation in the field.

SGS North America Inc. defines sample custody as follows:

- The sample is in the actual custody or possession of the assigned responsible person,
- The sample is on a secure area.

SGS North America Inc. does not have legal chain of custody protocols for accepting samples that are to be used for evidentiary or legal purposes. Sample(s) collected for legal purposes will be accepted using SGS North America Inc.'s usual and customary procedures. Should a client request that their samples be maintained for evidentiary purposes, then SGS would develop procedures to maintain legal chain-of-custody.

The SGS North America Inc. facility is defined as a secure facility. Perimeter security has been established, which limits access to authorized individuals only. Visitors enter the facility through the building lobby and must register with the receptionist prior to entering controlled areas. While in the facility, visitors are required to wear a visitor's badge and must be accompanied by their hosts at all times. After hours, building access is controlled using a computerized password system. This system limits building access to individuals with a pre-assigned authorization status. After hours visitors are not authorized to be in the building. Clients delivering samples after hours must make advanced arrangements through client services and sample management to assure the staff is available to take delivery and maintain custody.

Upon arrival at SGS North America Inc., the sample custodian reviews the chain of custody for the samples received to verify that the information on the form corresponds with the sample delivered.

This includes verification that all listed samples are present and properly labeled, checks to verify that samples were transported and received at the required temperature, verification that the sample was received in proper containers, verification that sufficient volume is available to conduct the requested analysis, and a check of individual sample containers to verify test specific preservation requirements including absence of headspace for volatile compound analysis.

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Sample conditions and other observations are documented on the chain of custody by the sample custodian prior to completing acceptance and in an online database that creates a permanent record of all sample login activities. The sample custodian accepts sample custody upon verification that the custody document is correct. Discrepancies or non-compliant situations are documented and communicated to the SGS North America Inc. project manager, who contacts the client for resolution. The resolution is documented and communicated to sample management for execution.

The sample management staff maintains an electronic sample receipt log that is part of the sample login procedure. This log details all sample-related information and is stored as part of the LIMS job number record. The log records include critical date and time information, numbers of samples, numbers of bottles for each parameter, descriptions of bottles for each parameter, descriptions of bottles for each parameter, preservation conditions, bottle refrigerator location, and bottle conditions. Data entry into the log is secured using individual passwords.

During initial login, each bottle is assigned a unique number and is labeled with a barcode corresponding to that number. Internal custody documentation may be required for compliance with regulatory agency or contractual specifications.

9.4 LABORATORY PRESERVATION OF IMPROPERLY PRESERVED FIELD SAMPLES – SGS North America Inc. will attempt to preserve field samples that were received without proper preservation to the extent that it is feasible and supported by the methods in use. Laboratory preservation of improperly preserved or handled field samples is routinely performed for metals samples. Special handling procedures may also be applied to improperly preserved volatile organics.

Aqueous metals samples that were not nitric acid preserved to pH 2 in the field are laboratory preserved and held for twenty-four (24) hours to equilibrate prior to analysis. Aqueous metals samples requiring field filtration may be filtered in the laboratory within seventy-two (72) hours of receipt provided that the sample has not been acid preserved.

Unpreserved volatile organics samples must be analyzed within seven (7) days to minimize degradation of volatile organics if the laboratory is notified in advance of the failure to preserve upon collection. Laboratory preservation of unpreserved aqueous samples is not possible. A pH check of volatile organic samples prior to analysis will compromise the sample by allowing volatile organics escape during check. If the laboratory is not notified of the failure to field preserve an aqueous volatile organic sample, the defect will not be identified until sample analysis has been completed and the data is qualified accordingly.

Samples that require thermal preservation shall be stored at 4.0 ^{0}C +/-2 ^{0}C. Acceptable temperature range is from just above the freezing of water to 6 ^{0}C.

9.5 SAMPLE TRACKING – An automated, electronic LIMS procedure records sample exchange transaction between departments and changes in analytical status. This system tracks all preparation, analytical, and data reporting procedures to which a sample is subjected while in the possession of the laboratory. This step is required to maintain an accurate electronic record of sample status, dates of analytical activity, and custody throughout the laboratory.

Sample tracking is initiated at login where all chronological information related to sample collection dates and holding times are entered into the LIMS. This information is entered on an individual sample basis.

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9.6 SAMPLE ACCEPTANCE POLICY – Incoming samples must satisfy SGS North America Inc.'s sample acceptance criteria before being logged into the system. Sample acceptance is based on the premise that clients have exercised proper protocols for sample collection. This includes complete documentation, sufficient volume, proper chemical preservation, temperature preservation, sample container sealing and labeling, and appropriate shipping container packing.

The sample management staff will make every attempt to preserve improperly preserved samples upon arrival. However, if preservation is not possible, the samples may be refused unless the client authorizes analysis. No samples will be accepted if holding times have been exceeded or will be exceeded before analysis can take place unless the client authorizes analysis.

Sample acceptance criteria include proper custody and sample labeling documentation. Proper custody documentation includes an entry for all physical samples delivered to the laboratory with an identification code that matches the sample bottle and date and signature of the individual who collected the sample and delivered them to the laboratory.

SGS North America Inc. reserves the right to refuse any sample which in its sole and absolute discretion and judgment is hazardous, toxic and poses or may pose a health, safety or environmental risk during handling and processing. The company will not accept samples for analysis using methodology that is not performed by the laboratory or for methods that lab does not hold valid accreditations unless arrangements have been made to have the analysis conducted by a qualified subcontractor.

9.7 ASSIGNMENT OF UNIQUE SAMPLE IDENTIFICATION CODES – Unique identification codes are assigned to each sample bottle to assure traceability and unambiguously identify the tests to be performed in the laboratory.

The sample identification coding process begins with assignment of a unique alphanumeric job number. A job is defined as a group of samples received on the same day, from a specific client pertaining to a specific project. A job may consist of groups of samples received over a multi-day period. Samples are assigned an eight-digit identification number (job number). The first 1 letter, "L" stands for Louisiana and the second letter, "A" currently, is a sequential letter for starting the next 100,000 samples. For example, "LA" then "LB" followed by "LC" then "LD"etc. The following 4-5 digits are based numerically on when the samples are logged in. This numbering system will be used until the last of the 4-5 digit numbers are used. For example, the first sample logged in had an ID of LA0001, the last sample ID would be LA99999. Once the 4-5 digit number system is complete, the new ID system would start as LB00001 and so on.

Unique sample numbers are assigned to each bottle collected as a discrete entity from a designated sample point. This number begins with the work order number and incorporates a second series of numbers beginning at one and continuing chronologically for each point of collection. Multiple sample bottles collected for analysis of the same parameter are numbered bottle 1, 2, etc.

Alpha suffixes may be added to the sample number to identify special designations such as subcontracted tests, in-house QC checks, or re-logs. Multiple sample bottles for a specific analysis are labeled Bottle 1, Bottle 2, etc.

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The sample management department affixes waterproof with indelible blank or blue ink, permanent labels with these sample identification numbers to each sample bottle before they are stored for analysis by the labs.

9.8 SUBCONTRACTED ANALYSIS – Subcontract laboratories are employed to perform analyses not performed by SGS North America Inc. The quality assurance staff evaluates subcontract laboratories to assure their quality processes meet the standards of the environmental laboratory industry prior to engagement. Subcontracted laboratories must be TNI certified for any analytical results that will be used for regulatory purposes. Subcontracted laboratories for drinking water analysis must be certified through the Louisiana Department of Health. Throughout the subcontract process, SGS North America Inc. follows established procedures to assure that sample custody is maintained, and the data produced by the subcontractor meets established quality criteria. Please refer to SOP LPM002 (current revision), Subcontract Laboratory Submittal.

SUBCONTRACTING PROCEDURE - Samples for analysis by a subcontractor are logged into the LIMS system using regular login procedures. If subcontract parameters are part of the project or sample management has received subcontracting instructions for a specific project, a copy of the chain of custody (COC) is given to the appropriate project manager with the subcontracted parameters highlighted. This manager contacts an approved subcontractor that carries accreditation in the venue of the project location to place the subcontract order. A subcontract COC is simultaneously prepared in electronic format, by the project manager and filed with the original COC.

Sample management signs the subcontract chain of custody and ships the sample(s) to the subcontractor. The subcontract COC is filed with the original COC and the request for subcontract. Copies are distributed to the login department, the project manager, sample management and the client.

Clients are verbally notified of the need to subcontract analysis as soon as the need is identified by the client services staff. This may occur during the initial project setup or at the time of login if the project setup had not been initiated through the client services staff. Copies of the subcontract COC and the original COC, which are electronically distributed to clients, constitutes documented client notification of the laboratories intent to subcontract analysis.

Subcontractor data packages are reviewed by the PM Staff to assess completeness and quality compliance. If completeness defects are detected, the subcontractor is asked to immediately upgrade the data package. Subcontract data can be received by SGS either electronically or on hard copy. If data quality defects are detected, the PM staff retains the package for further review by the QA staff. The QA staff will pursue a corrective action solution before releasing defective data to the client.

Approved subcontract data is incorporated in its entirety as an addendum to the final report. The project manager includes a narrative statement addressing the subcontracted work to provide the client with a clear indication of its source. Copies of original subcontract data are included in the data report depending on the reporting level specified by the client. Applicable subcontractor accreditation information is provided with the subcontractor data.

SUBCONTRACT LABORATORY EVALUATION – The QA staff evaluates subcontract laboratories prior to engagement. The subcontract laboratory must provide SGS North America

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Inc. with proof of a valid certification to perform the requested analysis for the venue where they were collected and for a specific program should an approval or accreditation be required. In addition, the QA staff may require a copy of the laboratory's Quality Systems Manual, copies of SOPs used for the subcontracted analysis, a copy of the most recent performance evaluation study for the subcontracted parameter, copies of the internal data integrity policy and copies of the most recent regulatory agency or third-party accreditor audit report. Certification verification must be submitted to SGS North America Inc. annually. If possible, the QA staff may conduct a site visit to the laboratory to inspect the quality system. SGS North America Inc. Laboratories assumes the responsibility for the performance of all subcontractors who have successfully demonstrated their qualifications and should obtain an example data deliverable package prior to initiation of subcontract work for compliance review. Qualification of a subcontract laboratory may be bypassed if the primary client directs SGS North America Inc. to employ a specific subcontractor.

9.9 SAMPLE STORAGE - Following sample transfer to the sample custodian, samples are assigned to various secured, refrigerated storage areas depending upon the test to be performed and the matrix of the samples. The location (cooler and shelf) of each sample is entered into the LIMS. Samples remain in storage until the laboratory technician/analyst retrieves the samples for analysis.

Samples for volatile organics analysis are placed in storage in designated coolers by log-in personnel and immediately transferred to the organics group control. Sample custody is transferred to the department designee. These samples are segregated according to matrix to limit opportunities for cross contamination to occur. Samples are stored in the appropriate cooler, freezer, or at room temperature as required in the reference method. Samples shall not be store in coolers or freezers used for the storage of standards, reagent, media or food.

The Organics staff is authorized to retrieve samples from these storage areas for analysis. When analysis is complete, the samples are placed back into local storage in the VOA prep laboratory.

Samples for wet chemistry are stored in the wet chemistry coolers located in that laboratory. Wet chemistry staff is authorized to retrieve samples from storage to the area of analysis.

Metals samples are taken to the Digestion laboratory or placed in the metals storage area in sample receiving. Metals samples, digestates, and metals leachates will be stored at the same temperature as the original sample, unless the reference method requires the digestates and metals leachates to be stored at a different temperature.

9.10 SAMPLE LOGIN – Following sample custody transfer to the laboratory, the documentation that describes the client's analytical requirements are delivered to the sample login group for coding and entry to the Laboratory Information Management Systems (LIMS). This process translates all information related to collection time, turnaround time, sample analysis, and deliverables into a code which enables client requirements to be electronically distributed to the various departments within the laboratory for scheduling and execution.

The technical staff is alerted to client or project specific requirements through the use of a unique project code that is electronically attached to the job during login. The unique project code directs the technical staff to controlled specifications documents detailing the unique requirements.

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9.11 SAMPLE RETRIEVAL FOR ANALYSIS – Analysts from individual laboratory departments retrieve samples for analysis.

After sample analysis has been completed, the department returns the samples to the storage area.

9.12 SAMPLE DISPOSAL – SGS North America Inc. retains all samples and sample extracts under proper storage. Samples are stored for a minimum of 30 days following completion of the analysis report. Longer storage periods are accommodated on a client specific basis if required. Samples may also be returned to the client for disposal.

SGS North America Inc. disposes of all laboratory wastes following the requirements of the Resource Conservation and Recovery Act (RCRA). The Company has obtained and maintains a waste generator identification number, LAD000461608.

Sample management periodically generates a sample disposal dump sheet, which lists all samples whose holding period has expired. These samples are pulled by the sample management staff and tracked to the waste disposal room.

Samples containing constituents at concentrations above the criteria are labeled as hazardous and segregated into general waste categories for disposal as follows (specific profile IDs are documented on individual manifests at the time of custody transfer to disposal facility):

∴ Waste Oil
∴ Non-regulated Soil Mixed Aqueous (Acid)(not flammable)
∴ Mixed Aqueous (Flammable Contact Water)
∴ Sludges (semi-solids, TCLP)
∴ PCB Hazardous Waste (USEPA 40 CFR 761 criteria).
∴ Mercury Aqueous Acidic Waste
∴ Non-mercury Aqueous Acidic Waste
∴ Flammable Solvents
∴ Chlorinated solvents
∴ Cyanide Aqueous
∴ Pyridine Aqueous

Non-hazardous aqueous samples are captured in drums and evaporated as a hazardous waste reduction technique. Aqueous acidic non-mercury waste is contained in totes and sent for disposal as required. Solid samples are emptied into consolidation drums and disposed as hazardous wastes or non-hazardous wastes depending upon results of hazardous characteristics determination. Samples classified as PCB hazardous wastes are labeled and packaged according to the requirements in 40 CFR 761.

Empty glass and plastic bottles that are not sent to a commercial contractor for disposal are defaced and disposed of according to the laboratory-specific waste disposal procedure.

Laboratory wastes are collected by waste stream in designated areas throughout the laboratory. Waste streams are consolidated daily by the waste custodian and transferred to stream specific drums for disposal through a permitted waste management contractor. Filled, consolidated

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drums are tested and scheduled for removal from the facility for appropriate disposal based on historical data.

Digestates are collected for disposal following the thirty-day holding period and drummed according to their specific waste stream category. After at least 40 days from extraction, chlorinated solvent extracts are drummed as Acetonitrile/DCM waste vials. Non-chlorinated extracts are drummed as non-chlorinated wastes, (i.e., acetone, hexane, methanol, and mixed solvents). Digestates are collected for disposal following the thirty-day holding period and drummed as corrosive liquid containing metals.

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10.0 LABORATORY INSTRUMENTATION AND MEASUREMENT STANDARDS

REQUIREMENT – The laboratory has established procedures, which assure that instrumentation is performing to a pre-determined operational standard prior to the analysis of any samples. In general, these procedures follow the regulatory agency requirements established in promulgated methodology. The instrumentation selected to perform specified analysis are uniquely identified and capable of providing the method specified uncertainty of measurement needed. These procedures are documented and incorporated into the standard operating procedures for the method being executed.

10.1 MASS TUNING-MASS SPECTROMETERS – The mass spectrometer tune and sensitivity are monitored to assure that the instrument is assigning masses and mass abundances correctly and that the instrument has sufficient sensitivity to detect compounds at low concentrations. This is accomplished by analyzing a specific mass tuning compound at a fixed concentration. If the sensitivity is insufficient to detect the tuning compound, corrective action must be performed prior to the analysis of standards or samples. If the mass assignments or mass abundances do not meet criteria, corrective action must be performed prior to the analysis of standards or samples.

10.2 WAVELENGTH VERIFICATION-SPECTROPHOTOMETER – Spectrophotometer detectors are checked on a regular schedule to verify proper response to the wavelength of light needed for the test in use. If the detector response does not meet specifications, corrective action (detector adjustment or replacement) is performed prior to the analysis of standards or samples.

10.3 INTER-ELEMENT INTERFERENCE CHECKS (METALS) – **INDUCTIVELY** Coupled Plasma Emission Spectrophotometers (ICP) are subject to a variety of spectral interferences, which can be minimized or eliminated by applying interfering element correction factors and background correction points. Interfering element correction factors are checked on a specified frequency through the analysis of check samples containing high levels of interfering elements. Analysis of single element interferent solutions is also conducted at a specified frequency.

If the check indicates that the method criteria have not been achieved for any element in the check standard, the analysis is halted and data from the affected samples are not reported. Sample analysis is resumed after corrective action has been performed and the correction factors have been re-calculated.

New interfering element correction factors are calculated and applied whenever the checks indicate that the correction factors are no longer meeting criteria. At a minimum, correction factors are placed once a year.

Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) also is subject to isobaric elemental and polyatomic ion interferences. These interferences are corrected through the use of calculations. The accuracy of corrections is dependent on the sample matrix and instrument conditions and is verified by quality control checks on individual runs.

10.4 CALIBRATION AND CALIBRATION VERIFICATION – Many tests require calibration using a series of reference standards to establish the concentration range for performing quantitative analysis. Instrument calibration is performed using standards that are traceable to national standards. Method specific procedures for calibration are followed prior to any sample analysis.

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In general, if a reference method does not specify the number of calibration standards, the minimum number is three (one of which is at the reporting limit or limit of quantitation).

Calibration is performed using a linear regression calculation or calibration factors calculated from the curve. The calibration must meet method specific criteria for linearity or precision. If the criteria are not achieved, corrective action (re-calibration or instrument maintenance) is performed. The instrument must be successfully calibrated before analysis of samples can be conducted.

Initial calibration must be verified using a calibration standard from a second source (i.e., separate lot or different provider). The continuing validity of existing calibrations must meet pre-established criteria that indicate the initial curve remains valid. If the criteria are not achieved corrective action (re-calibration) is performed before any additional samples may be analyzed.

If continuing calibration verification results are outside established criteria, data associated with the verification may be fully useable under the following conditions:

- When the acceptance criteria for the continuing calibration verification are exceeded high, i.e., high bias, and there are associated samples that are non-detects, then those non-detects may be reported.
- When the acceptance criteria for the continuing calibration verification are exceeded low, i.e., low bias, those sample results may be reported if they exceed a maximum regulatory limit/decision level.

The laboratory shall use and document a measure of relative error in the calibration.

- for calibrations evaluated using an average response factor, the determination of the relative standard deviation (RSD) is the measure of the relative error;

- for calibrations evaluated using correlation coefficient or coefficient of determination, the laboratory shall evaluate relative error by either:

a. measurement of the Relative Error (%RE)

Relative error is calculated using the following equation:

$$\%\ Relative\ Error = \frac{x'_i - x_i}{x_i} \times 100$$

x_i = True value for the calibration standard
x'_i = Measured concentration of the calibration standard

This calculation shall be performed for two calibration levels: the standard at or near the mid-point of the initial calibration and the standard at the lowest level.

The Relative Error at both of these levels shall meet the criteria specified in the method. If no criterion for the lowest calibration level is specified in the method, the criterion and the procedure for deriving the criterion shall be specified in the laboratory SOP.

or:

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b. measurement of the relative Standard Error (%RSE)

Relative Standard Error is calculated using the following equation:

$$\% RSE = 100 \times \sqrt{\sum_{i=1}^{n} \left[\frac{x_i' - x_i}{x_i}\right]^2 \Big/ (n-p)}$$

x_i = True value of the calibration level i.
x'_i = Measured concentration of calibration level i.
p = Number of terms in the fitting equation.
(average = 1, linear = 2, quadratic = 3).
n = Number of calibration points.

The RSE shall meet the criterion specified in the method. If no criterion is specified in the method, the maximum allowable RSE shall be numerically identical to the requirement for RSD in the method. If there is no specification for RSE or RSD in the method, then the RSE shall be specified in the laboratory SOP.

Test procedures that specify calibration with a single calibration standard and a zero point (blank or zero, however specified by the method), the following shall occur:

- The zero point and single calibration standard within the linear range shall be analyzed at least daily and used to establish the slope of the calibration.
- To verify adequate sensitivity a standard shall be analyzed at or below the lowest concentration for which quantitative data are to be reported without qualification. This standard shall be analyzed prior to sample analysis with each calibration and shall meet the quantitation limit criteria established by the method. If no criteria exist, the laboratory shall specify criteria in the SOP;

Calibration verification is also performed whenever it appears that the analytical system is out of calibration or no longer meets the calibration requirements. It is also performed when the time period between calibration verifications has expired.

Sample results are quantitated from the initial instrument calibration unless otherwise required by regulation, method, or program specific criteria.

10.5 LINEAR RANGE VERIFICATION AND CALIBRATION (ICP & ICP/MS METALS) – Linear range verification is performed for all ICP and ICP/MS instrumentation. The regulatory program or analytical method specifies the verification frequency. A series of calibration standards are analyzed over a broad concentration range. The data from these analyses are used to determine the valid analytical range for the instrument. ICP instrument calibration is routinely performed using a single standard at a concentration within the linear range and a blank.

Some methods or analytical programs require a low concentration calibration check to verify that instrument sensitivity is sufficient to detect target elements at the reporting limit. The analytical method or regulatory program defines the criteria used to evaluate the low concentration calibration check. If the low calibration check fails criteria, corrective action is performed and verified through reanalysis of the low concentration calibration check before continuing with the field sample analysis. ICP-MS instrument calibration is normally performed

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using multiple standards within the linear range and a blank but may be done with a single standard at a concentration within the linear range and a blank.

RETENTION TIME DEVELOPMENT AND VERIFICATION (GC) – Chromatographic retention time windows are developed for all analysis performed using gas chromatographs with conventional detectors. An initial experimental study is performed, which establishes the width of the retention window for each compound. The retention time width of the window defines the time ranges for elution of specified target analytes on the primary and confirmation columns. Retention time windows are established upon initial calibration, applying the retention time range from the initial study to each target compound. Retention times are regularly confirmed through the analysis of an authentic standard during calibration verification, the instrument must be recalibrated, and new windows defined. New studies are performed when major changes, such as column replacement are made to the chromatographic system.

10.6 BALANCES, OVENS, REFRIGERATORS, FREEZERS – For ovens, refrigerator, freezers, water baths, etc. the temperature shall be verified daily when in use. The date, time, thermometer used, correction factor, observed temperature, and corrected temperature shall be documented in the appropriate logbook or temperature monitoring form. Balance calibrations shall be verified daily when in use and the calibration documented in the appropriate log book. The analyst will document that the leveling bubble is centered in the leveling circle. If the balance verification does not meet specification, then the balance will be taken out of service and labeled as such until it can be repaired.

10.7 VOLUMETRIC DESPENSING DEVICES and VOLUME VERIFICATION – Quantitative results that are dependent on the accuracy of mechanical devices, such as automated pipettes, bottle top dispensers, and any other mechanical volumetric devices shall be verified as followed. 1. Mechanical devices shall be verified prior to first use and on a quarterly basis(minimum), 2. Mechanical devices used at more than one volume shall be verified at volumes bracketing the range of use, and at the mid-point of the volumes used by the device.

All other volumetric support equipment shall be checked for accuracy prior to or in conjunction with its first use. If so, required this is to be completed on lot basis.

The verification check shall be documented in the appropriate logbook.

10.8 EQUIPMENT LIST – All equipment is labeled with a unique ID. See Appendix IV for a listing of all equipment used for measurement and support of laboratory processes. The firmware version is required for all equipment used for ISO 17025 testing. This information can be found in a separate document, form LQA125.

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11.0 INSTRUMENT MAINTENANCE

REQUIREMENT – Documented procedures have been established for conducting equipment maintenance. The procedure includes maintenance schedules if required or documentation of daily maintenance activities. All instrument maintenance activities are documented in instrument specific logbooks.

Instruments requiring calibration will be labeled with an identification number, date of calibration and next due date for calibration.

11.1 ROUTINE, DAILY MAINTENANCE – Routine, daily maintenance is required on an instrument specific basis and is performed each time the instrument is used. Daily maintenance includes activities to insure a continuation of good analytical performance. This may include performance checks that indicate if non-routine maintenance is needed. If performance checks indicate the need for higher level maintenance, the equipment is taken out of service until maintenance is performed. Analysis cannot be continued until all performance checks meet established criteria and return to operational control has been demonstrated and documented. The individual assigned to the instrument is responsible for daily maintenance.

NON-ROUTINE MAINTENANCE – Non-routine maintenance is initiated for catastrophic occurrences such as instrument failure. The need for non-routine maintenance is indicated by failures in general operating systems that result in an inability to conduct required performance checks or calibration. Equipment in this category is taken out of service, tagged accordingly, and repaired before attempting further analysis. Data derived from this instrument will be reviewed to determine the effect of the instrument failure. Before initiating repairs, all safety procedures for safe handling of equipment during maintenance, such as lock-out/tag-out are followed. Analysis is not resumed until the instrument meets all operational performance checks criteria, is capable of being calibrated and a return to operational control has been demonstrated and documented. Section supervisors are responsible for identifying non-routine maintenance episodes and initiating repair activities to bring the equipment on-line. This may include initiating telephone calls to maintenance contractors if necessary. The service technician is responsible for documenting all details of the occurrence and repair. Instruments that are outside the requirements must be shown to be back in control before analyses restart.

11.2 SCHEDULED MAINTENANCE – Modern laboratory instrumentation rarely requires regular preventative maintenance. If required, the equipment is placed on a schedule, which dictates when maintenance is needed. Examples include annual balance calibration by an independent provider or ICP preventative maintenance performed by instrument manufacturer. Section supervisors are responsible for initiating scheduled maintenance on equipment in this category. Scheduled maintenance is documented using routine documentation practices.

11.3 MAINTENANCE DOCUMENTATION – Routine and non-routine maintenance activities are documented in logbooks assigned to instruments and equipment used for analytical measurements. The logbooks contain preprinted forms, which specify the required maintenance activities. The analyst or supervisor performing or initiating the maintenance activity is required to check the activity upon its completion and initial the form. This includes documenting that the instrument has been returned to operational control following the completion of the activity. Non-routine maintenance (repairs, upgrades) is documented either on the back page of the service log or by affixing a copy of the service report to the next sequential page in the maintenance log.

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12.0 QUALITY CONTROL PARAMETERS, PROCEDURES, AND CORRECTIVE ACTION

REQUIREMENT - All procedures used for test methods incorporate quality control parameters to monitor elements that are critical to method performance. Each quality parameter includes acceptance criteria that have been established by regulatory agencies for the methods in use. Criteria may also be established through client dictates or through the accumulation and statistical evaluation of internal performance data. Data obtained for these parameters during routine analysis must be evaluated by the analyst and compared to the method criteria in use. If the criteria are not achieved, the procedures must specify corrective action and confirmation of control before proceeding with sample analysis. QC parameters, procedures, and corrective action must be documented within the standard operating procedures for each method. In the absence of client specific objectives, the laboratory must define qualitative objectives for completeness and representativeness of data.

Where multiple requirements exist, the most stringent quality control requirements are used. The Code of Federal Regulations (40 CFR) supersedes state specific regulations which supersede published methods. When a method or regulation is unclear, SGS North America Inc. – Scott seeks guidance from Louisiana Department of Environmental Quality.

12.1 PROCEDURE - Bench analysts are responsible for methodological quality control and sample specific quality control. Each method specifies the control parameters to be employed for the method in use and specific procedures for incorporating them into the analysis. These control parameters are analyzed and evaluated with every designated sample group (batch).

The data from each parameter provides the analyst with critical decision-making information on method performance. The information is used to determine if corrective action is needed to bring the method or the analysis of a specific sample into compliance. These evaluations are conducted throughout the course of the analysis. Each control parameter is indicative of a critical control feature. Failure of a methodological control parameter is indicative of either instrument or batch failure. Failure of a sample control parameter is indicative of control difficulties with a specific sample or samples.

SAMPLE BATCH - All samples analyzed in the laboratory are assigned to a designated sample batch, which contains all required quality control samples and a defined maximum number of field samples in the batch is 20. SGS North America Inc. has incorporated the TNI batching policy as the sample-batching standard. This policy incorporates the requirement for blanks and spiked blanks as a time-based function as defined by TNI. Accordingly, the specified time period for a sample batch is 24 hours. Matrix spike/matrix spike duplicate, matrix spikes and duplicates are defined as sample frequency-based functions and may be applied to several batches until the frequency requirement has been reached. A matrix spike/matrix spike duplicate, matrix spikes and/or duplicate is required every 20 samples.

Client criteria that defines a batch as a time-based function which includes a matrix spike/matrix spike duplicates as a contractual specification will be honored. The typical batch contains a blank and a laboratory control sample (LCS or spiked blank). Batch documentation includes lot specifications for all reagents and standards used during preparation of the batch.

12.2 METHODOLOGICAL CONTROL PARAMETERS AND CORRECTIVE ACTION - Prior to analysis of field samples the analyst must determine that the method is functioning properly.

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Specific control parameters indicate whether critical processes meet specified requirements before continuing with the analysis. Method specific control parameters must meet criteria before sample analysis can be conducted. Each of these parameters is related to processes that are under the control of the laboratory and can be adjusted if out of control.

METHOD BLANK - A method blank is analyzed during the analysis of any field sample. The method blank is defined as a sample. It contains the same standards (internal standards, surrogates, matrix modifiers, etc.) and reagents that are added to the field sample during analysis, with the exception of the sample itself. If the method blank contains target analyte(s) at concentrations that exceed method detection limit concentrations (organics) or reporting limit concentrations (inorganics), the source of contamination is investigated and eliminated before proceeding with sample analysis. Target analyte(s) in method blanks at concentrations no greater than one-half of the reporting limit concentrations (metals) may be requested on a client or project specific basis. Systematic contamination is documented for corrective action and resolved following the established corrective action procedures.

Method blanks are not required for all test methods such as pH, conductivity, flash point, and temperature.

LABORATORY CONTROL SAMPLES (LCS OR BLANK SPIKE (BS)) - A laboratory control sample (blank spike or commercially prepared performance evaluation sample) is analyzed along with field samples to demonstrate that method accuracy is within acceptable limits. These spike solutions may be from different sources than the sources of the solutions used for method calibration depending upon the method requirements. All target components are included in the spike mixture over a two-year period. The performance limits are derived from published method specifications or from statistical data generated from the analysis of laboratory method performance samples. Spiked blanks are blank matrices (reagent water or clean sand) spiked with target parameters and analyzed using the same methods used for samples. Accuracy data is compared to laboratory derived limits to determine if the method is in control. Some laboratory control samples (LCS) are commercially prepared spiked samples in an inert matrix. Performance criteria for recovery of spiked analytes are pre-established by the commercial entity preparing the sample. The sample is analyzed in the laboratory as an external reference.

Accuracy data is compared to the applicable performance limits. If the spike accuracy exceeds the performance limits, corrective action, as specified in the SOP for the method is performed and verified before continuing with a field sample analysis. In some cases, decisions are made to continue with sample analysis if performance limits are exceeded, provided the unacceptable result has no negative impact on the sample data.

Blanks and spikes are routinely evaluated before samples are analyzed. However, in situations where sample analysis is performed using an auto-sampler, they may be evaluated after sample analysis has occurred. If blanks and spikes do not meet criteria, sample analysis is repeated.

PROFICIENCY TESTING - Proficiency test samples (PTs) are single- or double-blind spikes, introduced to the laboratory to assess method performance. PTs may be introduced as double blinds submitted by commercial clients, single or double blinds from regulatory agencies, or internal blinds submitted by the QA group.

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A minimum of two single blind studies must be performed each year for every parameter in aqueous and solid matrices for each field of testing for which the laboratory maintains accreditation. Proficiency samples must be purchased as blinds from TNI accredited vendor. Data from these studies are provided to the laboratory by the vendor and reported to accrediting agencies. If unsatisfactory performance is noted, corrective action is performed to identify and eliminate any sources of error. A new single blind must be analyzed if the accrediting authority requires the corrective action PT to demonstrate continuing proficiency.

PT samples performed for accrediting agencies or clients, which do not meet performance specifications, requires a written summary that documents the corrective action investigation, findings, and corrective action implementation. A copy of this summary shall be submitted to the TNI primary Accrediting Authority, Louisiana Environmental Laboratory Accreditation Program or the Louisiana Department of Health or any other accrediting authority for review if required.

Single- or double-blind proficiency test samples may be employed for self-evaluation purposes. Data from these analyses are compared to established performance limits. If the data does not meet performance specifications, the system is evaluated for sources of acute or systematic error. If required, corrective action is performed and verified before initiating or continuing sample analysis.

TREND ANALYSIS FOR CONTROL PARAMETERS - The quality assurance staff is responsible for continuous analytical improvement through quality control data trend analysis. Accuracy data for spike parameters in the spiked blank are statistically evaluated periodically for trends indicative of systematic problems in relation to documented internal nonconformance reports. Data from LCS parameters and surrogates are evaluated by comparison to existing control and warning limits. Trends that indicate potential loss of statistical control are communicated to the supervisor and further evaluated to determine the impact on data quality and to determine if corrective action is necessary. If corrective action is indicated, the supervisor informs the analysts of the corrective actions to be performed. Return to control is demonstrated before analysis resumes.

12.3 SAMPLE CONTROL PARAMETERS AND CORRECTIVE ACTION - The analysis of samples can be initiated following a successful demonstration that the method is operating within established controls. Additional controls are incorporated into the analysis of each sample to determine if the method is functioning within established specifications for each individual sample. Sample QC data is evaluated and compared to established performance criteria. If the criteria are not achieved the method or the SOP specifies the corrective action required to continue sample analysis. In many cases, failure to meet QC criteria is a function of sample matrix and cannot be remedied. Each parameter is designed to provide quality feedback on a defined aspect of sampling and analysis episode.

DUPLICATES - Duplicate sample analysis is used to measure analytical precision. This can also be equated to laboratory precision for homogenous samples. Precision criteria are method dependent. If precision criteria are not achieved, corrective action or additional action may be required. Recommended action must be completed before sample data can be reported.

LABORATORY SPIKES & SPIKED DUPLICATES - Spikes and spiked duplicates are used to measure analytical precision and accuracy for the sample matrix selected. Precision and accuracy criteria are method dependent. If precision and accuracy criteria are not achieved, corrective action or additional action may be required. Recommended action must be completed

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before reporting sample data. All target components are included in the spike mixture over a two-year period.

SERIAL DILUTION (METALS) - Serial dilutions of metals samples are analyzed to determine if analytical matrix effects may have impacted the reported data. If the value of the serially diluted samples does not agree with the undiluted value within a method-specified range, the sample matrix may be causing interferences, which may lead to either high or low bias. If the serial dilution criterion is not achieved, it must be flagged to indicate possible bias from matrix effects.

POST DIGESTION SPIKES - Digested samples are spiked and analyzed to determine if matrix interferences are biasing the results when the pre-digestion spike (matrix spike) recovery falls outside the control limits. It may also be used to determine potential interferences per client's specification. The sample is spiked at the concentration specified in the method SOP. No action is necessary if the post digestion spike is outside of the method criteria, unless a preparation problem is suspected with the spike, in which case the post digestion spike should be re-prepared and reanalyzed.

SURROGATE SPIKES (ORGANICS) - Surrogate spikes are organic compounds that are similar in behavior to the target analytes but unlikely to be found in nature. They are added to all quality control and field samples to measure method performance for each individual sample. Surrogate accuracy limits are derived from published method specifications or from the statistical evaluation of laboratory generated surrogate accuracy data. Accuracy data is compared to the applicable performance limits. If the surrogate accuracy exceeds performance limits, corrective action, as specified in the method or SOP is performed before sample data can be reported.

INTERNAL STANDARDS (ORGANIC METHODS) - Internal standards are retention time and instrument response markers added to every sample to be used as references for quantitation. Their response is compared to reference standards and used to evaluate instrument sensitivity on a sample specific basis. Internal standard retention time is also compared to reference standards to assure that target analytes are capable of being located by their individual relative retention time.

If internal standard response criteria are not achieved, corrective action or additional action may be required. The recommended action must be completed before sample data can be reported. If the internal standard retention time criteria are not achieved corrective action or additional action may be required. This may include re-calibration and re-analysis. Additional action must be completed before sample data is reported.

INTERNAL STANDARDS (ICP AND ICP/MS METALS) - Internal standards are used on ICP instruments to compensate for variations in response caused by differences in sample matrices. Multiple internal standards are used for each sample on ICP/MS instruments to compensate for variations in response caused by differences in sample matrices. This adjustment is performed automatically during sample analysis. The internal standard response of replicated sample analysis is monitored to detect potential analytical problems. If analytical problems are suspected, then the field samples may be reanalyzed or reanalyzed upon dilution to minimize the interferences. A different internal standard may be employed for quantitation in situations where the field sample contains the element typically used as the internal standard.

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12.4 LABORATORY DERIVED QUALITY CONTROL CRITERIA - Control criteria for in-house methods and client specific modifications that exceed the scope of published methodology are defined and documented prior to use of the method. The Quality Assurance Officer is responsible for identifying additional control criteria needs. Control parameters and criteria based on best technical judgment are established using input provided by the operations staff. These control parameters and criteria are documented and incorporated into the method.

The laboratory-derived criteria are evaluated for technical soundness on spiked samples prior to the use of the method on field samples. The technical evaluation is documented and archived by the Quality Assurance Staff. When sufficient data from the laboratory developed control parameter is accumulated, the data is statistically processed, and the experimentally derived control limits are incorporated into the method.

12.5 BENCH REVIEW & CORRECTIVE ACTION - The bench chemists are responsible for all QC parameters. Before proceeding with sample analysis, they are required to successfully meet all instrumental QC criteria. They have the authority to perform any necessary corrective action before proceeding with sample analysis. Their authority includes the responsibility for assuring that departures from documented policies and procedures do not occur.

The bench chemists are also responsible for all sample QC parameters. If the sample QC criteria are not achieved, they are authorized and required to perform the method specified corrective action before reporting sample data.

12.6 DATA QUALIFIERS - An alpha character coding system is employed for defining use limitations for reported data. These limitations are applied to analytical data by the analyst to clarify the usefulness of the reported data for data user. Common data qualifiers and their definitions are as follows (additional qualifiers may be identified in the footnotes of the analytical report).

ORGANICS

J: Indicates an estimated value. Applied to calculated concentrations for tentatively identified compounds and qualitatively identified compounds whose concentration is below the reporting limit, but above the MDL.

N: Indicates qualitative evidence of a tentatively identified compound whose identification is based on a mass spectral library search and is applied to all TIC results.

C: Applied to pesticide data that has been qualitatively confirmed by GC/MS.

B: Used for analytes detected in the sample and its associated method blank

E: Applied to compounds whose concentration exceeds the upper limit of the calibration range

METALS AND INORGANICS

B: Applied if the reported concentration value was less than the reporting limit but greater than the MDL.

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U Applied if the reading is less than the MDL (or IDL if IDL reporting is being used).

E: Estimated concentration caused by the presence of interferences, normally applied when the serial dilution is out.

N: Spike sample recovery not within control limits.

*: Duplicate or matrix spike duplicate analysis not within control limits.

12.7 QA MONITORING - The QA Staff conducts a spot review of completed data packages prior to client release for specified projects. This review includes an examination of QC data for compliance and trends indicative of systematic difficulties. If non-conformances are detected, the QA staff places an immediate stop on the release of the data and initiates corrective action to rectify the situation. The data package is released when the package becomes compliant with all quality requirements. If compliance is not possible, the data is qualified, and an appropriate case narrative is generated for inclusion in the data package.

If the review reveals trends indicative of systematic problems, QA initiates an investigation to determine the cause. If process defects are detected, a corrective action is implemented and monitored for effectiveness.

PERFORMANCE LIMITS - The Quality Assurance Manager is responsible for compilation and maintenance of all precision and accuracy data used for performance limits. Quality control data for all test methods are accumulated and stored in the laboratory information management system (LIMS). Parameter specific QC data is extracted annually and statistically processed to develop laboratory specific control limits. The new limits are reviewed and approved by the supervisory staff prior to their use for data assessment. The new limits are used to evaluate QC data for compliance with method requirements for a period of one year. Laboratory generated limits appear on all data reports.

12.8 DATA PACKAGE REVIEW - SGS North America Inc. employs at least two levels of data review to assure that reported data has satisfied all quality control criteria and that client specification and requirements have been met. Each production department has developed specific data review procedures, which must be completed before data is released to the client. The final review must be performed by a manager, supervisor or designated reviewer.

ANALYTICAL REVIEW - The analyst conducts the primary review of all data. This review begins with a check of all instrument and method quality control and progresses through sample quality control, concluding with a check to assure that the client's requirements have been executed. Analyst checks focus on a review of qualitative determinations and checks of precision and accuracy data to verify that existing laboratory criteria have been achieved. Checks at this level may include comparisons with project specific criteria if applicable. The analyst has the authority and responsibility to perform corrective action for any out-of-control parameter or nonconformance at this stage of review.

Analysts who have met the qualification criteria for the method in use perform secondary, peer level data reviews. Analyst qualification requirements include a valid demonstration of capability and demonstrated understanding of the method SOP. Section supervisors may perform secondary review in-lieu of a peer review. Managers, supervisors, or designated reviewers

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evaluate 100% of the data produced by their department. It includes a check of all manual calculations; an accuracy check of manually transcribed data from bench sheets to the LIMS, a check of calibration and continuing calibration, all QC criteria and a comparison of the data package to client specified requirements, including client specified parameter lists. Also included are checks to assure the appropriate methodology was applied and that all anomalous information was properly flagged for communication in the case narrative. Supervisors have the authority to reject data and imitate re-analysis, corrective action, or reprocessing.

All laboratory data requiring manual entry into LIMS system is double-checked by the analyst performing initial data entry and/or peer reviewer or the section supervisor. Verification of supervisory review is indicated on the raw data summary by the manager, supervisor, or designated reviewer's initials and date.

Electronic data that is manually edited at the bench by the primary analyst is automatically flagged by the instrument data system indicating and override by the analyst. All manual overrides must be verified and approved by a supervisor who initials and dates all manual changes.

Hard copies or PDF's of manually integrated chromatographic peaks are printed that clearly depict the manually drawn baseline. The hard copy or PDF is reviewed and approved by the section manager, supervisor, or designated reviewer (initialed and dated) and included in the data package of all full tier reports or the archived batch records of commercial report packages.

Edits to electronic data that have already been committed to the LIMS database are controlled through the use of the QA function in LIMS which does not allow edits unless the data is released back to the laboratory by a senior staff member with administrative rights. Permission to access this program is limited to those approved by the upper levels of laboratory management and is controlled by the Information Technology staff. A GALP electronic audit report trail is maintained for all changes that are made and is automatically appended to the record.

The group manager performs a tertiary review on a spot check basis. This review includes an evaluation of QC data against acceptance criteria and a check of the data package contents to assure that all analytical requirements and specifications were executed.

PROJECT MANAGEMENT/QUALITY CONTROL REVIEW - The project managers review reports to verify that the report meets the client's specifications. Project management reviews focus on project specifications. If the project manager identifies defects in the product prior to release, he initiates immediate corrective action to rectify the situation.

The QA staff performs a post-delivery check of completed data packages to verify completeness and compliance with established quality control procedures. Approximately 10% of Full-Deliverables data packages are reviewed. Detected deficiencies are documented and corrective actions initiated as necessary. Data review checklists are electronic documents that may be used to assist with the review process. These checklists are archived in the QA Directory of the network server.

The QA review focuses on all elements of the deliverable including the client's specifications and requirements, analytical quality control, sample custody documentation and sample identification. QA reviews at this step in the production process are geared towards systematic process defects, which require procedural changes to affect a corrective action. However, if defects are identified that have an adverse effect on data, the client is immediately informed

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following standard notification procedures. QA data review is not used in lieu of a peer level review of a supervisory review.

DATA REPORTING - Analytical data is available for release to clients following a secondary review by the manager, supervisor, or designated reviewer. Data release at this stage of the process is limited to electronic information, which is released to clients through a secure, encrypted, password protected, Internet connection. Hard copy support data is compiled by the report generation group and assembled into the final report. The report is sent to the client following reviews by the report generation staff and the project manager.

All data reports include specified information, which is required to identify the report and its contents. This information includes a title, name and address of the laboratory, a unique report number, total number of pages in the report, clients name and address, analytical method identification, arriving sample condition, sample and analysis dates, test results with units of measurement, authorized signature of data release, statement of applicability, report reproduction restrictions and TNI certification requirements. Data reports for the Department of Defense ELAP also include the time of preparation and analysis.

12.9 ELECTRONIC DATA REDUCTION - Raw data from sample analysis is entered into the laboratory information management system (LIMS) using automated processes or manual entry. Final data processing is performed by the LIMS using procedures developed by the company.

All LIMS programs are tested and validated prior to use to assure that they consistently produce correct results. The Information Technology Staff performs software validation testing. The testing procedures are documented in an SOP. Software programs are not approved for use until they have demonstrated that they are capable of performing the required calculations.

12.10 REPRESENTATIVENESS - Data representativeness is based on the premise that qualitative and quantitative information developed for field samples is characteristic of the sample that was collected by the client and analyzed in the laboratory. The laboratory objective for representativeness defines data as representative if the criteria for all quality parameters associated with the analysis of the sample are achieved.

12.11 COMPARABILITY - Analytical data is defined as comparable when data from a sample set analyzed by the laboratory is representatively equivalent to other sample sets analyzed separately regardless of the analytical logistics. The laboratory will achieve 100% comparability for all sample data which meets the criteria for the quality parameters associated with its analysis using the method requested by the client.

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13.0 CORRECTIVE ACTION SYSTEM

REQUIREMENT - The laboratory employs policies and procedures for correcting defective processes, systematic errors, and quality defects enabling the staff to systematically improve product quality. The system includes procedures for communicating items requiring corrective action to responsible individuals, corrective action tracking procedures, corrective action documentation, monitoring of effectiveness, and reports to management. The system is fully documented in a standard operating procedure. Individual corrective actions and responses are documented in a dedicated database.

13.1 PROCEDURE - Corrective action is the step that follows the identification of a process defect. The type of defect determines the level of documentation, communication, and training necessary to prevent re-occurrence of the defect or non-conformance. The formal system is maintained by the quality assurance department. Operations management is responsible for working within the system to resolve identified deficiencies.

ROUTINE CORRECTIVE ACTION - Routine corrective action is defined as the procedures used to return out of control analytical systems back to control. This level of corrective action applies to all analytical quality control parameters or analytical system specifications.

Bench analysts have full responsibility and authority for performing routine corrective action. The resolution of defects at this level does not require a procedural change or staff re-training. The analyst is free to continue work once corrective action is complete and the analytical system has been returned to in-control. Documentation of routine corrective action is limited to logbook comments for the analyses being performed.

PROCESS CHANGES - Corrective actions in this category require procedural modifications. They may be the result of systematic defects identified during audits, the investigation of client inquiries, failed proficiency tests, product defects identified during data review, or method updates. Resolution of defects of this magnitude requires formal identification of the defect, development and documentation of a corrective action plan, and staff training to communicate the procedural change.

TECHNICAL CORRECTIVE ACTION - Technical corrective action encompasses routine corrective action performed by bench analysts for out of control systems and corrective actions performed for data produced using out of control systems. Technical corrective action for routine situations is conducted using the procedures detailed above.

Non-routine corrective actions apply to situations where the bench analysts failed to perform routine corrective action before continuing analysis. Supervisors and Department Managers perform corrective in these situations. Documentation of all non-routine corrective action is performed using the corrective action system.

Sample re-analysis is conducted if sufficient sample and holding time remain to repeat the analysis using an in-control system. If insufficient sample or holding time remains, the data is processed, and qualifiers applied that describe out of control situation. The occurrence further documented in the case narrative and in the corrective action response. The corrective action

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must include provisions for retraining the analysts who failed to perform routine corrective action.

13.2 DOCUMENTATION AND COMMUNICATION - Routine corrective actions are documented as part of the analytical record. Notations are made in the comments section of the analytical chronicle or data sheet detailing the nonconformance and corrective action. Continuation of the analysis indicates that return to control was successful.

Corrective actions for process changes are documented, tracked, and monitored for effectiveness. Supervisors or senior staff members may initiate corrective actions by generating a corrective action using the corrective action database application. The corrective action is assigned to the responsible party at the time the corrective action is initiated. Corrective action due dates are set for 14 calendar days from initiation.

The corrective action database is an Access application. The initiator generates the corrective action investigation form, which is documented, tracked, distributed to responsible parties, and archived through an application. The application assigns a tracking number, initiation date, due date to each action and copies the corrective action form to the database. An e-mail message containing the form is automatically distributed to the responsible parties for resolution. Any time a corrective action is initiated QA will notify the responsible party, the appropriate department supervisor, the laboratory director, and the QA Officer that a corrective action has been initiated. The e-mail should include the due date. The QA department will review the corrective action database twice a week. An e-mail will be sent to the responsible party any time a corrective action is due date is about to expire. Once a week the QA department will hold a corrective action meeting with all department supervisors, managers, and the laboratory director to discuss the status of any open corrective actions. If there aren't any open corrective actions, then the meeting will be cancelled.

The responsible party must identify the root cause of the non-compliance, initiate the immediate fix and must develop and implement the procedural changes. Existing documentation such as SOPs are edited to reflect the change. The affected staff is informed of the procedural change through a formal training session. The training is documented, and copies are placed into individual training files. The corrective action form is completed by the responsible party and date completed is entered into the database. An email acknowledgment is sent to the QA staff using the database application. The QA staff must review the root cause investigation and the corrective action. The department supervisor and the QA department must agree with the proposed corrective action prior to implementation.

Completed corrective action forms are maintained in the corrective action database. This entire database is backed up and archived daily.

MONITORING - The QA Staff evaluates the corrective action no later than 30 days after the corrective action has been implemented and continues monitoring until it is evident that the action has been effective, and the defect has been eliminated. The corrective action database is updated by QA to reflect closure of the corrective action. Additional monitoring of the corrective action is conducted during routine laboratory audits.

Additional monitoring of the corrective action is conducted by adding the corrective action to a verification list by the QA staff at closure. Verification is performed by the QA Staff to assure that

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the corrective action has remained in effect is scheduled six (6) months from the initial closure date.

If QA determines that the corrective action response has not effectively remedied the deficiency, the process continues with a re-initiation of the corrective action. Corrective action continues until the defect is eliminated. If another procedural change is required, it is treated as a new corrective action, which is documented and monitored using established procedures.

CLIENT NOTIFICATION - Defective processes, systematic errors, and quality defects, detected during routine audits may have negative impacts on data quality. In some cases, data that has been released to clients may be affected. If defective data has been released for use, SGS North America Inc. will notify the affected clients of the defect and provide specific details regarding the magnitude of the impact to their data.

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14.0 PROCEDURES FOR EXECUTING CLIENT SPECIFICATIONS

REQUIREMENT - Systems have been established for evaluating and processing client specifications for routine and non-routine analytical services. The systems enable the client services staff to identify, evaluate, and document the requested specifications to determine if adequate resources are available to perform the analysis. The system includes procedures for communicating the specifications to the laboratory staff for execution and procedures for verifying the specifications have been executed.

14.1 CLIENT SPECIFIC REQUIREMENTS - The project manager is the primary contact for clients requesting laboratory services. Client specifications are communicated using several mechanisms. The primary sources of information are the client's quality assurance project plan (QAPP) and the analytical services contract both of which detail the analytical, quality control and data reporting specifications for the project. In the absence of a QAPP, projects specifications can also be communicated using contracts, letters of authorization, letters of agreement, or client statement of work which may be limited to a brief discussion of the analytical requirements and the terms and conditions for the work. These documents may also include pricing information, liabilities, and scope of work, in addition to the analytical requirements. QAPPs include detailed analytical requirements and data quality objectives, which may supersede those found in the referenced methods. This information is essential to successful project completion.

The client services staff provides additional assistance to clients who are unsure of the specifications they need to execute the sampling and analysis requirements of their project. The client services staff provide additional support to clients who require assistance in results interpretation as needed, provided they possess the expertise required to render an opinion.

The project manager is responsible for obtaining project documents, which specify the analytical requirements. Following project management review, copies are distributed to the QA Manager and the appropriate departmental managers for review and comment. The original QAPP may be filed in a secure location or electronic version stored on the server.

14.2 REQUIREMENTS FOR NON-STANDARD ANALYTICAL SPECIFICATIONS - Client requirements that specify departures from documented policies, procedures, or standard specifications must be submitted to SGS North America Inc. in writing. These requirements are reviewed and approved by the technical staff before the project is accepted. Once accepted, the non-standard requirements become analytical specifications, which follow the routine procedure for communicating client specifications. Departures from documented policies, procedures, or standard specifications that do not follow this procedure are not permitted.

14.3 EVALUATION OF RESOURCES - A resource evaluation is completed prior to accepting projects submitted by clients. The evaluation is initiated by the client services staff who prepares a brief synopsis that includes the logistical requirements of the project. Logistical specifications for new projects are summarized in writing for evaluation by the affected departments. The specifications are evaluated by the department manager from a scheduling hardware resources perspective. The project is not accepted unless the department managers have the necessary resources to execute the project according to client specifications. SGS maintains a record of all certification parameters on the quality assurance directory and displays the current certificates for each state that is accredited in the front lobby of the laboratory.

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14.4 DOCUMENTATION - New projects are initiated in LIMS which is completed prior to the start of the project. This form details all the information needed to correctly enter the specifications for each client sample into the laboratory information management system (LIMS). The form includes data reporting requirements, billing information, data turnaround times, QA level, state of origin, and comments for detailing project specific requirements. The project manager is responsible for obtaining this information from the client and completing the form prior to sample arrival and login.

Sample receipt triggers project creation and the login process. Information on the set-up is entered into the LIMS prior to logging in the first sample. The set up may be accompanied by a quotation, which details the analytical product codes and sample matrices. These details are also entered into the LIMS during login.

Special information is distributed to the laboratory supervisors and login department in electronic or hardcopy format upon project setup. All project specific information is retained by the project manager in a secure file. The project manager maintains a personal telephone log, which details conversations with the client regarding the project.

Client specific analytical requirements for each test can be found through a combination of reviews of the project codes and associated project plans which are located on a central server. Bench analysts use these tools to obtain information regarding client specific analytical requirements before analyzing samples. A project code is established for each client that links the client specifications to a client project. This code is attached to a project by the project manager at login and listed on the work backlog for each work group conducting analysis for clients with standing requirements. Additional notes pertinent to the analysis can be appended to the login screen by the project manager for display on the laboratory's work backlog.

14.5 COMMUNICATION - A pre-project meeting is held between client services and the operations managers to discuss the specifications described in the QAPP, contract and/or related documents. Project logistics are discussed and finalized, and procedures are developed to assure proper execution of the client's analytical specifications and requirements. Questions, raised in the review meeting, are discussed with the client for resolution. Exceptions to any requirements, if accepted by the client, are documented, and incorporated into the QAPP or project documentation records.

Non-standard specifications for individual clients are documented in the LIMS at the client account level or program level. Simple specifications are documented as comments for each project. Once entered the LIMS, these specifications become memorialized for all projects related to the client account. Complex specifications are assigned program codes that link the specification to detailed analytical specifications. Specifications that are not entered into the LIMS are prohibited unless documented in an interdepartmental memo, which clearly identifies the project, client and effective duration of the specification.

14.6 OPERATIONAL EXECUTION - A work schedule is prepared for each analytical department on a daily basis. Analytical specifications or program codes from recently arrived samples have now been entered into the LIMS database. The database is sorted by analytical due date and holding time, into product specific groups. Samples are scheduled for analysis by due date and holding time. The completed schedule, which is now defined as a work list, is printed. The list contains the client requested product codes, program codes and specifications required for the selected sample(s). Special requirements are communicated to the analyst using the comments section or relayed through verbal instructions provided by the supervisor. The bench analyst

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assumes full responsibility for performing the analysis according to the specifications printed on the work sheet.

VERIFICATION – Prior to the release of data to the client the project manager reviews the report and compare the completed product to the client specifications documentation to assure that all requirements have been met.

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15.0 CLIENT COMPLAINT RESOLUTION PROCEDURE

REQUIREMENT - The laboratory follows a formal system for managing and reconciling client complaints. The system includes procedures for documenting the complaint and communicating it to the appropriate department for resolution. The system also includes a quality assurance evaluation to determine if the complaint is related to systematic defects requiring corrective action and process changes.

15.1 PROCEDURE. Client complaints are communicated to program manager, quality assurance staff, and or senior management staff for resolution. The individual receiving the complaint retains the responsibility for documentation and communicating the nature of the complaint to the responsible department(s) for resolution. An investigation will be completed by the required person and or group to validate the complaint determining the required actions. The responsible party addresses the complaint. The resolution is communicated to quality assurance (QA) and the originator for the communication to the client. QA reviews the complaint and resolution to determine if systematic defects exist. If systematic defects are present, QA initiates a corrective action for the responsible party who develops and implements a response that eliminated the defect. If systematic defects are not present and the resolution is satisfactory, the QA Staff will close the complaint/inquiry with a "No further action required" tag.

15.2 DOCUMENTATION - Client complaints are documented by the individual receiving the complaint using the Corrective Action Database, Client Complaint section. Once created, an email is generated that contains detailed information essential to the complaint resolution. The system distributes an email to the QA officer, lab director and to the party bearing responsibility for resolution. The investigation will be documented within the correction action database. The Project Manager that initiated the client complaint will send an e-mail to the QA department, lab manager, and the responsible party notifying them that a client complaint was initiated and the due date for resolution of the complaint. The complaint resolution is documented in the database by the responsible party and a status update email is generated and forwarded to the department manager and QA staff to prompt the next stages of review and approval.

15.3 CORRECTIVE ACTION - Responses to data queries are required from the responsible party. At a minimum, the response addresses the query and provides an explanation to the complaint. Formal corrective action may focus on the single issue expressed in the complaint. Corrective action may include reprocessing of data, editing the initial report, and re-issue to the client. If the QA review indicates a systematic error, process modification is required. The defective process at the root of the complaint is changed. SOPs are either created or modified to reflect the change. The party responsible for the process implements process changes.

15.4 QA MONITORING - Process changes, implemented to resolve systematic defects, are monitored for effectiveness by QA. If monitoring indicates that the process change has not resolved the defect, QA works with the department management to develop and implement an effective process. If monitoring indicates that the defect has been resolved, monitoring is slowly discontinued, and the corrective action is closed. Continued monitoring is incorporated as an element of the annual system audit and annual Management Report (see 18.8)

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16.0 CONTROL OF NONCONFORMING PRODUCT

REQUIREMENT - Policies and procedures have been developed and implemented that describe the procedures employed by the laboratory when any aspect of sample analysis or data reporting do not conform to established procedures or client specifications. These procedures include steps to ensure that process defects are corrected and affected work is evaluated to assess its' impact to the client.

PROCEDURE - Nonconforming product is identified through routine internal review and audit practices or through client inquiry. The individuals who identify the nonconformance or receiving a nonconformance inquiry immediately inform the Laboratory Director and the Quality Assurance Officer. The Laboratory Director initiates an evaluation of the nonconformance through the Quality Assurance Department and takes full responsibility for managing the process and identifying the course of action to take, initiating corrective action and mitigating the impact of the nonconformance to the client.

16.1 **CORRECTIVE ACTION -** The outcome of the evaluation dictates the course of action. This includes client notification when the quality of data reported has been impacted and may also include corrective action if applicable. Immediate corrective action is performed using the procedures specified in SGS North America Inc. SOP LQA013. However, additional action may be required including cessation of analysis and withholding and or recalling data reports. If the evaluation indicates that nonconforming data may have been issued to clients, the client is immediately notified, and data may be recalled following the procedures specified in SOP LQA013. If work has been stopped because of a nonconformance, the Laboratory Director is the only individual authorized to direct a resumption of analysis.

16.2 Non-conformances caused by systematic process defects require retraining of the personnel involved as an element of the corrective action solution.

17.0 CONFIDENTIALITY PROTECTION PROCEDURES

REQUIREMENT - Policies and procedures have been developed to protect client data from release to unauthorized parties or accidental release of database information through accidental

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electronic transmission or illegal intrusion. These policies have been communicated to clients and staff. Electronic systems are regularly evaluated for effectiveness.

All employees are required to sign a confidentiality agreement upon hire.

17.1 CLIENT ANONYMITY - Information related to the Company's clients is granted to employees on a "need to know" basis. An individual's position within the organization defines his "need to know". Individuals with "need to know" status are given password access to systems that contain client identity information and access to documents and document storage areas containing client reports and information. Access to client information by individuals outside of the Company is limited to the client and individuals authorized by the client.

Individuals outside of the Company may obtain client information through subpoena issued by a court of valid jurisdiction. Clients are informed when subpoenas are received ordering the release of their information.

Client information may be released directly to regulatory agencies without receiving client authorization under specified circumstances. These circumstances require that the regulatory agency have statutory authority under the regulations for laboratory certification and that SGS North America Inc.'s operations fall under the purview of the regulation. In these situations, SGS North America Inc. will inform the client of the regulatory agencies request for information pertaining to his data and proceed with the delivery of the information to the regulatory agency.

17.2 DOCUMENTS - Access to client documents is restricted to employees in need to know positions. Copies of all client reports are stored in secure electronic archives with restricted access. Reports and report copies are distributed to individuals who have been authorized by the client to receive them. Data reports or data are not released to third parties without verbally expressed or written permission from the client.

17.3 ELECTRONIC DATA

DATABASE INTRUSION - Direct database entry is authorized for employees of SGS North America Inc. only on a need to know basis. Entry to the database is restricted through a user specific multiple password entry system. Direct access to the database outside of the facility is possible through an SGS North America Inc. portal. A unique password is required for access to the local area network. A second unique password is required to gain access to the database. The staff receives read or write level authorization on a hierarchical privilege basis.

CLIENT ACCESSIBILITY - Accessibility to client data delivered via electronic means follows strict protocols to insure confidentiality. Clients accessing electronic data are assigned a company account. The account profile, which is established by the MIS staff, grants explicit access to specific information pertaining to the client's project activity. Passwords are assigned on an individual basis within a client account. These accounts can be activated or deactivated by the MIS staff only.

17.4 INFORMATION REQUESTS - Client specific data or information is not released to third parties without verbally expressed or written permission from the client. Written permission is required from third parties, who contact the Company directly from the release of information. Verbal requests will be honored only if they are received directly from the client. These requests must be documented in a record of communication maintained by the authorized recipient.

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17.5 TRANSFER OF RECORDS - Archived data, which has previously been reported and transmitted to clients, is the exclusive property of SGS North America Inc. Laboratories. In the event of a cessation of business activities due to business failure or sale, The Company's legal staff will be directed to arrange for the final disposition of archived data.

The final disposition of archived data will be accomplished using the approach detailed in the following sequence:

1. All data will be transferred to the new owners for the duration of the required archive period as a condition of sale.
2. If the new owners will not accept the data or the business has failed, letters will be sent to clients listed on the most recent active account roster offering them the option to obtain specific reports (identified by SGS North America Inc. Job Number) at their own expense.
3. A letter will be sent to the TNI accrediting authority with organizational jurisdiction over the company offering them the option to obtain all unclaimed reports at their own expense.
4. All remaining archived data will be recycled using the most expedient means possible.

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18.0 QUALITY AUDITS AND SYSTEM REVIEWS

REQUIREMENT - The quality assurance group conducts regularly scheduled audits of the laboratory to assess compliance with quality system requirements, technical requirements of applied methodology, and adherence to documentation procedures. The information gathered during these audits is used to provide feedback to senior management and perform corrective action where needed for quality improvement purposes.

18.1 QUALITY SYSTEM REVIEWS - Quality system reviews are performed annually by the Quality Assurance Manager for the Laboratory Director. In the review, the laboratory is evaluated for compliance with the laboratory Quality Systems Manual (QSM) and the quality system standards of TNI 2016 as well as ISO/IEC 17025:2017. Findings, which indicate non-compliance or deviation from the standards, are flagged for corrective action. Corrective actions require either a return to compliance or a plan change to reflect an improved quality process. The Quality Assurance officer is responsible for making and documenting changes to the QSM or other quality system documents. These changes are reviewed by the Laboratory Director and department managers and or supervisors prior to the approval of the revised system.

18.2 QUALITY SYSTEM AUDITS - Quality system audits are conducted to evaluate the effectiveness and laboratory compliance with individual quality system elements. These audits are conducted on an established schedule. Audit findings are documented and communicated to the management staff and entered into the corrective action system for resolution. If necessary, retraining is conducted to assure complete understanding of the system requirements.

18.3 TEST METHOD AUDITS - Test Method Audits are performed throughout the year following an established schedule. Selected analytical procedures are evaluated for compliance with standard operating procedures (SOPs) and reference method requirements. If non-conformances exist, the published method serves as the standard for compliance. SOPs are edited for compliance if the document does not reflect method requirements. Analysts are retrained to the new requirements and the process is monitored by quality assurance. Analysts are retrained in method procedures if an evaluation of bench practices indicates non-compliance with SOP requirements.

18.4 DOCUMENTATION AUDITS. Documentation audits are conducted during routine internal audits. This audit includes a check of measurement processes that require manual documentation. It also includes checks of data archiving systems and a search to find and remove any inactive versions of SOPs that may still be present in the laboratory and being accessed by the analysts. Non-conformances are corrected on the spot. Procedural modifications are implemented if the evaluation indicates a systematic defect.

18.5 CORRECTIVE ACTION MONITORING - Defects or non-conformances that are identified during client or internal audits are documented in the corrective action systems and corrected through process modifications and/or retraining. Once a corrective action has been designed and implemented, it is monitored for compliance on a regular basis by the QA staff. Spot corrections are performed if the staff is not following the new procedure. Monitoring of the corrective action continues until satisfactory implementation has been verified.

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18.6 **PREVENTIVE ACTION -** Laboratory systems or processes, which may be faulty and pose the potential for non-conformances, errors, confusing reports, or difficulties establishing traceability may be identified during internal audits. These items are highlighted for systematic change using the corrective action system and managed to resolution using the procedures for corrective action identified in LQA013.

18.7 **CLIENT NOTIFICATION -** Defective processes, systematic errors, and quality defects, detected during routine audits may have negative impacts on data quality. In some cases, data that has been released to clients may be affected. If defective data has been released for use, SGS North America Inc. will immediately notify the affected clients of the defect and provide specific details regarding the magnitude of the impact to their data.

18.8 **MANAGEMENT REVIEW** - Formal reports of all audit activities are prepared for the management staff. These reports are prepared annually. The report details the status of the Quality System.

The formal report also addresses the following topics, along with actions and objectives for the next year:

- *the suitability of policies and procedures.*
- *reports from managerial and supervisory personnel.*
- *the outcome of recent internal audits.*
- *corrective and preventive actions.*
- *assessments by external bodies.*
- *the results of inter-laboratory comparisons or proficiency tests.*
- *changes in the volume and type of the work.*
- *customer feedback.*
- *complaints.*
- *recommendations for improvement.*
- *other relevant factors, such as quality control activities, resources, and staff training.*
- *assessment of any risks to impartiality.*
- *annual re-assessment of ISO 17025 vendors.*
- *assessment of risks and opportunities to the business.*
- *results from the voice of the customer survey.*

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19.0 HEALTH AND SAFETY

REQUIREMENT – The company operates a formal health and safety program that complies with the requirements of the Occupational Health and Safety Administration. The program consists of key policies and practices that are essential to safe laboratory operation. All employees are required to receive training on the program elements. Job specific training is conducted to assure safe practices for specific tasks. All employees are required to participate in the program, receive initial and annual training, and comply with the program requirements. All plan and program requirements are detailed in the Health and Safety Program Manual.

19.1 POLICY – SGS North America Inc. Laboratories will provide a safe and healthy working environment for its employees and clients while protecting the public and preserving the Company's assets and property. The company will comply with applicable government regulations pertaining to safety and health in the laboratory and workplace.

The objective of the SGS North America Inc. Health and Safety Program is to promote safe work practices that minimize the occurrence of injuries and illness to the staff through proper health and safety training, correct laboratory technique application and the use of engineering controls.

19.2 RESPONSIBILITIES – The Health and Safety Program assists managers, supervisors and non-supervisory employees in control of hazards and risks to minimize the potential for employee and client injuries, damage to client's property and damage or destruction to SGS North America Inc.'s facility.

The lab managers and supervisors are responsible for implementing the program's elements and updating its contents as necessary. The management staff conducts periodic audits to monitor compliance and assess the program's effectiveness. The SGS OI team is responsible for creating and administering safety training for all new and existing employees.

The employee is responsible for following all safety rules established for their protection, the protection of others and the proper use of protective devices provided by the Company. The employee is also expected to comply with the requirements of the program at all times. Department Managers and Supervisors are responsible for ensuring the requirements of the Safety Program are practiced daily.

19.3 PROGRAM ELEMENTS – The SGS North America Inc. Health and Safety Program consist of key program elements that complement the company's health and safety objective. These elements form the essence of the health and safety policy and assure that the objectives of the program are achieved.

SAFETY EDUCATION AND TRAINING AND COMMUNICATION – Training is conducted to increase the staff's awareness of laboratory hazards and their knowledge of the safety practices and procedures required to protect them from those hazards. It is also used to communicate general safety procedures required for safe operation in a chemical laboratory.
Initial health and safety training for new employees is conducted during orientation. The training focuses on the SGS North America Inc. Health and Safety Program and includes specific training for the hazards that may be associated with the employee duties. Training is also

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conducted for all program elements focusing on general, acceptable, laboratory safety procedures. Targeted training is conducted to address hazards or safety procedures that are specific to individual employee's work assignments. All training activities are documented and archived in individual training folders.

SAFETY COMMITTEE – The safety committee provides the employee with an opportunity to express their views and concerns on safety issues in a forum where those concerns will be addressed. This committee meets monthly to assure that the interests of the company and the well-being of the employee are protected. The safety committee is comprised of department managers, supervisors, and the QA officer(s). The safety committee acts as safety champions within the laboratory.

HAZARD IDENTIFICATION AND COMMUNICATION – The hazard communication program enables employees to readily identify laboratory hazards and the procedures themselves from those hazards. This program complies with OSHA's Hazard Communication Standard, Title 29 Code of Federal Regulations 1910.1200 that requires the company to adopt and adhere to the following key elements:

- Safety Data Sheets (SDS) must be available to any employee wishing to view them,
- The Company must maintain a Hazardous Chemicals Inventory (by location), which is updated on an annual basis,
- Containers are properly labeled,
- All employees must be provided with annual Hazard Communication and Right to Know training,

The hazard communication program also complies with the requirements of the New Jersey Worker and Community Right to Know Law, NJAC 8:95.

IDENTIFICATION OF WORKPLACE HAZARDS – The workplace hazard identification procedures have been designed to assure that hazards that have the potential to cause personnel injury or destruction of property are identified, managed and/or systematically eliminated from the operation. This system eliminates hazards, limits the potential for injury and increases the overall safety of the work environment.

EMPLOYEE EXPOSURE ASSESSMENT – Employee exposure assessment is performed to identify and evaluate potential exposure hazards associated with the employee's workstation. The exposure assessment data is used to determine if changes or modifications to the workstation are needed to limit exposure to laboratory conditions that could negatively affect an employee's health or disclosed existing medical conditions.

BLOOD BORNE PATHOGENS – SGS North America Inc. has implemented awareness training on the OSHA Blood borne Pathogen Standard, 29 CFR 1910.1030 to reduce occupational exposure to Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV) and other blood borne pathogens that employees may encounter in their workplace.

RESPIRATORY PROTECTION PLAN – The respiratory protection plan assures that SGS North America Inc. employees are protected from exposure to respiratory hazards. This program is used in situations where engineering controls and/or safe work practices do not completely control the identified hazards. In these situations, respirators and other protective equipment are used. Supplemental respiratory protection procedures are applied to specified

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maintenance personnel, employees who handle hazardous waste storage area, and any employee that voluntarily elects to wear a respirator.

CHEMICAL HYGIENE PLAN –The Chemical Hygiene Plan complies with the requirements of the Occupational Safety and Health Administration's Occupational Exposure to Hazardous Chemicals in the Laboratory Standard, 29 CFR 1910.1450. This plan establishes procedures, identifies safety equipment, personal protective equipment, and work practices that protect employees from the hazardous chemicals in the laboratory when properly used and applied.

CHEMICAL SPILL RESPONSE PLAN – The chemical spill response plan has been designed to minimize the risks from a chemical spill or accidental chemical release in the laboratory. Risk minimization is accomplished through a planned response that follows a defined procedure. The designated staff are trained to execute spill response procedures according to the specifications of the plan, which identifies the appropriate action to be taken based on the size of the spill.

EMERGENCY ACTION & EVACUATION PLAN – The Emergency Action and Evacuation Plan details the procedures used to protect and safeguard SGS North America Inc.'s employees and property during emergencies. Emergencies are defined as fires or explosions, gas leaks, building collapse, hazardous material spills, emergencies that immediately threaten life and health, bomb threats and natural disasters such as floods, hurricanes or tornadoes, terrorism or terrorist actions. The plan identifies and assigns responsibility for executing specific roles in situations requiring emergency action. It also describes the building security actions coinciding with the "Alert Condition", designated by the Department of Homeland Security.

LOCKOUT/TAG-OUT PLAN – Lockout/tag-out procedures have been established to assure that laboratory employees and outside contractors take steps to render equipment inoperable and/or safe before conducting maintenance activities. The plan details the procedures for conducting maintenance on equipment that has the potential to unexpectedly energize, start up, or release energy or can be operated unexpectedly or accidentally resulting in serious injury to employees. The plan ensures that employees performing maintenance render the equipment safe through lock out or tag out procedures.

PERSONAL PROTECTION POLICY – Policies have been implemented which detail the personal protection requirements for employees. The policy includes specifications regarding engineering controls, personal protective equipment (PPE), hazardous waste, chemical exposures, working with chemicals and safe work practices. Safety requirements specific to processes or equipment are reviewed with the department supervisor or the EHS Director before beginning operations.

VISITOR AND CONTRACTOR SAFETY PROGRAM – All visitors and contractors who visit or conduct business at the facility are instructed on the laboratory's safety requirements. The safety instructions are designed to inform anyone who is not an employee of SGS North America Inc. Laboratories of the laboratory programs and plans while on SGS Acutest property. This program also outlines procedures for visitors and contractors in the event of an emergency. Visitors are required to acknowledge receipt and understanding of the SGS North America Inc. policy.

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APPENDIX I

Glossary of Terms

GLOSSARY OF TERMS

Acceptance Criteria: specified limits placed on characteristics of an item, process, or service defined in requirement documents.

Accuracy: the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator.

Analyst: the designated individual who performs “hands-on” analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

Audit: a systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity.

Batch: environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A preparation batch is composed of one to 20 environmental samples of the same TNI-defined matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group.

Blank: a sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage and analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results.

Blind Sample: a sub-sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test the analyst’s or laboratory’s proficiency in the execution of the measurement process.

Calibration: to determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument, or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements.

Calibration Curve: the graphical relationship between the known values, such as concentrations of a series of calibration standards and their instrument response.

Calibration Method: a defined technical procedure for performing a calibration.

Calibration Range: the range of concentrations between the lowest and highest calibration standards of a multi-level calibration curve. For metals analysis with a single-point calibration, the low-level calibration check standard and high standard establish the linear calibration range, which lies within the linear dynamic range.

Calibration Standard: a substance or reference material used to calibrate an instrument.

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Certified Reference Material (CRM): a reference material of one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation, which is issued by a certifying body.

Chain of Custody: an unbroken trail of accountability that ensures the physical security of samples and includes the signatures of all who handle the samples.

Confirmation: verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to second column confirmation, alternate wavelength, derivatization, mass spectral, interpretation, alternative detectors or, additional cleanup procedures.

Continuing Calibration Verification: the verification of the initial calibration that is required during the course of analysis at periodic intervals. Continuing calibration verification applies to both external standard and internal standard calibration techniques, as well as to linear and non-linear calibration models.

Corrective Action: the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent reoccurrence.

Data Reduction: the process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useable form.

Demonstration of Capability: a procedure to establish the ability of the analyst to generate acceptable accuracy. For initial DOC, generally 4 LCS or BS are logged in for the analyst for the new test method. The analyst performs the analysis of the 4 samples. The results are review by the supervisor and submitted to QA. Result for the 4 samples must meet acceptance criteria for the method

Document Control: the act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed.

Duplicate Analyses: the analyses or measurements of the variable of interest performed identically on two sub-samples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation or storage internal to the laboratory.

Field of Testing: TNI's approach to accrediting laboratories by program, method and analyte. Laboratories requesting accreditation for a program-method-analyte combination or for an updated/improved method are required to submit to only that portion of the accreditation process not previously addressed. Field of Testing approach is used by Louisiana Department of Environmental Quality.

Laboratory Control Sample (such as laboratory fortified blank, spiked blank, blank spike or QC check sample): a sample matrix, free from analytes of interest, spiked with verified known amounts of analytes from a source independent of the calibration standards or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

Limit of Detection (LOD): an estimate of the minimum amount of a substance that an analytical process can reliably detect. An LOD is analyte and matrix specific. DoD clarification is the smallest

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amount or concentration of a substance that must be present in a sample in order to be detected at a high level of confidence (99%). At the LOD, the false negative rate (Type II error) is 1%.

Limit of Quantitation (LOQ): the minimum levels, concentrations, or quantities of a target analyte that can be reported with a specified degree of confidence. DoD clarification is the lowest concentration that produces a quantitative result within specified limits of precision and bias. The LOQ shall be at or above the concentration of the lowest initial calibration standard.

Matrix: the component or substrate that contain the analyte of interest. For purposed of batch and QC requirement determinations, the following matrix distinctions shall be used:

Aqueous: any aqueous sample excluded from the definition of Drinking Water matrix or Saline/Estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.

Drinking Water: any aqueous sample that has been designated a potable or potential potable water source. Saline/Estuarine: any aqueous sample from an ocean or estuary, or other salt-water source such as the Great Salt Lake. Non-aqueous Liquid: any organic liquid with <15% settle-able solids.

Solids: includes soils, sediments, sludges and other matrices with >15% settle-able solids

Chemical Waste: a product or by-product of an industrial process that results in a matrix not previously defined.

Air: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinge solution, filter, or other device.

Biota: animal or plant tissue, consisting of entire organisms, homogenates, and/or organ or structure specific subsamples.

Matrix Spike (spiked sample or fortified sample): a sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

Matrix Spike Duplicate (spiked sample or fortified sample duplicate): a second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

Method Blank: a sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest, which is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes of interferences are present at concentrations that impact the analytical results for sample analyses.

Method Detection Limit: the minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte.

TNI: the overall National Environmental Laboratory Accreditation Program.

TNI Standards: the plan of procedures for consistently evaluating and documenting the ability of laboratories performing environmental measurements to meet nationally define standards established by the National Environmental Laboratory Accreditation Conference.

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Performance Audit: the routine comparison of independently obtained qualitative and quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory.

Precision: the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms.

Preservation: refrigeration and/or reagents added at the time of sample collection (or later) to maintain the chemical and/or biological integrity of the sample.

Proficiency Testing: a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.

Proficiency Test Sample (PT): a sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria.

Quality Assurance: an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

Quality Control: the overall system of technical activities whose purpose is to measure and control the quality of a producer or service so that it meets the needs of users.

Quality Manual: a document stating the management policies, objectives, principles, organizational structure or authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.

Quality System: a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

Reporting Limits: the maximum or minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be quantified with the confidence level required by the data user.

Reagent Blank (method reagent blank or method blank): a sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps.

Reference Material: a material or substance one or more of the properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

Reference Method: a method of known and documented accuracy and precision issued by an organization recognized as component to do so.

Reference Standard: a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

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Replicate Analyses: the measurements of the variable of interest performed identically on two or more sub-samples of the same sample within a short time interval.

Sample Duplicate: two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method including sampling and analysis.

Spike: a known mass of target analyte added to a blank sample or sub-sample; used to determine recovery efficiency or for other quality control purposes.

Standard: the document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of TNI and meets the approval requirements of TNI procedures and policies.

Traceability: the property of a result of a measurement whereby it can be related to appropriate standards. Generally international or national standards, through an unbroken chain of comparisons.

Validations: the process of substantiating specified performance criteria.

Work Cell: A defined group of analysts that together perform the method analysis. Members of the group and their specific functions within the work cell must be fully documented. A “work cell” is considered to be all those individuals who see a sample through the complete process of preparation, extraction, or analysis. The entire process is completed by a group of capable individuals; each member of the work cell demonstrates capability for each individual step in the method sequence.

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Appendix II

Standard Operating Procedures Directory

See control document

F-LQA001-Current revision for list of Master List of Standard Operating Procedures

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Appendix III

Analytical Capabilities

Accredited Fields of Testing

DRINKING WATER PARAMETERS

Analytes	Method Number	Program	Chemistry Field
Mercury	EPA 245.1	Drinking Water	Metals Analysis
Metals	EPA 200.8	Drinking Water	Metals Analysis
Metals	EPA 200.7	Drinking Water	Metals Analysis
Chloride, Fluoride, Sulfate & Nitrate	EPA 300.0	Drinking Water	Inorganic Analysis
Nitrate-Nitrite as N	EPA 300.0	Drinking Water	Inorganic Analysis
EDB & DBCP	EPA 504.1	Drinking Water	Organics Analysis
Volatile Organics (Regulated Volatiles)	EPA 524.2	Drinking Water	Organics Analysis
Volatile Organics (THMs)	EPA 524.2	Drinking Water	Organics Analysis
Volatile Organics (Unregulated Volatiles)	EPA 524.2	Drinking Water	Organics Analysis

AIR EMISSIONS

Analytes	Method Number	Program	Chemistry Field
Lead	EPA EQL-0311-196	Air Emissions	Metals Analysis
Semi Volatiles	EPA TO-13A	Air Emissions	Organics Analysis

OILS

Analytes	Method Number	Program	Chemistry Field
PCB's(Aroclor-1016,1221, 1232, 1242, 1248, 1254, 1260, 1262, Total)	EPA 8082A	Oil	Organic Analysis

NON-POTABLE WATER

Analytes	Method Number	Program	Chemistry Field
EDB & DBCP	EPA 504.1	Non-potable water	Organics Analysis
EDB & DBCP	EPA 8011	Non-potable water	Organics Analysis
Formaldehyde	EPA 1667A	Non-potable water	HPLC
Formaldehyde & Acetaldehyde	EPA 8315A	Non-potable water	HPLC
Alkalinity as CaCO3	SM2320 B	Non-potable water	Inorganic Analysis
Ammonia	EPA 350.1 rev 2	Non-potable water	Inorganic Analysis
Ammonia	SM 4500-NH3-H	Non-potable water	Inorganic Analysis
Ammonia as N	EPA 350.1 rev 2	Non-potable water	Inorganic Analysis

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Accredited Fields of Testing

Ammonia as N	SM 4500-NH3 H	Non-potable water	Inorganic Analysis
Biochemical Oxygen Demand	SM 5210 B	Non-potable water	Inorganic Analysis
Carbonaceous BOD (CBOD)	SM 5210 B	Non-potable water	Inorganic Analysis
Bromide, Chloride, Fluoride, Sulfate, Nitrate, & Nitrite	EPA 300.0	Non-potable water	Inorganic Analysis
Bromide, Chloride, Fluoride, Sulfate, Nitrate, & Nitrite	EPA 9056A	Non-potable water	Inorganic Analysis
Chemical Oxygen Demand (COD)	EPA 410.4	Non-potable water	Inorganic Analysis
Chemical Oxygen Demand (COD)	SM 5220 D	Non-potable water	Inorganic Analysis
Chlorine, Total Residual	SM 4500-Cl G	Non-potable water	Inorganic Analysis
Chromium (VI)	SM 3500-Cr D or B)	Non-potable water	Inorganic Analysis
Chromium (VI)	EPA 7196A	Non-potable water	Inorganic Analysis
Color, Apparent or True	HACH 8025	Non-potable water	Inorganic Analysis
Color, Apparent or True	SM 2120 B	Non-potable water	Inorganic Analysis
Kjeldahl Nitrogen – Total	EPA 351.2 rev 2	Non-potable water	Inorganic Analysis
Nitrate/Nitrite	SM 4500-NO_3 E	Non-potable water	Inorganic Analysis
Nitrate/Nitrite	EPA 300.0	Non-potable water	Inorganic Analysis
Nitrite	SM 4500-NO_3 E	Non-potable water	Inorganic Analysis
Nitrite	SM 4500-NO_2 B	Non-potable water	Inorganic Analysis
Oil & Grease, HEM	EPA 1664A	Non-potable water	Inorganic Analysis
Oil & Grease, SGT-HEM, Non-Polar	EPA 1664A	Non-potable water	Inorganic Analysis
Oil & Grease	EPA 9070A	Non-potable water	Inorganic Analysis
Orthophosphate	SM 4500-P E	Non-potable water	Inorganic Analysis
Oxygen, Dissolved	SM 4500-O G	Non-potable water	Inorganic Analysis
pH Hydrogen Ion	SM 4500-H^+ B	Non-potable water	Inorganic Analysis
pH	EPA 9040C	Non-potable water	Inorganic Analysis
Phenols	EPA 420.1or 420.4	Non-potable water	Inorganic Analysis
Total Phenols	EPA 9065	Non-potable water	Inorganic Analysis
Phosphorus	SM 4500-P E	Non-potable water	Inorganic Analysis
Phosphorus-Total	SM 4500-P E	Non-potable water	Inorganic Analysis
Residue, Filterable (TDS)	SM 2540 C	Non-potable water	Inorganic Analysis
Residue, Nonfilterable (TSS)	SM 2540 D	Non-potable water	Inorganic Analysis
Residue, Settable	SM 2540 F	Non-potable water	Inorganic Analysis
Residue, Total	SM 2540 B	Non-potable water	Inorganic Analysis
Residue, Total	SM 2540 G	Non-potable water	Inorganic Analysis

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Accredited Fields of Testing

Residue, Volatile	EPA 160.4	Non-potable water	Inorganic Analysis
Residue, Volatile	SM 2540 E	Non-potable water	Inorganic Analysis
Residue, Volatile	SM 2540 G	Non-potable water	Inorganic Analysis
Total, fixed, and volatile solids (SQAR)	SM 2540 G	Non-potable water	Inorganic Analysis
Salinity	SM 2520 B	Non-potable water	Inorganic Analysis
Specific Conductance	EPA 120.1	Non-potable water	Inorganic Analysis
Specific Conductance	SM 2510 B	Non-potable water	Inorganic Analysis
Sulfide	SM 4500-$S2^-$ D	Non-potable water	Inorganic Analysis
Sulfide	SM 4500-$S2^-$ F	Non-potable water	Inorganic Analysis
Sulfite (SO_3)	SM 4500-SO_3 B	Non-potable water	Inorganic Analysis
Surfactants (MBAS)	SM 5540 C	Non-potable water	Inorganic Analysis
Turbidity	EPA 180.1	Non-potable water	Inorganic Analysis
Metals, Total – Water	EPA 200.7	Non-potable water	Metals Prep
Metals, Total – Water	EPA 200.8	Non-potable water	Metals Prep
Metals, Total – Water	SW846 3010A	Non-potable water	Metals Prep
Metals, Total – Water, Rec. & Dissolved	SW846 3005A	Non-potable water	Metals Prep
Metals, Total – Water	SW846 3015A	Non-potable water	Metals Prep
Hardness, Total as $CaCO_3$	EPA 200.7	Non-potable water	Metals Analysis
Hardness, Total as $CaCO_3$	SM 2340 C	Non-potable water	Metals Analysis
Mercury	EPA 245.1	Non-potable water	Metals Analysis
Metals, ICP	EPA 200.7	Non-potable water	Metals Analysis
Metals, ICP	EPA 6010C or 6010D	Non-potable water	Metals Analysis
Metals, ICP/MS	EPA 200.8	Non-potable water	Metals Analysis
Metals, ICP/MS	EPA 6020A or 6020B	Non-potable water	Metals Analysis
Mercury, Liquid Waste	SW846 7470A	Non-potable water	Metals Analysis
Base/Neutrals and Acids	EPA 8270D or 8270E	Non-potable water	Organic Analysis
Base/Neutrals and Acids	EPA 625.1	Non-potable water	Organics Analysis
Extractable Petroleum Hydrocarbons MA & RECAP EPH	MADEP EPH	Non-potable water	Organics Analysis
Purgeable Aromatics	EPA 602	Non-potable water	Organics Analysis
Volatile Organics	EPA 624.1	Non-potable water	Organics Analysis
Volatile Organics	EPA 8260B or 8260D	Non-potable water	Organics Analysis
Volatile Petroleum Hydrocarbons	MADEP VPH Rev.2.1	Non-potable water	Organic Analysis
Coliform, Fecal (Count per 100 mL)	SM 9222 D	Non-potable water	Microbiology

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Accredited Fields of Testing

Coliform, Total (Count per 100 mL)	SM 9222 B	Non-potable water	Microbiology
Heterotrophic Plate Count	SM 9215 D	Non-potable water	Microbiology
Enterococci	SM 9230 D-2007 (ENTEROLERT METHOD)	Non-potable water	Microbiology
PCB's(Aroclor-1016,1221, 1232, 1242, 1254, 1260, 1262, Total)	EPA 8082A	Non-potable water	Organic Analysis

SOLID CHEMICAL MATERIALS

Analytes	**Method Number**	**Program**	**Chemistry Field**
Acetaldehyde & Formaldehyde	EPA 8315A	Solid Chemical Materials	HPLC
Bromide, Chloride, Fluoride, Sulfate, Nitrate, Nitrite	SW846 9056A	Solid Chemical Materials	Inorganic Analysis
Total Coliforms	SM 9222B (m-Endo)	Solid Chemical Materials	Microbiology
Fecal Coliforms	SM 9222D (m-FC)	Solid Chemical Materials	Microbiology
Heterotrophic Plate Count	SM 9215D (PCA)	Solid Chemical Materials	Microbiology
Nitrite as N	SM 4500-NO2 B-2011	Solid Chemical Materials	Inorganic Analysis
Nitrate as N	SM 4500-NO3 E-2011	Solid Chemical Materials	Inorganic Analysis
Chlorine	SM 4500-Cl G-2011	Solid Chemical Materials	Inorganic Analysis
Cation, Exchange Capacity	SW846 9081	Solid Chemical Materials	Inorganic Analysis
Chromium VI	SM 3500-CR B-2011	Solid Chemical Materials	Inorganic Analysis
Chromium (VI)	SW846 7196A	Solid Chemical Materials	Inorganic Analysis
Corrosivity/pH, >20% H2O	SW846 9040C	Solid Chemical Materials	Inorganic Analysis
Oil & Grease and Sludge, HEM	SW846 9071B	Solid Chemical Materials	Inorganic Analysis
pH, Hydrogen Ion	SW846 9040C	Solid Chemical Materials	Inorganic Analysis
pH, Hydrogen Ion, Waste, >20% Water	SW846 9040C	Solid Chemical Materials	Inorganic Analysis

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Accredited Fields of Testing

pH, Soil and Waste	SW846 9045D	Solid Chemical Materials	Inorganic Analysis
Phenols	SW846 9065	Solid Chemical Materials	Inorganic Analysis
SPLP Metals/Organics	SW846 1312	Solid Chemical Materials	Leachate
TCLP Metals/Semi Volatile Organics	SW846 1311	Solid Chemical Materials	Leachate
TCLP Volatile Organics	SW846 1311	Solid Chemical Materials	Leachate
Metals, Solids	SW846 3050B	Solid Chemical Materials	Metals Prep
Metals, Solids	SW846 3051A	Solid Chemical Materials	Metals Prep
Mercury, Solid Waste	SW846 7471B	Solid Chemical Materials	Metals Analysis
Metals by ICP	SW846 6010D	Solid Chemical Materials	Metals Analysis
Metals by ICP	SW846 6010C	Solid Chemical Materials	Metals Analysis
Metals by ICP/MS	SW846 6020A	Solid Chemical Materials	Metals Analysis
Metals by ICP/MS	SW846 6020B	Solid Chemical Materials	Metals Analysis
Microwave Extraction	SW846 3546	Solid Chemical Materials	Organics Prep
Semi volatile Prep, Waste Dilution	SW846 3580A	Solid Chemical Materials	Organics Prep
Semi volatile Prep Solid, Sonication	SW846 3550C	Solid Chemical Materials	Organics Prep
Semi volatile Prep Solids, Soxhlet	SW846 3541	Solid Chemical Materials	Organics Prep
Semi volatile Prep Water	SW846 3510C	Solid Chemical Materials	Organics Prep
Semi volatile Prep Water	SW846 3511	Solid Chemical Materials	Organics Prep
Semi volatile Prep Water	SW846 3570	Solid Chemical Materials	Organics Prep
Volatile, Purge & Trap, Solids–High	SW846 5035B	Solid Chemical Materials	Organics Prep

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Accredited Fields of Testing

Volatile, Purge & Trap, Solids–Low	SW846 5035B	Solid Chemical Materials	Organics Prep
Volatile, Purge & Trap, Water	SW846 5030B	Solid Chemical Materials	Organics Prep
Aromatic/Halogenated Volatile	SW846 8021B	Solid Chemical Materials	Organics Analysis
Base/Neutrals and Acids	SW846 8270D	Solid Chemical Materials	Organics Analysis
Base/Neutrals and Acids	SW846 8270E	Solid Chemical Materials	Organics Analysis
EDB & DBCP	SW846 8011	Solid Chemical Materials	Organics Analysis
Diesel Range Organic	SW846 8015C	Solid Chemical Materials	Organics Analysis
Extractable Petroleum Hydrocarbons – MA	MA EPH	Solid Chemical Materials	Organics Analysis
Gasoline Range Organic	SW846 8015C	Solid Chemical Materials	Organics Analysis
Polynuclear Aromatic Hydrocarbons	SW846 8270D	Solid Chemical Materials	Organics Analysis
Polynuclear Aromatic Hydrocarbons	SW846 8270E	Solid Chemical Materials	Organics Analysis
Volatile Organics	SW846 8260B	Solid Chemical Materials	Organics Analysis
Volatile Organics	SW846 8260D	Solid Chemical Materials	Organics Analysis
Moisture Content	ASTM D2216	Solid Chemical Materials	Inorganic Analysis
Cation Exchange Capacity (CEC)	LDNR 29B	Solid Chemical Materials	Inorganic Analysis
Electrical Conductivity (EC)	LDNR 29B	Solid Chemical Materials	Inorganic Analysis
Exchangeable Sodium Percentage (ESP)	LDNR 29B	Solid Chemical Materials	Metals Analysis
Leachate Test	LDNR 29B	Solid Chemical Materials	Extraction Procedure
Oil and Grease (LDNR 29B)	LDNR 29B	Solid Chemical Materials	Inorganic Analysis
Sodium Absorption Ration (SAR)	LDNR 29B	Solid Chemical Materials	Metals Analysis

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Accredited Fields of Testing

Soluble Cation Extraction Procedure	LDNR 29B	Solid Chemical Materials	Extraction Procedure
True Total Barium	LDNR 29B	Solid Chemical Materials	Metals Analysis
PCB's(Aroclor-1016,1221, 1232, 1242, 1254, 1260, 1262, Total)	EPA 8082A	Solid Chemical Materials	Organic Analysis

Method Capabilities—Non-Accredited Methods

Analytes	Method Number	Program	Chemistry Field
Redox Potential vs H^+	ASTM D1498-76	Non-potable water	Inorganic Analysis
Volatile Suspended Solids	EPA 160.4	Non-potable water	Inorganic Analysis
Chemical Oxygen Demand	HACH 8000M	Solid Chemical Materials	Inorganic Analysis
Redox Potential vs H^+	ASTM D1498-76M	Solid Chemical Materials	Inorganic Analysis
Total Plate Count	SM 9215BM	Solid Chemical Materials	Inorganic Analysis
Total Volatile Solids	EPA 160.4M	Solid Chemical Materials	Inorganic Analysis
Extractable Petroleum HCs	Massachusetts EPH	Solid Chemical Materials	Organics Analysis
Volatile Petroleum HCs	Massachusetts VPH	Solid Chemical Materials	Organics Analysis

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ISO 17025 Accredited Fields of Testing

Environmental		
MATERIAL/MATRIX	**METHOD REFERENCE**	**METHOD TITLE**
Drinking Water, Wastewater, Natural Water, Water for Industrial Use, Sea Water, Saltwater and Brackish Water, Surface Water, Groundwater	SM 4500-H^+ B (2011)	Ph
	SM 2540 D (2011)	Total Suspended Solids (TSS)
	EPA 300	Determination of Inorganic Anions by Ion Chromatography (Nitrogen, Nitrate + Nitrite only)
	EPA 200.8	Determination of Trace Elements in Waters and Wastes by Inductively Coupled Plasma-Mass Spectrometry
	EPA 245.1	Determination of Mercury in Water by Cold Vapor Atomic Absorption Spectrometry
	EPA 8015C	Nonhalogenated Organics by Gas Chromatography (Diesel Range Organics (DRO) and Total Petroleum Hydrocarbons (TPH) only)
	EPA 8270D	Semi-volatile Organic Compounds by Gas Chromatography/Mass Spectrometry (Polynuclear Aromatic Hydrocarbons (PAHs) only)

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Appendix IV

Laboratory Equipment List

See F-LQA319 current revision for current list of Analytical Laboratory Equipment

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Appendix V

Certification Summary

Certifying Authority	Certification Program	Registration No.
Alaska (DEC-CS-LAP)	Air/Emissions, Non-Potable Water, Soil/Solid/Haz Waste/Chemical Materials	23-001
Arizona (DoH)	Soil/Solid/Haz Waste/Chemical Materials, Non-Potable Water, Potable Water	AZ0805
Arkansas (DEQ)	Soil/Solid/Haz/Chemical Materials, Trace, Non-Potable Water	20-056-0
California (Water Board)	Non-Potable Water, Soil/Solid/Haz Waste/Chemical Materials	3093
Colorado Division of Oil & Public safety	Non-Potable Water, Soil/Solid/Haz Waste/Chemical Materials	n/a
Florida (DoH) (NELAP)	Non-Potable Water, Soil/Solid/Haz Waste/Chemical Materials	E87657
Illinois (EPA)	Non-Potable Water, Soil/Solid/Haz Waste/Chemical Materials	200082
Louisiana (DHH) (NELAP)	Potable Water, Trace	LA025
Louisiana (LDEQ)	Non-Potable Water, Soil/Solid/Haz Waste/Chemical Materials, Tissue	02048
New Jersey (NJDEQ) (NELAP)	Non-Potable Water, Soil/Solid/Haz Waste/Chemical Materials	LA007
North Carolina (DoWR)	Non-Potable Water, Soil/Solid/Haz Waste/Chemical Materials	487
North Dakota (State Health Dept)	Non-Potable Water, Soil/Solid/Haz Waste/Chemical Materials	R-224
Oklahoma (DEQ) (NELAP)	Non-Potable Water, Soil/Solid/Haz Waste/Chemical Materials	1707-2021--099
South Carolina (DoH)	Non-Potable Water, Soil/Solid/Haz Waste/Chemical Materials	73004001
Texas (TCEQ) (NELAP)	Non-Potable Water, Soil/Solid/Haz Waste/Chemical Materials	T104704186-21-20
Washington (WA DOE)	Air/Emission	C1098
ISO/IEC 17025: 2017	Water Matrix, See Appendix III	TL-1159

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Quality Manual

2790 Whitten Road Memphis TN 38133
(901) 213-2400 (901) 213-2440 fax
www.waypointanalytical.com

The Quality Manual has been prepared for the sole use of Waypoint Analytical, LLC.

1 Quality Mission Statement

The goal of Waypoint Analytical, LLC (WA) is to provide its clients with data of the highest quality, integrity, accuracy, precision and defensibility. To achieve this goal, the management of Waypoint Analytical commits its support to the establishment and full implementation of the policies and procedures described in this Quality Manual and in supporting documents. This Quality Manual describes the established Quality System in meeting this commitment. This Quality System applies to all personnel. Management recognizes that this Quality System is an essential element of our business for sustaining profitability with the dedicated support of our personnel and clients. This Quality System governs specific quality control standard operating procedures documented in this Quality Manual which enables this laboratory to achieve the maximum accuracy of reported results. In addition, this Quality System complies with all regulations and requirements of the 2016 TNI Standard, EPA and other federal and state regulatory agencies. Management is committed to good professional practice, the quality of environmental testing in service to clients, and complying with the 2016 TNI Standard as applicable. Management and all employees are committed to acceptable laboratory practices and to the quality of testing services. Refer to Section 6.1 of this Quality Manual for further information on the Quality System.

Nathan A. Pera, IV

President

1.1 Management Review and Authorization

The following individuals attest that the information provided in this Quality Manual to be true and an accurate representation of the policies and procedures of Waypoint Analytical, LLC. Further, the following individuals are authorized to enter data and sign or initial laboratory records and are recognized approved signatories. All individuals listed below may be contacted at (901) 213-2400.

President

Signature: Nathan A Pera IV Digitally signed by Nathan A Pera IV Date: 2025.06.16 11:04:36 -05'00' 06/16/2025

Name: Nathan A. Pera, IV Date

Chief Technical Officer

Signature: Michael T. Kauffman Digitally signed by Michael T. Kauffman Date: 2025.06.16 11:06:10 -05'00' 06/16/2025

Name: Michael T. Kauffman Date

Chief Quality Officer

Signature: Richard Medina Digitally signed by Richard Medina Date: 2025.06.06 15:08:09 -05'00' 06/06/2025

Name: Dr. Richard Medina Date

1.2 Distribution Control

Distribution Copy No. _____

1.3 Amendments

None.

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3 Introduction

This Quality Manual (QM) describes the Quality System established for use by Waypoint Analytical, LLC, (formerly Waypoint Analytical, Inc.), and has adopted the procedures and policies established in this document. This manual and its procedure and policies also serve as a standard for its subsidiary laboratories located throughout the United States. This document and associated Quality System documents are written in the declarative grammatical mood for ease of readability. The use of this grammatical mood declares the description of the laboratory's Quality System in the present tense. This Quality Manual and associated quality documents indicate the requirements from the most current promulgated version until it is subjected to revision and superseded by the updated revision with a new effective date. Occasionally, this document contains sentences in the imperative grammatical mood to provide emphasis to a critical requirement. The word 'shall', used as an auxiliary verb in these imperative sentences denotes a requirement for both the present and the future. Waypoint Analytical, LLC (WA) interpretation of the word 'shall' is not limited to only future commitment as it is in everyday usage. Likewise, the word 'must' denotes a requirement for both the present and the future. The auxiliary verbs 'should' or 'may', which are used sparingly in the text, allow some discretion in the execution of the stated activity but are used to delineate strongly recommended actions or as indicated by reference methods.

This QM provides employees, clients, subcontractors and accrediting agencies with information about how the Quality System operates within the laboratory. The Quality System includes Quality Assurance, Quality Control measures, and laboratory systems including feedback mechanisms for continuous improvement to meet client and/or regulatory requirements.

Implementation of the Quality System is accomplished by documenting procedures, training personnel and reviewing operations for compliance and improvement. The Quality System procedures are contained within this QM and in auxiliary analytical and administrative Standard Operating Procedures (SOPs). The QM and SOPs are available to all laboratory staff as hard copies and in read-only electronic form. The provisions of the Quality System are binding on all temporary and permanent laboratory personnel. All laboratory personnel must adhere strictly to the QM and SOPs.

The QM is composed of sixteen (16) sections that provide overview descriptions of laboratory, policies, procedures, operations and the program defined by the laboratory for Quality Assurance and Quality Control activities. Additional sections are provided as Appendices.

The QM describes the Quality System components of WA to demonstrate competency in the operations for performing environmental analyses. The foundation for the analytical procedures are the methods published by the United States Environmental Protection Agency (EPA), US Army Corps of Engineers, ASTM, AOAC, NIOSH, and other procedures including those supplied by clients and state regulators. This Quality System is based on the 2016 TNI Standard as applicable and other requirements of accrediting authorities.

The QM includes requirements and information for assessing competence and determining compliance by the laboratory to the Quality System. When more stringent standards or requirements are included in a mandated test method, by regulation, or specified in a project plan, the laboratory shall demonstrate these requirements through its procedural and documented processes.

The Quality Manual has been prepared for the sole use of Waypoint Analytical, LLC.

The Quality Manual is for the sole use by WA for developing, implementing, and maintaining the Quality System. Accrediting authorities and regulators use the Quality Manual as a guide to monitor the Quality Systems of Waypoint Analytical, LLC.

3.1 References

Solid Waste Manual, SW-846 Update III, December 1996 and published updates.

Standard Methods for the Examination of Water and Wastewater.

Methods for Chemical Analysis of Water and Wastes, EPA –600/4-79-020, March 1983.

Manual for the Certification of Laboratories Analyzing Drinking Water, 5th Ed, January 2005.

Laboratory Procedures for Analysis of Exploration and Production Waste, Louisiana Department of Natural Resources, Office of Conservation, Injection and Mining Division, November 2011.

TNI Standard, 2016 Standard.

40 CFR Part 136 Appendix B, April 16, 2024

40 CFR Part 141, May 26, 2021

EPA Guidance for Preparing Standard Operating Procedures (SOPs), EPA QA/G-6, EPA/240/B-01/004, March 2001.

EPA 2185 – Good Automated Laboratory Practices (GALP).

A register of current promulgated reference documents and manuals are available for staff to determine the latest edition or version of the reference methods, regulations or national standards.

3.2 Definitions

Appendix A lists definitions as adopted by the laboratory. The definitions are derived from the 2016 TNI Standards. The definitions are reviewed and updated, as necessary, after publication of updated versions of the TNI-adopted Glossary.

4 Organization and Management

4.1 Legal Definition of Laboratory

This Quality Manual is applicable to the laboratory located at 2790 Whitten Road, Memphis, Tennessee. The laboratory is a privately held limited liability company in the State of Tennessee.

Waypoint Analytical, LLC was formerly the result of a joint venture of two established independent laboratories whose sum analytical experience total over 60 years. A&L Analytical Laboratories, Inc. and Environmental Testing and Consulting, Inc., joined forces in 2004 and became singly Waypoint Analytical, Inc. in 2015. Combining these two laboratories into a single laboratory allows for centralized analytical services. In 2018, a significant share of the company was acquired by Nutrien, Ltd., and is domiciled in Delaware as an LLC with headquarters in Memphis, TN. The laboratory was fully acquired in 2023. Presently, Waypoint Analytical, LLC serves:

Consulting firms
Engineering firms
Waste management companies
Industrial and wastewater treatment facilities
Government and state agencies
Private sector
Universities and R&D organizations and
Other commercial businesses

Waypoint Analytical, LLC has acquired and has direct over-sight of the operational activities of several other environmental and agricultural laboratories located in the continental United States. Refer to the corporate structure organizational chart as a separate document for a complete listing of its subsidiaries.

4.2 Organization

The laboratory operates a Quality System approach to management in order to produce data of known quality and integrity. The laboratory organization provides effective communication and lines of authority to produce analytical data meeting regulatory and client specifications. The organizational design provides open communication while ensuring that undue pressures and day-to-day operations do not compromise the integrity and authenticity of generated reportable data. This management structure is organized in such a way that confidence in the laboratory's independence of judgment and integrity is maintained at all times. This structure has been established so that adequate supervision is available for all employees. Waypoint Analytical, LLC attempts to maintain a low supervisor to employee ratio. It is believed that with a strong supervisory structure the quality objectives of the laboratory can be achieved. Further, this structure is highly interactive in that each member of management is kept informed of the daily operations of the laboratory.

As required under employee qualification requirements, supervisors and managers employed by WA are familiar with all the testing procedures and quality control requirements for which the employees they supervise are responsible. Supervisors possess knowledge, training and experience necessary to train and educate new employees to perform these tests. Further, they are capable of monitoring the performance of these tests to ensure that they are performed correctly. All employees who generate data understand the necessary calculations required to transform raw data into final results, the necessary quality control checks that must be performed and the acceptable limits. Laboratory supervisors are capable of troubleshooting problems and instrumentation, and are able to assist analysts with samples that pose difficulty or require non-routine analytical techniques.

As the operations of the laboratory may demonstrate flux and may change occasionally, it is important that the structure and organization of the laboratory change as well. Such changes may take place at any time. However, the need for such changes may be evident following internal audits and managerial review. At this managerial review, the laboratory management will review the need to need to alter the structure of the laboratory. Indicators that might suggest this need may include, for example, a significant increase in the volume of sample load or required analyses, an increase or change in the documentation or quality control checks required or required holding time or analysis due date.

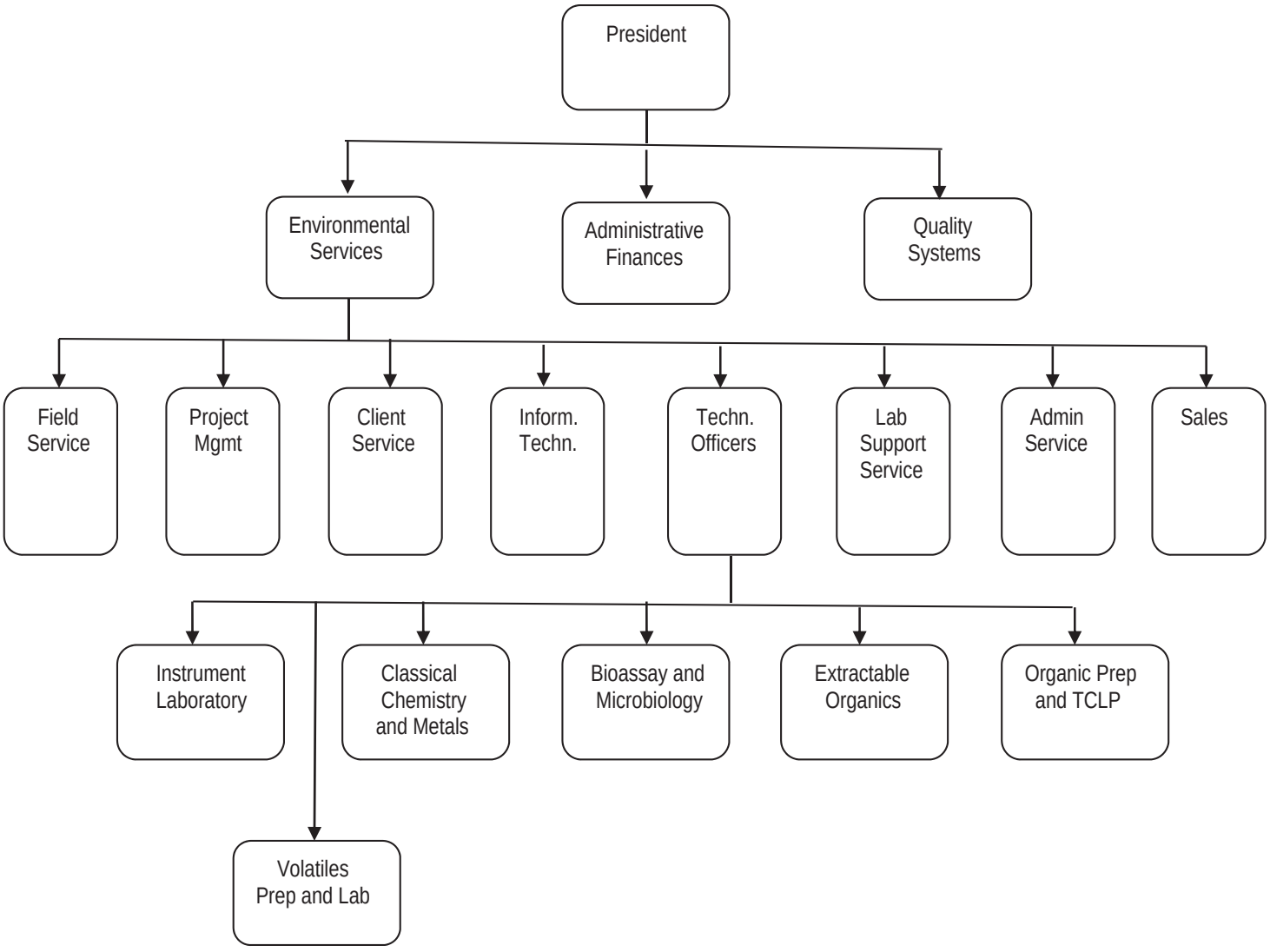
As indicated above, the Quality System that has been established at WA affects every operation of the laboratory. A graphical representation of this organization is found in the following page. A detailed and complete discussion of this interaction is provided throughout this quality manual, however a general description is given here.

In the event that there are changes in laboratory name, ownership, location, personnel, facilities, methodology, or any factors significantly affecting the performance of analyses for which the laboratory was originally accredited by its primary NELAP accrediting body, LA DEQ, it shall be reported to their Office of Environmental Assessment within 30 days. This shall include in any aspect of its status or operation including resources and premises.

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Waypoint Analytical, LLC.

Organizational Chart



4.3 Business Practices

WA maintains certifications and accreditations for the applicable programs as required. A complete listing of various certifications and validations from multiple accreditation programs are available upon request. WA is open for normal business operations Monday through Friday from 8:00 a.m. to 5:00 p.m. CST. The laboratory operates a second shift Monday through Friday and also maintains shifts on Saturday and Sunday. Sample delivery occurs during normal business and Saturday morning unless arranged in advance. Management prepares the annual holiday schedule for the year indicating the closed days of operations.

WA's reputation depends on timely reporting of quality data. The standard turnaround time for samples from engineering and consulting firms is project specific and is indicated in the Quality Assurance Project Plan or contractual agreements. Standard turnaround that is not project specific is seven to ten business days from time of sample receipt, unless restricted by sample holding time. The time of sample receipt is verified upon meeting sample acceptance policy and is documented on the Chain of Custody or Shipment Receipt Form, where applicable. Laboratory project management staff must approve any special arrangements such as RUSH services, non-routine methods or lower than normal reporting limits. The basis for data quality depends on client, regulation or reference method performance criteria. Representiveness, accuracy, precision, completeness, sensitivity and comparability are expressions of method performance criteria.

All work is performed in the strictest confidence. New and any contract employees must review corporate confidentiality policy and protect client confidentiality and proprietary rights. The policy review occurs during orientation and ethics training. It is the policy of the laboratory to release data only to client-authorized contacts. Personnel authorized in interacting with clients may only review project files and discuss data related to the project. Personnel whose duties do not include routine client contact must obtain approval from management before discussing data with regulators or third parties approved by the client. Clients must provide written authorization to discuss any details of their analytical results or project data with another party.

4.4 Laboratory Ethics Program

WA is committed and dedicated to providing only the highest quality analytical data possible to its clients. Data produced, managed and reported must meet the requirements of its clients and comply with the letter and spirit of the various municipal, state and federal regulations and guidelines. Protocols and procedures are based primarily on EPA guidelines for the analysis of multimedia samples for a broad range of constituents. WA's Quality System encompasses the requirements for producing and reporting data of known and documented quality to its clients. It is understood that data is used by clients to make rational, confident, cost-effective decisions regarding assessment and resolution of their environmental compliance requirements and other management activities.

It is the policy of WA to incorporate the highest standards of quality in all analytical programs by adhering to the following practices:

A. WA must only offer environmental analyses for which it can consistently demonstrate compliance with high quality, traceable and scientifically defensible performance standards;

B. WA's staff are committed to the practice of complete honesty in the production and reporting of data;

C. WA's staff that are aware of misrepresentation of facts regarding analytical data, or the unauthorized manipulation of data, are required to immediately inform the Chief Quality Officer, Chief Technical Officer and/or President.

D. WA operates under an *Open Door Policy* that enables every staff member to have free access to the corporate officers. This *Open Door Policy* is intended to foster two-way communication and encourage each staff member to carefully consider their duty and responsibility to report inappropriate data production and reporting practices to the corporate leadership. It is clearly understood that such information brought forth shall be treated confidentially, if so requested by the reporting staff member.

The *Ethical Conduct and Data Integrity Agreement* is signed at the time of hire. Furthermore, each staff member is required to read and acknowledge their support of the laboratory's Ethics Program and undertake annual refresher ethics training. Such commitment is a condition of continued employment at Waypoint Analytical, LLC. Failure to comply with these requirements may result in immediate discharge from WA employment. The *Ethical Conduct and Data Integrity* Agreement supports the company's *Employment Agreement Policy* and *Laboratory Ethics Program.*

The Laboratory Ethics Program establishes the laboratory's commitment in the generation of quality data under the premise of high ethical standards. The ultimate goal of this Program is to generate analytical information that is both accurate and legally defensible while meeting the needs of the end user without compromising established laboratory procedures and policies. The Ethics Program directs laboratory employees at all phases of operations in nurturing a strong and pro-active approach towards ethical conduct. The Program also outlines overall laboratory conduct and ethical practices in the supporting activities associated with the generation of analytical data. Details may be found in the laboratory's Ethics Program document.

Annual ethics training is conducted under the supervision of the QA Office. Evidence of training and acknowledgement is found in employee training records.

5 Personnel

5.1 Laboratory Management Responsibilities

Management is responsible for communicating the requirements of the Quality System, client specifications and regulatory needs to all personnel. Management is responsible for reviewing the client/project needs and providing the manpower and resources needed to complete the work. All personnel are responsible for complying with all QA/QC requirements that pertain to their function. Job descriptions detail the responsibilities of each position.

The Quality Assurance Office maintains job descriptions for all positions in the laboratory defining the level of qualifications, training, and experience and laboratory skills. During initial training, management provides documented operations procedures, observes personnel performance, and evaluates personnel proficiency. Management documents laboratory staff's proficiency initially and on a continuing basis through use of method performance procedures and proficiency testing samples. Corrective Action for noncompliance results is re-evaluation, retraining and re-testing until proficiency is established. Management requires successful proficiency demonstration before allowing independent production testing.

Management is responsible for verification of proper sample management and all aspects of data quality and reporting. The communication of the operating practices of the laboratory is through the document control and acknowledgement processes.

It is the responsibility of all analysts and the Management team to ensure the production of quality data. Further, when any member of the analytical team including managers and supervisors observes an analytical output that may be suspect, based on technical experience, deviation from historical data, failures in quality control or non-compliances, then they have the authority to cease work. All observations derived for making this decision must be fully documented and be made known to the supervisor responsible for the analytical section. A Supervisor assessment will verify that cease work is justified and that corrective measures are implemented in order to resume work. Only through this supervisional assessment process and the appropriate corrective action(s) undertaken can work continue. Corrective action measures are dependent on the type and complexity of the infraction observed and the adequacy of laboratory responsiveness.

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Executive Management

President, Environmental Division - Nathan A. Pera has over 40 years' experience in laboratory operations and project management. He has completed course work in chemistry/computer science at Christian Brothers University and University of Memphis in Memphis, TN.

Mr. Pera is responsible for daily environmental laboratory operations with a primary responsibility of ensuring that the company is prepared to accept and execute environmental projects for laboratory analysis. He also directly manages client services and project management and is a senior level project manager.

His project management responsibility begins as client liaison and extends through developing management plans that will ultimately present the client with valid data in an acceptable format. As project manager, Mr. Pera initiates project management plans for client specific projects. The plans include all project specific criteria such as detection limits, reporting formats and deliverables, turnaround times and methodology requirements. These project criteria are then relayed and implemented throughout the laboratory.

Mr. Pera has managed large multidisciplinary environmental projects for programs such as the Department of Defense (DOD), US Army Corps of Engineers (USACE), Air Force (AFCEE) and Superfund (EPA) as well as corporate client programs.

President, Ag Division - Chris Langford has 29 years of experience in laboratory operations, systems design and coding experience. He received his B.S. in Computer Science from Christian Brothers University in Memphis, TN in 1989.

Mr. Langford is responsible for the daily operations of the agricultural laboratory, administrative personnel and lab support activities. Mr. Langford works with agricultural lab personnel on a daily basis to ensure that clients receive accurate results in a timely manner. All operational needs are determined and supplied to ensure that lab staff is completely equipped.

Mr. Langford also oversees adjunct administrative operations of WA including IT (information technology) and corporate business as applicable.

Chief Financial Officer – As CFO, Michael Sterling is responsible for all accounting oversight including general ledger, taxation and reporting matters. Mr. Sterling is also involved in insurance, financing and employee benefit matters as well as mergers and acquisition opportunities.

Director of Environmental Operations – George Dunlap oversees the environmental operations at all of Waypoint's locations that engage in environmental testing. This includes the overall performance of the labs, personnel decisions, and assuring that client needs and expectations are being met in regards to quality of data and turnaround times. Mr. Dunlap has been with the laboratory for 35 years and extends his expertise on laboratory operations.

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Chief Technical Officer - Michael T. Kauffman has over 40 years of experience in laboratory operations, analyses, methods development and laboratory and project management. He is familiar with the analytical and QA/QC protocols of EPA CLP, SW-846, and Methods for Chemical Analysis of Water and Wastes. He received his B.S. in Chemistry from Christian Brothers University Memphis, TN in 1983.

Mr. Kauffman is responsible the day-to-day supervision of technical laboratory operations. These include monitoring standards of performance in quality control and quality assurance and monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data.

As Chief Technical Officer, Mr. Kauffman

- Is responsible for all technical operational activities of the laboratory.
- Plans and implements laboratory strategies and makes recommendations to management.
- Final approval of all data and ensures the quality data is technically valid.
- Provides technical service to all laboratory personnel and supports sales staff through technical expertise.
- Ensures that all analytical practices are technically sound.
- Development, implementation and updating of laboratory standard operating procedures (SOPs) which includes establishment of Method QA/QC criteria.
- Ensuring that all technical aspects of methods are performed according to standard operating procedures and references method.
- Implementation of project management plans as defined by the project manager.

Assistant Technical Director - Jimmy Ferguson has over 25 years of experience performing a wide variety of laboratory procedures in both the environmental area as well as agricultural. He received his B.S. in Environmental Science from Delta State University in 1998.

Mr. Ferguson assists the technical director in the day-to-day supervision of technical laboratory operations. These include monitoring standards of performance in quality control and quality assurance, monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data.

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Chief Quality Officer - Dr. Richard Medina has 35 years' experience in laboratory operations and 33 years' experience as Chief Quality Officer. He received his B.A. in Biology from Austin College in Sherman, TX and a Doctoral of Dental Surgery from University of Tennessee in Memphis, TN in 1989.

Dr. Medina is responsible for implementing and maintaining the Quality System for the entire laboratory. He works independently of the laboratory production management, has a thorough knowledge of the analytical test methods and reports directly to the President. His office serves as the focal point for QA issues, performs oversight and QA review for all nonconformance reports, and performs independent QA review for a percentage of laboratory analytical batches and project data packages.

In addition, Dr. Medina is responsible for all audits, internal and external, conducted at this facility. He will report and initiate corrective action responses to any audit findings and ensure that these corrections are implemented through follow-up monitoring. Additionally, Dr. Medina will:

- Assist the President with design of the Quality Systems and makes recommendations that will improve the effectiveness of the Quality Systems for WA and its subsidiaries.
- Report to management the status of the Quality System including deficiencies.
- Perform internal Quality System audits. These include submitting blind (system audit) PE samples as well as the auditing of support documentation, personnel and facilities. Audit findings and conclusions are relayed to President for review and subsequent action.
- Coordinate external audits requested by clients and regulatory agencies and maintain applicable certifications and validations.
- Acts as liaison between the laboratory and certifying and auditing agencies.
- Review and approval of all Administrative Standard Operation Procedures (SOPs).
- Assists the President in providing an objective review of final report packages as needed.
- Monitors all Corrective Action Reports generated during the execution of analytical performance testing projects.
- Oversees the archiving all physical data and supporting documents.
- Implementation and maintenance of the laboratory's Waste Management Program and Health and Safety Plan.
- Responsible for maintenance of the Quality Manual, SOP's and forms.
- Oversees and directs the QA Supervisor and QA Administration Coordinator.
- Has direct oversight and guidance of the Quality Systems and the quality managers of the corporates subsidiary laboratories where warranted.

In the absence of the Chief Quality Officer, the Quality Assurance Supervisor and or the President may act in behalf of the Chief Quality Officer.

Quality Assurance Manager – Seth Sumrow acts as the QA Manager and assists the CQO in PT data review and internal audits, maintains oversight of corrective action activities, and in implementation and maintenance of all Quality System activities. Under the direction of the CQO, the QA Manager orders Performance Testing Samples. The QA Manager reports to the Chief Quality Officer. The QA Manager also assists the CQO with waste management and the lab's radiological program and also assists and guides the corporate's subsidiary laboratories in QA matters as needed.

The QA Administration Coordinator supervises daily balance, thermometer and Eppendorf/variable pipettor calibration verifications and the daily monitoring of the laboratory water supply. The QA Supervisor is responsible for the archiving of Quality System documents such as completed logbooks and is responsible for maintenance and updating of employee training records and assists with the laboratory's safety program.

The Chief Quality Officer, QA Manager and QA Administration Coordinator collectively comprise the Quality Assurance Unit, QAU.

Project Manager - Randall H. Thomas has 44 years of environmental laboratory experience and managing environmental laboratory programs. He received his B.A. in Accounting from Memphis State University in Memphis, TN in 1985. Mr. Thomas also oversees the sample collection activities performed by the field crew and coordinates and schedules sampling events with clients.

Project Managers – An assigned Project Manager will support and provide guidance to clients related to sample analysis and reporting. In coordination with the Client Services Department the Project Manager will act as a liaison between the laboratory and the client related to completing project requirements. Additionally, the Project Manager's responsibilities include the following:

- Review of scope of work, when available, detailing client requirements and translating those requirements to the LMS and laboratory personnel.
- Delivery of reports to the client and ensuring that client reporting requirements are met. Processing of final reports including a completeness review that ensures all pertinent information from the chain-of-custody is included.
- Interface with clients concerning price quotations and review of project invoices to ensure that the client is properly invoiced. Daily communication with sales staff to monitor quotations and prospective project status.
- Coordinating field activities for clients that require sampling and/or courier services
- Assists the laboratory managers and supervisors in project implementation, oversight and delivery of the final report.

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Chief Operations Officer – As Chief Operations Officer, Sam Hanson coordinates daily laboratory operations. This includes managing operations related to sample analyses, employee resources, assessing laboratory area efficiencies, employee training, data disposal and resource allocations. The overall goal of his responsibilities is to facilitate the efficient and coordinated efforts within the analytical areas in completing tasks such as the completion of analyses and project requirements. The Chief Operations Officer is supported by laboratory supervisors.

Laboratory Supervisors - Responsible for data review, personnel training and implementation of the documented procedures defined by the laboratory. Laboratory supervisors provide input on technical and personnel needs to the Chief Technical Officer.

Laboratory supervisor responsibilities include:

- Supervising all activities within their section from instrument maintenance to execution of analytical projects and review of analytical data.
- Ensuring implementation of the QA/QC plan within this section.
- Providing technical support for analysts when questions or problems arise concerning sample preparation and/or analysis.
- Reporting all non-conformance issues to the Chief Technical Officer and initiation of corrective action reports.
- Training of new analysts.

Client Services Manager – The Client Services Manager is responsible for client services, sample management and directing information between the client and laboratory management. Client services works closely with project managers and handles the majority of routine events. Client services coordinates sample reception, log-in and logistical activities of the laboratory and acts as a primary customer point of contact. They ensure that testing and other services are performed in a timely manner by providing the project managers and laboratory managers input and includes recommendations concerning client issues and complaints. The client services manager supervises clerical support staff and assists sales staff in effective customer service. Responsibilities include oversight and direction of sample receiving; project implementation and client phone calls and email correspondences.

Chief Information Officer – The Chief Information Officer is responsible for the proper operation of all hardware and software applications including, maintenance of existing applications, installation and maintenance of computer hardware, daily maintenance and administration of the network, workstations, and all servers. Communicates daily with all information technology staff to ensure the individual components of all computer systems are functioning properly and efficiently.

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5.2 Laboratory Staff Requirements

Recruitment is the responsibility of the Chief Technical Officer (CTO), the Chief Operations Officer (COO) and the Laboratory Manager with input from other personnel as required. The CTO defines the minimal levels of qualifications, experience, and skills for each position to ensure personnel have adequate skills and competence for the job function.

Job descriptions detail the necessary requirements for each job and include position title, minimum educational requirements, skills, responsibilities and reporting relationships and any supervisory responsibility.

The QA Office provides orientation training for all new employees including review of the ethics policy/data integrity, Quality Manual and the Health and Safety Plan.

Managers and supervisors ensure that training of new employees is complete and review the continuing training for current employees. Training may include on-site, on-line and off-site programs presented by staff members, regulators, contractors, equipment manufacturers, and institutions of higher learning. Training will be relevant to the anticipated tasks of the laboratory or position. Some training may be required by state, DOT or federal requirements.

Training of new personnel to any job assignment takes place on-site. An individual performs the technical procedure without supervision after documentation of acceptable proficiency. Employee training files contain the information on the current training status.

Off-site and on-line training takes place on an as-needed basis. Recommendations and suggestions about educational programs come from all levels of staff. The CTO approves off-site training for analysts. It is the employee's responsibility to present a copy of any certificates or attendance information. The information is maintained in the individual's training record.

5.3 Training

The Quality Manual and supporting documents are available to all employees. Cross training, peer/supervisory training and other related training takes place on a scheduled and as needed basis. Training ensures the communication and understanding of all personnel in the laboratory-documented procedures and practices.

On-the-job training includes demonstration of skills during job performance, continuing demonstration of capability and periodic (annual) review of SOPs. Safety and health training takes place at orientation with careful introduction to new principles. Personnel have access to the Safety Manual and Material Safety Data Sheets. On-site training includes side-by-side hands-on training with the SOP or a meeting to discuss procedural changes or to address questions related to laboratory operations.

Training is an on-going opportunity to evaluate the laboratory operations. In all cases, a Document Acknowledgement Form (DAF) is signed and dated by the trainer and the trainee(s) and documents training. For documenting initial analyst proficiency, the laboratory completes a Demonstration of Capability (DOC) Form. The Chief Technical Officer, upon successful completion, signs the DOC Form. This form documents the performance of the analyst. Training records are updated as needed. Analysis of real-life samples is only allowed with completion of a successful DOC.

Analyzing four Lab Control or QC samples and demonstrating acceptable precision and accuracy will document initial performance of any test method that allows spiking. Acceptable performance is defined as within precision and accuracy of the reference method or laboratory-generated limits when reference method limits are not available. Ongoing performance demonstration must be

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conducted once per year by performing analyses of at least 4 consecutive lab control samples with acceptable levels of precision and accuracy or successful completion of a proficiency testing sample. All supporting documentation is maintained by the laboratory.

The DOC is completed prior to using any test method, and at any time there is a substantial change in instrument type, personnel or test method. In general, this demonstration does not test the performance of the method in real world samples, but in the applicable and available clean matrix (a sample of a matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method). In addition, for parameters, which do not lend themselves to spiking, e.g., Total Solids, the demonstration of capability is performed using replicates of real world samples.

When a work cell is used in the generation of an ongoing DOC, the effort is fully documented. Changes to a member of a work cell will include working with the experienced analyst and completing and documenting a new DOC. Likewise, continued performance is verified with continuing performance checks such as LCSs and or performance testing samples. It will be the responsibility of each laboratory supervisor to provide supporting data in the generation of the DOC.

The DOC Certification Statement shall be used to document the completion of each demonstration of capability. Each DOC is assigned a unique file identifier which becomes referenced in each employees training records for traceability. This certification form must be completed each time a demonstration of capability study is completed. DOCs are electronically archived by the QA Office.

5.4 Training Records

The QA Office is responsible for maintaining training records. Training forms, DOCs and other records of training are maintained in the employee's electronic training file.

Manager and supervisors will notify the QA Department when an SOP revision is complete for processing as a controlled final version of that document. Laboratory staff will acknowledge receipt of the change/update and agree to abide by the SOP as of the effective date on the appropriate record, such as a Document Acknowledgment Form, DAF. The training records are updated with these documented acknowledgements. The laboratory supervisor of the area determines when a change is significant to require training.

Job descriptions are included in the training record files. Technical information in the training records is audited periodically for completeness as part of the internal review process of the laboratory.

The laboratory will only use personnel who are employed by the laboratory or are under documented contract. When contracted personnel are used the laboratory shall ensure that they are supervised and competent and work in accordance with the laboratory's Quality System.

When analytical or administrative plans are updated, effective communication amongst all personnel is maintained and when subsequent training is required such training will be documented and the employees training record shall be updated accordingly.

6 Quality System

6.1 Establishment

The Quality Mission Statement presents the policy and objectives for WA. The purpose of the Quality Manual is to provide the framework for the processes and operations conducted at the laboratory in the generation of quality data. The Quality Manual and all associated supporting documents detail the management-authorized operations for achieving the quality objectives. Further, it is the requirement and policy of WA that all employees abide by, implement and maintain the quality policies and activities detailed in this Quality Manual and supporting documents during the execution of their work.

The laboratory operates a Quality System approach to management in order to produce data of known quality and legally defensible that meets regulatory requirements and guidelines. WA is a full service laboratory designed to provide its clients with accurate, precise and defensible data. WA employs chemists, environmental scientists and analysts with the highest training, ethics and caliber in the fields of analytical chemistry and environmental sciences. Combining an experienced staff with state of the art instrumentation, documented procedures and enhanced automation ensures data of known and documented quality. The laboratory documents all analytical and operational activities.

In order to provide a structure for the documentation used in establishing a Quality System, a hierarchy of quality documentation is implemented at this laboratory. The following classical 4-Tier Hierarchy is used: Tier 1: Quality Manual; Tier 2: QA SOPs; Tier 3: Technical SOPs and Reference Methods and Tier 4: Support Forms and Documents.

6.2 Quality Manual

The CQO is responsible for the management and distribution of the Quality Manual. The Quality Manual is reviewed by management minimally once per year. The Chief Quality Officer is responsible for monitoring and implementing the quality system in all sections of operation. Implementation of major changes in the quality system occurs after revision to the quality manual, other supporting documents and authorization by upper management. Based on input from laboratory operations, a document revision form may be submitted to indicate revision to the QM based on current operations. The Quality Manual is also reviewed to ensure that laboratory practices meet applicable city, state, federal, and national independent accreditation bodies.

The signatures found on the authorization page in Section 1.1 of this manual signify management review and approval of the Quality Manual. The signature section is kept current and reflects any organizational changes affecting the authorizing positions. Updates to this manual occur at any time throughout the year. The effective date indicates the most current version of the QM, which has undergone management review and approval.

Document control procedures apply to the Quality Manual. Distributions of controlled copies of the manual are made to laboratory personnel, authorized clients and certifying agencies. Persons or organizations outside of WA may receive uncontrolled copies. These copies are distinctly marked as “Uncontrolled Document”. A distribution list is maintained for all controlled copies of the Quality Manual. Copies marked as uncontrolled copies are not subject to updates.

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6.3 Internal and External Audits

Internal and external audits review and examine the operations performed in the laboratory. Internal audits are self-evaluations and external audits are compliance-performance reviews by external organizations to evaluate the ability of the laboratory to meet regulatory or project requirements. These audits are performed by trained qualified personnel to provide an objective evaluation of compliance with established requirements, methods and procedures.

The Chief Quality Officer schedules internal audits for each operational area. The internal audit is designed to ensure that the laboratory and its personnel are in compliance with the Quality Manual, laboratory SOPs and regulatory agency requirements by reviewing the analytical and administrative processes and implementation of the documented Quality System. The audits are performed annually and will include the various areas of laboratory operations.

The purpose of the internal system audit is:

- Verification that adequate written instructions are available for use;
- Analytical practices performed in the laboratory are consistent with SOP's;
- The quality control practices are applied correctly during production;
- Corrective actions are implemented as necessary;
- Deviations from approved protocols are occurring only with proper authorization and documentation;
- Reported data is correct and accurate for reporting;
- SOP's, quality records, analytical records are maintained properly; and
- Personnel training and records are satisfactory and current.
- Review of safety protocols and assessment of near-miss events

Before a scheduled internal audit, the assigned auditor may review checklists or the SOPs specific to the area. The checklist may be from an external source or prepared by the auditor. The checklist includes all references to the documented Quality System or referenced method requirements. Upon completion the audit findings are presented to the representative supervisor as an Internal Audit Report. The supervisor will document a proposed Corrective Action(s) where applicable. The QA Department will perform surveillance monitoring with subsequent reporting as required. Once any corrective action and follow-up procedures have been completed, the entire audit package will be filed by the CQO. An Internal Audit Report will be completed following any internal audit. The Internal Audit Report records any deficiencies or discrepancies found during the audit and subsequent corrective action(s).

Technical personnel are responsible for the inspection and monitoring of in-process and final data. The Quality Assurance Office and personnel independent of those having direct responsibility for the work may perform the audit of the Quality System and processes.

Representatives sent by clients and government or accrediting bodies often perform external audits. These audits are most often announced inspections. The CQO and QA Supervisor accompany the external audit team through the laboratory. All laboratory personnel and applicable data will be made available to the assessor and the audit team during the audit. The auditors receive a brief overview of company objectives, activities, and facilities. Interviews with essential supervisory staff and technical staff are arranged, along with retrieval of any documentation pertinent to the objective of the audit. Auditors usually provide an exit or final report on their findings shortly after the audit. The CQO receives the audit report and initiates Corrective Action Reports in response to any cited deficiencies. During the on-site audit, the audit team may come into possession of information claimed as Confidential Business Information (CBI). The EPA regulations

for handling confidential business information are detailed in *Title 40, Code of Federal Regulations, Part 2, Subpart B*. Subpart B defines a business confidentiality claim as "a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality or a request for a determination that such information is entitled to such treatment."

Where the findings of an audit cast doubt on the correctness or validity of the laboratory's calibrations or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose data was affected.

6.4 Audit Review

Management reviews internal and external audit reports to evaluate system effectiveness. Tracking and documentation of the audit findings occurs through the corrective action process. The CQO, CTO and or lab supervisors shall agree upon corrective action(s) for noted deficiencies, along with the timetable for implementation and completion. The QA Department tracks the time line and informs the person responsible for its completion of any open corrective actions. The QA Department may perform surveillance monitoring of any corrective action(s) as appropriate for its effectiveness.

6.5 Laboratory Performance Testing Program

WA participates in various inter-laboratory performance testing programs required by clients and accrediting bodies. The performance audits provide information on laboratory performance from the analytical data generated. Performance evaluation or proficiency testing samples received by the laboratory are handled following routine laboratory procedures. Laboratory personnel analyze these samples using techniques utilized as with real life samples.

Proficiency evaluation samples are unpacked and undergo the sample receipt policy procedures including the generation of a Chain of Custody. Reporting requirements and deviations to routine practices are noted as required for any project. Proficiency samples are analyzed minimally twice per year per matrix and analyte to meet the TNI Standards. State or other accrediting authorities may require a different frequency. Consult the SOP on Performance Testing for additional information.

6.6 Corrective Actions

The Corrective Action (CA) program at WA utilizes an electronic reporting format conducive to specified laboratory operations to document the investigative and remediation processes inherent to the corrective action program. The mechanism for recording, reviewing and acting upon all quality issues is self-evident to the electronic format utilized at the laboratory. This process ensures continuous self-improvement of company performance by an active corrective action program to prevent the recurrence of quality issues and improve the quality system.

Laboratory personnel document any deviations or departures from the documented quality manual, standard operation procedures, method or client specifications or recommended improvements to the quality system on the corrective action report form. Management and supervisory staff investigate any systemic quality issues in an attempt to identify the root cause, identify potential corrective actions, implement remediation and approve the corrective action recommendation for implementation. The completed CA date for implementation is specified in each corrective action report. The QA Department will monitor the corrective action process and surveys completed CAs to evaluate the effectiveness of the corrective action implemented.

Corrective Action Reports are tracked for closure date and category. On a timely basis, reports to management may include the listing of open Corrective Action Reports. The QA Department

monitors their completeness and will close out corrective actions as appropriate. Consult the SOP on Implementing Corrective Actions for further details.

Any findings that cast doubt on the effectiveness of the laboratory operation to produce data of known and documented quality or that question the correctness or validity of sample results will be investigated. The corrective action process is followed and clients will be notified if the investigation shows the laboratory results have been negatively affected and the client's requirements have not been met. Clients will be notified immediately after the laboratory discovers the issue and completes all investigative efforts. Laboratory management will ensure that this notification is carried out within this specified time frame.

6.7 Managerial Review

Management review occurs on an annual basis as part of the Quality Systems monitoring process. Documentation of the associated management reports are the responsibility of the Quality Assurance team including the corrective action process derived from the managerial review. The focus of the quality management review identifies area for improvement of the Quality System derived from the corrective process, internal audit reviews, assessments by external bodies, the results of inter-laboratory comparisons or proficiency tests, any changes in volume and type of work undertaken, feedback from clients and other quality assurance actions. Meetings may include discussion and progress on Quality System initiatives since the last meeting. Minimally, on an annual basis, the QA team generates a Quality System Report to Management indicating all factors, corrective actions and remediation efforts impacting the Quality System.

6.7.1 Reports to Management

In support of the quality system, management review process reports are generated reassessing the effectiveness and suitability of the quality system implemented. The review encompasses a composite of the various quality objectives implemented at the laboratory. These quality assessments will include reports from managerial and supervisory personnel.

The various types of feedback mentioned above determine the form and function of the managerial review of quality systems being generated. A report may be generated regarding any one department indicating a review of quality systems. All reviews and assessments will address the President, the CTO, the CQO, other administrators, managers, supervisors, and/or any combination of the above. Support information for the reports may take the form of memos, e-mails, letters, and/or specialty reports such as Production-QA meetings, internal audits, performance testing, corrective action reports, and findings from external audits or the like.

Each report will identify components of the Quality System including, but not limited to:

- Quality System Report to Management Identification Number
- Purpose of the Quality System Report to Management
- Suitability of policies and procedures
- Reports from managerial and supervisory personnel or other specialized reports
- Outcome of recent internal audits
- Corrective and preventive actions
- Assessments by external bodies
- Results of interlaboratory comparisons or proficiency tests
- Changes in the volume and type of work

- Client feedback
- Complaints
- Recommendations for Improvement
- Other relevant factors such as QC activities, resources and training
- Changes in internal and external issues impacting the laboratory

Refer to the SOP on the Management Review of the Quality System for further information.

6.8 Essential Quality Control Procedures

To ensure the generation of quality data under the system of analytical quality objectives, the laboratory establishes and maintains essential quality control procedures in the analytical scheme of data generation. The following sections list the essential quality control elements and requirements for routine assessment of analytical data as required by reference methods, the current 40 CFR Part 136/141 or project requirements. These sections provide standard criteria for defining, implementing, evaluating and reporting of these elements to be used by the laboratory. However, these requirements may be superseded by specific method and/or project requirements. Further, laboratory SOPs specify the quality control requirements for assuring precision, accuracy, representiveness, comparability, completion and sensitivity of each test method.

The following essential quality control procedures apply according to the requirements of the test method.

6.8.1 Batch

The basic unit for application of laboratory quality control is the batch. Samples shall be prepared, analyzed, and reported in batches and be traceable to their respective batches. Each batch shall be uniquely identified within the laboratory. Field QC samples (i.e., trip blanks, rinsates, etc.) shall not knowingly be used for batch QC purposes. Samples are grouped together by similar method and similar matrix. A batch is defined as samples prepared together using the same process and reagents and prepared over a limited continuous time period. Batch size is defined by the analytical method and or project requirements and is detailed in the method SOP.

Each batch is assigned a unique batch number that will allow the analysis of any sample to be traced back to the original preparation. In addition, QC samples (e.g. blank, laboratory control sample, MS/MSD) are assigned using the batch number in order to link the environmental samples with the appropriate QC samples. QC samples are assigned based on specific method requirements and is detailed within the analytical method SOP.

Analytical Batch (Sequence)

The analytical sequence or instrument run sequence is defined as samples that are analyzed together within the same time period or in continuous time periods on one instrument. Analytical sequences are bracketed by the appropriate continuing calibration verification standards and other QC samples as defined by the analytical method. Each sequence contains the requisite number and type of calibration standards, QC samples, and regular analytical samples as defined by the reference method. These requirements are defined in the method SOPs and summarized in part in the following sections.

6.8.2 Laboratory Blank (LB)/Laboratory Reagent Blank (LRB)

Purpose:

Laboratory blanks (LB) or laboratory reagent blanks (LRB) are analyzed to assess background interference or contamination that exists in the analytical system that might lead to the reporting of elevated concentration levels or false positive data. The LB/LRB is carried through the complete sample preparation, concentration, cleanup, and determinative procedures where applicable.

Frequency:

At least one LB or LRB is required for each preparation batch or analytical batch where equivalent. Refer to method SOPs for laboratory blank requirements.

Composition:

A LB or LRB is an analyte and interference-free matrix to which all reagents are added in the same volumes or proportions as used in sample analysis and is the same matrix as samples.

- Organics - Analyte-Free Reagent Water / Sand
- Metals - Analyte-Free Reagent Water / Inert Solid Matrix (i.e. Teflon chips)
- Inorganics - Analyte-Free Reagent Water / Inert Solid Matrix (i.e. Teflon chips or glass beads)

Evaluation Criteria and Corrective Action:

While the goal is to have no detectable analytes, each laboratory blank must be critically evaluated as to the nature of the contamination or interference and the effect on the analysis of each sample within the batch. The source of any contamination shall be investigated and measures taken to minimize or eliminate the problem. The LB/LRB is considered acceptable if it meets one or more of the following requirements dictated by the method or project:

- Less than the MQL
- Less than the MDL – This criterion is used when data is specifically evaluated against the MDL (e.g. Risk Based Action Levels).
- Less than the RL – This criterion is used when RLs are specified in a project specific statement of work (SOW).
- Less than 10% of the sample result(s)

If the LB/LRB results do not meet the acceptance criteria above, then the laboratory shall take corrective action to locate and reduce the source of the contamination. If feasible when the holding time is not exceeded, the lab shall re-extract and reanalyze any samples associated with the contaminated laboratory blank. Any samples associated with a contaminated laboratory blank shall be reprocessed for analysis or the results reported with the appropriate data qualifying code (i.e., “B” flag).

If an analyte is found only in the laboratory blank, but not in any batch samples, no further corrective action may be necessary. Steps shall be taken to find/reduce/eliminate the source of this contamination in the laboratory blank.

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Subtraction of the LB/LRB results from associated samples is not permitted unless expressly allowed in the reference method. Laboratory blanks and/or solvent blanks may also be used to check for contamination by carryover from a highly -concentrated sample into subsequent samples.

Reporting Criteria:

Laboratory blanks are evaluated to the MDL.

Results for an analyte above the MDL, but below the MQL, are reported as estimated values (i.e. “J” flag).

For lab contaminants identified in a sample and the laboratory blank and when its concentration is less than 10 times the laboratory blank (10X Rule) sample results will be reported with a “B” flag. This indicates that the concentration of the analyte in the sample may be due to an interferent introduced in the laboratory. Sample results above the MDL but below the MQL are reported as estimated values ('JB' flag).

There are instances where no contamination was present in the associated blank, but qualification of the sample(s) data is deemed necessary. Contamination introduced through dilution water is one example. Instances of this type contamination can be detected when contaminants are found in the diluted sample result, but are absent in the undiluted sample result. An explanation is provided in the case narrative.

6.8.3 Laboratory Control Sample (LCS)

Purpose:

The LCS is used to evaluate the performance of the entire analytical system, including all preparation and analytical steps. Recoveries of the LCS are compared to established recovery acceptance criteria and, if found to be outside of these criteria, indicates that the analytical system is “out of control”. LCSs are not performed for methods for which spiking solutions are not typically used, (i.e., TS, Settleable solids, pH).

Frequency:

A LCS is required for each preparation batch or analytical batch where applicable. A laboratory control sample duplicate (LCSD) is required when a matrix spike/matrix spike duplicate cannot be performed. Whenever an LCS/LCSD pair is analyzed with a MS/MSD pair, the first LCS result is used when the MS/MSD pair criteria are acceptable. When the MS/MSD pair criteria fail and the LCS/LCSD pair passes comparable criteria, the LCS/LCSD data may be used to demonstrate matrix interference and the sample data may be reported with appropriate narratives.

Composition:

The LCS is similar in composition to the laboratory blank. An analyte and interference-free matrix to which all reagents are added in the same volumes or proportions as used in sample preparation. The LCS is spiked with all single-component (single peak) target analytes before it is carried through the preparation, cleanup, and determinative procedures.

- Organics - Analyte-Free Reagent Water / Sand
- Metals - Analyte-Free Reagent Water / Inert Solid Matrix When Available
- Inorganics - Analyte-Free Reagent Water / Sand

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When multi-component (multiple peaks) analytes are the only targets (e.g. method 8082 or project specific pesticide for Chlordane or Toxaphene) the LCS must be spiked with at least one of the multi-component analytes. Method 8082 for PCBs requires that the LCS contain at least one PCB (e.g., 1016/1260 mixture). The LCS contains all target analytes of interest that are reported under a particular method. The LCS is generally performed near the middle of the procedure's analytical range. The recommended concentration of the LCS is detailed within the analytical SOP.

Evaluation Criteria and Corrective Action:

The results of the individual batch LCS are calculated in percent recovery. Where a LCSD is performed, the relative percent difference (RPD) is also evaluated.

The LCS is evaluated by comparing the percent recovery/RPD for all of the target analytes to the quality objectives as determined by method performance criteria detailed in this manual. Control limits are established for each analyte/analytical method/prep method performed by WA. Refer to method performance procedures for details on how control limits are established. For an LCS/LCSD to be acceptable:

- Recoveries for all target analytes are within acceptance criteria.
- Recoveries are high and no target analytes are identified in associated samples (requires reference in Level II, III, and IV case narrative).
- RPDs for all analytes are within acceptance criteria.
- RPDs for an analyte is high, however, recoveries are within acceptance criteria (requires reference in Level II, III, IV case narrative).

Note: When samples are not subjected to a separate preparatory procedure (i.e., low-level GC or GC/MS volatile organic analyses) the CCV may be used as the LCS, provided the CCV acceptance limits are used for evaluation.

The effect of any LCS QC failure on the associated samples must be evaluated. Regardless of this assessment, steps shall be taken to find the source of the problem and correct it.

Typically, the LCS is reanalyzed for the failed analytes only. If the second analysis fails, then the entire batch (QC samples and field samples) would be re-prepared and reanalyzed for the failed analytes only. If sufficient sample is not available for re-preparation and reanalysis or if the corrective action is ineffective, the sample results reported within that batch shall be flagged accordingly, and a discussion of the impact included within the case narrative.

The case narrative shall discuss the corrective action taken and any other information that will assist in the evaluation of the impact of the QC failure on the data quality objectives.

Method SOPs will contain additional guidance for compounds that are considered marginal, problem or non-standard analytes (e.g. Benzidine method 8270, Antimony method 6010).

6.8.4 Matrix Spike Sample (MS)

Purpose:

The Matrix Spike (MS) and Matrix Spike Duplicate (MSD) are QC samples that indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method. The information from these QC samples is project/sample/matrix specific and would not

normally be used to determine the validity of the entire batch. MSs are not performed for methods for which spiking solutions are not used.

Frequency:

A MS/MSD is required for most preparation batches or analytical batch where equivalent. A MS and MS Duplicate (MSD) are used to assess precision and accuracy.

Composition:

The MS/MSD are performed on a field sample contained in a batch. The MS/MSD contains all target analytes that are reported under a particular method. The MS is generally performed at the same concentration as the LCS and is spiked with all single-component (single peak) target analytes before it is carried through the preparation, cleanup, and determinative procedures.

When multi-component (multiple peaks) analytes are the only targets (e.g. method 8082 or project specific pesticide for Toxaphene or Chlordane) the MS/MSD must be spiked with at least one of the multi-component analytes. Method 8082 for PCBs requires that the MS/MSD contain at least one PCB (e.g., 1016/1260 mixture).

The MS/MSD contains all target analytes that are reported under a particular method and is generally performed at the mid-range concentration of the initial calibration curve. The concentration of the MS/MSD is detailed within the analytical SOP. In situations where enough sample has not been provided to perform a MS/MSD, a LCS/LCSD is substituted.

Evaluation Criteria and Corrective Action:

The results of the individual batch MS are calculated in percent recovery. When a MSD is performed, the relative percent difference (RPD) is also evaluated.

The MS/MSD is evaluated by comparing the percent recovery/RPD for all of the target analytes to the recovery measurement quality objectives as determined according to Method Performance Criteria of this manual. Control limits are established for each analyte/analytical method/prep method performed by WA. Refer to method performance procedures for details on how control limits are established for an MS/MSD to be acceptable:

- Recoveries for all target analytes are acceptance criteria
- Recoveries are high and no target analytes are identified in associated samples (requires reference in Level II, III, IV case narrative)
- RPDs for all analytes are within acceptance criteria
- RPDs for an analyte is high, however, recoveries are within acceptance criteria (requires reference in Level II, III, IV case narrative)
- The LCS/LCSD % recovery and RPD for the failed analyte (MS/MSD) must be within acceptance limits. MS/MSD samples may indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method. The information from these QC samples is sample/matrix specific and is not used to determine the validity of the entire batch.

The effect of any MS/MSD QC failure on the associated samples must be evaluated. If necessary, corrective action is performed with the following order of priority:

- Perform specific corrective action as listed in analytical SOP (e.g. post digestion spike or dilution test for metals).
- Compare against project-specified MS acceptance range (if available). If the recovery is outside the LCS range but within the project-specified range, this indicates a matrix effect that is within tolerable limits as defined by the project. No corrective action is required.
- Analyte recovery that fails in the MS/MSD must be within QC limits in the associated LCS/LCSD. This indicates that the system is in control and that the failure is likely due to the sample matrix interference.
- Re-extract/Re-analyze – The availability of additional sample and holding times must be taken into account. Samples re-extracted outside of holding time may be useful in some instances to verify high levels of target analytes. Re-extraction should occur only if method specified corrective action (e.g. cleanup, reduced sample size) is expected to significantly reduce or eliminate the matrix interference.

Note: Problems with LCS or LB/LRB indicate a system problem, which makes it difficult to point to a sample matrix as the cause of problems with matrix spikes. The entire batch must be reviewed to decide the appropriate corrective action.

Always evaluate the specific effect the recoveries will have on the data. (Matrix spike data will only affect the project samples from which the MS sample was selected.) No further action is required for samples in the batch, which are not directly associated with the project. MS data may be provided for information purposes only for non-project samples.

Some typical review scenarios are provided below:

- If MS recoveries are high and no target analytes are identified in the sample, no further action is required. Any general trend in this direction should be investigated and corrected.
- If MS recoveries are low and no target analytes are identified, this indicates that the ability to detect target analytes at or near the detection limit may have been affected. Review surrogate recoveries to verify matrix effect if available.
- If MS recoveries are low and target analytes are identified, this indicates that the result may be biased low. This will directly impact data that is at or near a regulatory limit. Review surrogate recoveries to verify matrix effect if available. A case narrative is provided for project samples only to discuss the impact on the data.
- Some samples may require dilution in order to bring one or more target analytes within the calibration range or to overcome significant interferences with some analytes. This may result in the dilution of the MS responses to the point that the recoveries cannot be measured. Data is reported from the lowest dilution that yields usable data. If the MS recoveries are available from a less-diluted or undiluted aliquot of the sample or sample extract, those recoveries may be used to demonstrate that the MS was within the QC limits, and no further action is required. Provide a narrative to the client.
- Levels of non-target analytes (e.g. gasoline, diesel, oil…) may interfere with MS recoveries. If review of the raw data indicates obvious matrix interference, document the interference on the appropriate form (e.g. instrument-generated result forms,

Inorganic batch sheets, and metals result instrument printouts). Provide a narrative to the client.

- Review surrogate recoveries for all samples in the same QC Batch, if available. Look for trends that would indicate a system problem (e.g. calibration, solution…). Recovery problems across the entire batch would point towards a system problem and would require that all samples in the batch be re-extracted/ re-analyzed or report the data with the proper qualifiers and narrative. However, if all samples in a batch are from a single project and the LB/LRB/LCS recoveries are within QC limits, this could be indicative of a project-specific interference. The case narrative shall discuss the corrective action taken and any other information that will assist in the evaluation of the impact of the QC failure on the data quality objectives.

Method SOPs will contain additional guidance for compounds that are considered marginal, problem or non-standard analytes (e.g. Benzidine method 8270, and Antimony method 6010).

Reporting Criteria:

MS/MSD recovery, RPD and evaluation criteria are reported for Level II, III and IV data packages. Any QC issues/failures associated with the MS/MSD will be flagged on the recovery reports and detailed in the case narrative as part of the standard reporting process.

In all situations, regardless of the data package level, where MS/MSD issues/failures have an impact on the analytical data, a case narrative is generated to explain the impact on the data. The case narrative shall discuss the corrective action taken and any other information that will assist in the evaluation of the impact of the QC failure on the data quality objectives.

6.8.5 Matrix Duplicates (DUP)

Purpose:

Matrix duplicates are defined as replicate aliquots of the same sample taken through the entire analytical procedure. The results from this analysis indicate the precision of the results for the specific sample using the selected method. The matrix duplicate provides a usable measure of precision only when target analytes are found in the sample chosen for duplication.

Frequency:

Duplicates are performed, when required by the method, for every preparation batch.

Composition:

Matrix duplicates are performed on replicate aliquots of actual samples. The composition is usually not known.

Evaluation Criteria and Corrective Action:

The results from matrix duplicates are primarily designed to assess the precision of analytical results in a given matrix and are expressed as relative percent difference (RPD).

The matrix duplicate is evaluated by comparing the RPD for all of the target analytes to the recovery measurement quality objectives as determined according to Method Performance Criteria of this manual. Control limits are established for each applicable analyte/analytical method/prep method performed by WA. Refer to static procedures for assessing method

performance on how control limits are established. When no RPD are available or exist, the default RPD acceptance criteria are 20%.

Corrective action for RPD outliers is specified in the appropriate analytical SOP. In general, corrective action includes:

- Review calculations to ensure that no error has been made
- Re-analyze the samples to verify the RPD. If re-analysis shows RPD within range, then report from reanalysis

Reporting Criteria:

RPD and evaluation criteria are reported for Level II, III and IV data packages. Any QC issues/failures associated with the duplicate will be flagged on the RPD report and detailed in the case narrative as part of the standard reporting process.

In all situations, regardless of the data package level, where the duplicate issues/failures have an impact on the analytical data, a case narrative is generated to explain the impact on the data. The case narrative shall discuss the corrective action taken and any other information that will assist in the evaluation of the impact of the QC failure on the data quality objectives.

6.9 Additional Essential Quality Control Procedures

WA utilizes additional data quality control procedures to assess quality control for testing.

Surrogates are used most often in organic chromatography test methods and are chosen to reflect the chemistry of the targeted components of the method. Added prior to sample preparation/extraction, they provide a measure of recovery for every sample matrix. Except where the matrix precludes its use or when not available, surrogate compounds must be added to all samples, standards, and blanks for all appropriate organic test methods. Surrogate compounds are often specified by the mandated method and are deliberately chosen for being unlikely to occur naturally. Often this is accomplished by using deuterated analogs of select compounds. The results are compared to the acceptance criteria as published in the mandated test method, until internal criteria have been established. Where there are no established criteria, the laboratory determines internal criteria and documents the method used to establish the limits. Surrogates outside the acceptance criteria must be evaluated for the effect on the individual sample results. The appropriate corrective action is guided by the data quality objectives or other site-specific requirements. Results reported from analyses with surrogate recoveries outside the acceptance criteria shall include a case narrative. Other examples of spiking procedures used by the laboratory to provide quality control for testing as required by the reference methods and test protocols are described in the laboratory's technical method SOPs.

6.9.1 Surrogate Standard (Applies to Organics Only)

Purpose:

Surrogates are analyzed to assess the ability of the method to successfully recover these specific non-target analytes from an actual matrix. Surrogates are organic compounds that are similar to the analytes of interest in chemical behavior but are not normally found in environmental samples. Specific surrogates used are identified within the analytical SOPs.

Frequency:

Surrogate compounds are spiked into all field samples and accompanying QC samples requiring GC, GC/MS or HPLC analyses prior to any sample manipulation for every sample batch extracted/analyzed.

Composition:

Surrogates are added to all samples, field and QC, for each batch before they are carried through the preparation, cleanup, and determinative procedures. The amounts of surrogate to be added and specific surrogate compounds are detailed in the analytical SOP.

Evaluation Criteria and Corrective Action:

Surrogates are used in much the same way that matrix spikes are used, but cannot replace the function of the MS. The results of the surrogates are evaluated, in conjunction with other QC information, to determine the effect of the matrix on the bias of the individual sample determinations. Current surrogate acceptance criteria limits are calculated from laboratory blank and laboratory control samples.

The results of the surrogates are calculated in percent recovery. Surrogates are evaluated by comparing the percent recovery to the recovery measurement quality objectives. Control limits are established for each surrogate/analytical method/prep method performed by WA.

Surrogates outside the acceptance criteria must be evaluated for the effect indicated for the individual sample results. Corrective action includes the review of calculations, re-analysis of the sample or re-extraction/ re-analysis of the sample.

- If surrogate recoveries are high and no target analytes are identified, no further action is required.
- If the re-analysis or the re-extraction/re-analysis recovery is within QC limits, the results will be reported from the re-analysis and no further corrective action is required.
- If the surrogate failure is due to obvious high levels of target/non-target analytes based on review of the chromatogram, no re-analysis or re-extraction/re-analysis is required unless the specified corrective action (e.g. cleanup, reduced sample size) will significantly reduce or eliminate the matrix interference. However, based on action limits, re-analysis at a lower sample size may not be an option. A case narrative is required to detail the effects on the sample.

Reporting Criteria:

By default, surrogate recoveries are reported for all organic methods for all reporting levels. Surrogate recovery outside acceptance criteria must include the appropriate data qualifier. A case narrative is required when surrogate recovery outside acceptance criteria is deemed to have an impact on the sample results.

6.9.2 Dilution Test (DT – Applies to Metals Only)

Purpose:

A dilution test is performed to confirm the absence of chemical (positive or negative) interferences operating on any element to distort the accuracy of the reported value.

Frequency:

It is recommended that whenever a new or unusual sample matrix is encountered, a dilution test be performed on at least one sample per digestion batch. The sample used is generally the sample selected for the matrix spike/matrix spike duplicate. A dilution test is performed as corrective action when any failure is noted for the MS/MSD recoveries. Dilution tests are performed according to the following:

- Performed when there is a new or unusual matrix with high level of an analyte(s)
- Performed when MS/MSD failure is due to a high level of the analyte present relative to the spike amount
- A 1:5 dilution test may be performed for an analyte to evaluate matrix interference if the analyte concentration in the original (undiluted) sample is at least 50 times the MDL
- A 1:5 dilution test may be performed for an analyte to evaluate matrix interference if the analyte concentration is minimally a factor of 10 above the instrumental detection limit after dilution

Composition:

Dilution tests are performed on the digestates of actual samples.

Evaluation Criteria and Corrective Action:

A matrix effect for a particular analyte is suspected if the RPD between the undiluted and diluted result is greater than 10 percent.

Reporting Criteria:

Evaluation criteria are reported for Level II, III and IV data packages.

6.9.3 Post Digestion Spike (PDS - Applies to Metals only)

Frequency:

It is recommended that whenever a new or unusual sample matrix is encountered, a post digestion spike (PDS) be performed on at least one sample per digestion batch. The sample used is generally the sample selected for the matrix spike/matrix spike duplicate. A PDS is performed as corrective action when any failure is noted for the MS/MSD recoveries. PDS tests are performed according to the following:

- When there is a new or unusual matrix.
- When there is a MS/MSD failure.
- If the result of the sample is less than 25 times the detection limit.

Composition:

Post digestion spikes are performed on the digestates of actual samples. The digestate is spiked with a known amount of the failing element(s).

Evaluation Criteria and Corrective Action:

The recovery should be within 75% to 125% of the expected value.

Reporting Criteria:

Evaluation criteria are reported for Level II, III and IV data packages.

6.10 Method Performance

WA has established and maintains a Quality System based on the required elements of EPA methodologies or the 2016 TNI (The NELAC Institute).

WA's policy on Method Performance combines analytical assessment indicators that are designed to ensure that quality data is continuously produced during analysis. These data quality indicators are known as precision, accuracy, representativeness, comparability, completeness and sensitivity.

Precision:

Precision refers to the distribution of a set of reported values about the mean, or the closeness of agreement between individual test results obtained under prescribed conditions. Precision reflects the random error and may be affected by systematic error. In order to assess the effect these variables have on the total precision of data, both field and laboratory replicates should be acquired. Laboratory precision is determined on the basis of replicate analysis, usually duplicate or matrix spike duplicate samples. To determine the precision of a given analytical method without the effect of a matrix, a duplicate laboratory control sample is used. The statistical measure of precision is expressed as Relative Percent Difference (RPD).

Relative Percent Difference (RPD)

$$\frac{R_1 - R_2}{\frac{(R_1 + R_2)}{2}} * 100 = \% \; RPD$$

where: R_1 = Larger of two observed values
R_2 = Smaller of two observed values

And where applicable, Percent Difference is calculated as:

% Difference (%D)

where: $\overline{X}$ = Average of all values

$$\frac{X - \overline{X}}{\overline{X}} * 100 = \% \; D$$

X = Result of measurement

Use the Absolute Value if $X < \overline{X}$)

Accuracy

Accuracy is the measure of the closeness of an observed value to the “true” value (e.g., theoretical or reference value, or population mean). Accuracy is defined as the degree of bias in a measurement system. Accuracy may be determined using laboratory control samples or matrix spikes. The statistical measure of accuracy is expressed as percent recovery (%R).

% Recovery (R)

$$\frac{Xs - Xu}{K} * 100 = \%\ R$$

where: *Xs* = measured value of the spiked sample

Xu = measured value of the unspiked sample

K = known amount of the spike in the sample

% Recovery (LCS)

$$\frac{MV}{TV} * 100 = \%\ R_{LCS}$$

where: *MV* = Measured Value
TV = True Value

% Recovery (MS or MSD)

$$\frac{MV - SV}{TV} * 100 = \%\ R_{MS}$$

where: *MV* = Measured Value in MS or MSD
TV = True Value
SV = Amount found in sample

Representativeness

Representativeness is a parameter that is concerned primarily with the proper design of the sampling program or sub-sampling of a given sample. There is no measurement other than precision measurement of the field and laboratory duplicate samples. Representativeness refers to the degree to which sample data accurately and precisely describe the characteristics of a population of samples, parameter variations at a sampling point, or environmental condition. The representativeness criterion is best satisfied in the laboratory by making certain that all sub-samples taken from a given sample are representative of the sample as a whole. Representativeness can be assessed by a review of the precision obtained from the field and laboratory duplicate samples. In this way, they provide both precision and representativeness information. Applicability of representativeness in assessing a contaminant population is improved by using a larger number of samples.

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Comparability

Comparability is a qualitative objective of the data, expressing the confidence with which one data set can be compared with another. Calculating RPD assesses the measurement of comparability between data sets. Sample data should be comparable for similar samples and sample conditions. This goal is achieved through the use of standard techniques to collect representative samples, consistent application of analytical method protocols, and reporting analytical results with appropriate units. Comparability is unknown unless precision and bias are provided.

Completeness

Completeness goals, if defined for individual sampling and analytical protocols, are normally combined to ascertain the expectations of the project as a whole. Completeness is the percentage of measurements that are judged to be usable (i.e., which meet project-specific requirements) compared to the total number of measurements planned.

Overall level of completeness must be addressed as part of the project Data Quality Objectives, DQOs. It is important that critical samples are identified and appropriate QC maintained to ensure that valid data is obtained in order to ensure the type, quantity and quality of data necessary to complete the project. The desired level of completeness is dependent on the project-specific DQOs. This information should be conveyed to this laboratory in the Scope of Work or Sampling and Analysis Plan. The level of completeness must be established and data quality requirements defined in order to meet the intended use of the data (usability).

In the event that more than one data user is requesting the same data, the most stringent data user requirements are applied to ensure the suitability (validity) of the data by all requesting parties. This information is then used to decide the most appropriate analytical strategy to generate the required data. Realistic completeness goals (i.e., 85-90%) are determined based upon the size and complexity of the project. Percent completeness is calculated as

$$\text{Completeness} = N / P * 100$$

where: N = Number of usable measurements

P = Number of measurements planned

Sensitivity

This term is broadly used to describe prescribed project method detection/quantitation/reporting limits established to meet the project-specific data quality objectives. Several limits have been established to describe project sensitivity requirements such as MDL, SQL, MQL and RL.

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Method Detection Limit (MDL)

The MDL is defined as the minimum concentration of an analyte that can be determined with 99 percent confidence that the true value is greater than zero. The laboratory determines MDLs using the procedures and protocols presented in *40 CFR Part 136 Appendix B, Revision 2*.

MDL Procedure Revision 2: (See 40 CFR Part 136 for details)

where: *MDL* = The method detection limit

$$\left[\sqrt{\frac{\sum_{i=1}^{n} x_i^2 - \left(\sum_{i=1}^{n} x_i\right)^2 / n}{n-1}}\right] * t_{0.99} = MDL$$

X = Result of each measurement

n = Number of values

t(n-1,1 = .99) = The students' t value appropriate for a 99% confidence level and a standard deviation estimate with n-1 degrees of freedom. (See Students t Test Table)

Method Quantitation Limit (MQL)

The MQL is the lowest concentration of an analyte that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions. The MQL is defined as the lowest concentration calibration standard that is routinely utilized during an initial calibration. There may be instances where a calibration standard lower than the MQL is analyzed. The MQL in this case is a static concentration and is not adjusted to reflect the lower calibration standard.

Refer to SOP ‘The Determination of Detection Limits’ for details on how MDLs, MDLb and MQLs are determined and validated. Additionally, see this SOP for discussion on Limit of Detection, LOD and Limit of Quantitation, LOQ. The MDLs are performed quarterly and compiled annually as noted in this SOP.

Statistical Procedures for Assessing Method Performance

In order to assess method performance for accuracy and precision, procedures are in place for the generation of limits. These control limits are based on statistical computations using a minimum of 20-30 data points from historical data accumulated. The use of the average (mean), X, and standard deviation, S_x, from this population is used for generating the following control limits, Upper Control, Upper Warning, Lower Warning and Lower Control.

Average ($\overline{X}$)

$$\frac{\sum_{i=1}^{i} X_i}{n} = \overline{X}$$

where: $\overline{X}$ = Average of all values
X = Result of each measurement
n = Number of values

Standard Deviation of the sample (S_x) – expressed in sample concentration units

$$\sqrt{\frac{\sum \left(X - \overline{X}\right)^2}{n - 1}} = S_x$$

where: $\overline{X}$ = Average of all values
X = Result of each measurement
n = Number of values

Control Limits

Upper Control Limit: $\overline{X} + 3 * S_x = UCL$

Lower Control Limit: $\overline{X} - 3 * S_x = LCL$

Warning Limits

Upper Warning Limit: $\overline{X} + 2 * S_x = UWL$

Lower Warning Limit: $\overline{X} - 2 * S_x = LWL$

S_x = Standard Deviation

Normally to assess accuracy the use of % R values are used while for precision the use of RPDs are used to generate the standard deviation as noted above.

Before acceptance and use of any method, satisfactory initial demonstration of method performance is required. In all cases, appropriate forms are completed and retained by the laboratory and made available upon request. All associated supporting data necessary to reproduce the analytical results are retained. Initial demonstration of method performance is completed each time there is a significant change in instrument type, personnel or method. Initial demonstration of method performance acceptance criteria is defined in the corresponding SOP.

6.10.1 Measurement of Method Performance/Control Limits

Control limits for all analytes are established based on the following hierarchy:

Project Specific Control Limits

In some instances, the LCS, MS/MSD acceptance criteria are detailed within the specific project statement of work (SOW). These limits will supersede the laboratory defined control limits and be used to validate data quality and usability.

Method Specific Control Limits

While certain methods require the use of specific control limits (e.g. ICP method 6010D), WA will use historical data to generate in-house limits that will be used to monitor overall laboratory performance for routine comparison against the method requirements.

In some instances, the LCS, MS/MSD acceptance criteria are defined within the published method. These limits will supersede the laboratory defined control limits and be used to validate data quality and usability, (i.e. Method 624.1, 1664B).

In-House Statistically Generated Limits.

These limits will be statistically calculated from four (4) replicate laboratory control samples (Recent DOC studies may be used.) when sufficient data points are not available.

Where enough data points exist (e.g. using 20 or more data points), QC limits are generated from laboratory QC samples for each analyte. Refer to Method Performance Procedures for details on generating in-house QC limits.

Interim Default Limits.

Interim default limits may be established in-lieu of in-house generated limits in instances where not enough data points exist. Default limits must be established prior to the analysis of samples. Whenever interim limits are established, there must be scientific validity to the range used. The following criteria may be used:

Demonstration of Capability (DOC)

Interim control limits may be statistically calculated from the four (4) replicate laboratory control samples used in the DOC study. These limits remain in effect until in-house limits can be generated.

Method/Program Recommendations.

For example*, US EPA Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW-846), 3rd Edition, Section 9.4.4, Method 8000D*, recommends the following: “Many methods may not contain recommended acceptance criteria for LCS results. The laboratory should use 70 - 130% as interim acceptance criteria for recoveries of spiked analytes, until in-house LCS limits are developed."

Technical Knowledge

Technical knowledge of the method and predicted performance are the responsibility of the laboratory. In some instances, the method recommendation

may not be appropriate for all target analytes. For example, SW-846 recommends a 70-130% evaluation criterion. However, for the acid compounds for method 8270D, recoveries will usually fall in the 30-110% range.

6.11 Laboratory Records, Management and Document Control

WA has a record system that produces unequivocal, accurate legible records, which document all laboratory activities from sample receipt to sample disposal. All required records are retained for the period required by the prevailing accrediting authority. Record retention time shall be specified in the project's QA Plan. The system retains records longer than the prevailing minimum retention time upon the request of authorized clients, agencies or regulation.

WA shall retain at the minimum the following records:

- Analytical worksheets, batch sheets, supporting documents, and data output and instrument quantitation records;
- Calculation steps including dilutions and non-nominal sample size to assist in data reduction to a reportable value;
- Copies of all final reports including analysis, dates and time of analysis;
- Archived SOPs and supporting documents such as run logs;
- Correspondences relating to laboratory activities for a specific project;
- Corrective action reports, audits and audit responses;
- Proficiency test results and raw data;
- Data review, assessment, and validation processes.

In addition, WA maintains records of:

- Employee experience and training;
- Initial and continuing demonstration of proficiency for each analyst, where applicable;
- A record of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory records.

The TNI Standard record retention time period is five years.

6.11.1 Record System and Design

The record keeping system allows reconstruction of all laboratory processes that produce the analytical data for the sample.

- The records include the names of personnel involved in sampling, preparation, calibration or analysis.
- All information relating to laboratory facilities equipment, analytical methods, and activities such as sample receipt, preparation, or data verification are documented.
- The record keeping system facilitates retrieval of all working files and archived records for inspection and verification purposes.
- All generated data, except those generated by automated data collection systems, are recorded directly, promptly and legibly in permanent ink.

- All changes to records are signed or initialed and dated by responsible staff. The reason for the change/correction is clearly indicated. Entries in records are not obliterated by methods such as erasures, correction fluids, or scratch outs. All corrections to record-keeping errors are made by one line marked through the error.
- Whenever possible, data entry is minimized by electronic data transfer and ensuring the number of manual data transcriptions is reduced.

6.11.2 Records Management and Storage

The management of laboratory records is a vital and integral part of a Quality System. Not only do these documents provide a record of results, they document traceability of laboratory activities related to a specific analytical function. The essential laboratory logbooks and records follow Document Control Procedure. Controlled documents or logbooks are used at this facility. Documents and logbooks are regulated through the Document Control Procedures.

Procedures and systems are in place to handle the management, storage and archival of information generated by WA.

WA retains electronic records of all original observations (including those pertaining to calibration and test equipment), calculations and derived data, calibration records, raw data and a copy of the final report package for a minimum of five (5) years as specified by TNI, or as specified by project requirements, if longer periods are defined. Data related to drinking water analysis will be archived for 6 years. This includes all information necessary for the historical reconstruction of data.

- The laboratory maintains all hardware and software necessary for reconstruction of data.
- Records, which are stored only on electronic media, remain supported by the hardware and software necessary for their retrieval
- Records that are stored or generated by computers have hard copy or write-protected backup copies or image file copy.
- WA has established a record management system, for control of all laboratory logbooks.
- Logbooks and such not conducive to an electronic version are maintained for 5 years.
- Access to archived information is carefully controlled and is limited to authorized personnel. These records are protected against fire, theft, loss, environmental deterioration, vermin, and in the case of electronic records, electronic or magnetic sources.
- In the event that WA transfers ownership or goes out of business, the laboratory must ensure that the records are maintained or transferred according to the client's instructions.
- Only reviewed and approved documents shall be issued to personnel.
- Consult the SOP on Document Control Procedures.

6.11.3 Record Archival

Storage of boxed archived records are maintained in a secure environment. Archival of administration and laboratory records to the record storage area occurs to ensure traceability and data security. The QA Office maintains a record system index that uniquely identifies each box

with its contents and inclusive dates based on laboratory area or document category. The QA Office assigns and records on log sheets box numbers and dates when the boxes were transferred to storage. The QA Office also dictates when documents can be securely disposed by assigning a disposal date to each box in the index. Boxes are stored on site for the record retention period identified.

In support of WA's Quality System procedures and policies are in place detailing information directly related to EPA's recommendation and requirements for protecting, storing and archiving the integrity of data generated at this facility. All electronic raw data, logs, documents, correspondences and other documents relating to interpretation and evaluation of data collected, analyzed, processed, or maintained on the laboratory's automated data collection system(s) are retained as required by TNI or by other accreditation authorities. Its application supports those requirements outlined in *EPA's Good Automated Laboratory Practices 2185, Section 7.12* and other referenced documents. The scope for maintaining and archiving allows for the following:

- Systematic methods of creating and indexing reference documents
- Generating methods of traceability at various levels of data generation
- Accounting system for storing, archiving and retrieving records
- System of regenerating and/or retrieving data both electronically and physically
- Archiving data for specified time
- Method to retrieve data used for, or in support of, legal and non-legal issues

Archived data that is required for review in support of investigations and or to build a historical profile will be accessed by using the required form located in the QA Office. Presently only the QA Department or their designate are authorized to obtain archived physical data. The IT Department handles the generation, storage, archiving and retrieval of electronic data. Consult the SOP on LMS Update and Change Control.

7 Physical Facilities – Accommodation and Environment

WA maintains a secure testing complex that accommodates the proper performance for the type, range, and volume of analytical services it provides. This laboratory facility complex encompasses a total area of 20,000 square feet in two buildings. Floor plans are available upon request.

The laboratory functional areas include:

Administrative (Accounting, Data Reporting, Operations, Technical, QA and IT)
Sample Receipt and Shipping
Metals Laboratory (ICP, ICP/MS, CVAA)
Field Services
Microbiology and Bioassay
Agricultural, Plant and Soils Laboratories
Inorganic Chemistry Laboratory
Organic Sample Preparation Labs
Instrument and Extractable Organics (ICP, GC, GC/MS, HPLC, IC, Calorimeter)
Volatile Instrument Laboratory (GC, GC/MS, TOC)
Waste Management and Disposal
Miscellaneous Testing: FIA and Flame Atomic Absorption

7.1 Environment

Each laboratory section is provided with effective separation of any incompatible testing activities (e.g. separation of organic extractions from the volatile analytical section). Lighting, noise, humidity, heating, ventilation and air conditioning, and energy sources satisfy the needs of the testing performed in the permanent facilities. The laboratory building designs ensures regulated temperature control for analytical equipment. This ensures stability of voltage, temperature, and other pertinent environmental conditions. Air-handling systems minimize airborne contaminants that jeopardize sample integrity or analytical performance.

The analytical instrumentation is in separate areas from laboratory activities that involve the use of large quantities of organic solvents or inorganic acids. Separate areas are provided for Volatiles and Microbiological and Bioassay testing.

Standards and other materials requiring sub-zero storage temperatures are placed in freezers at temperatures of –10 to –20°C and separated from samples or potential contaminating materials. Refrigerators provide cooling temperature for samples requiring the appropriate range of 1 to 6°C. Sample storage areas for volatiles are separated from other samples and monitored for any effects due to cross contamination.

7.2 Laboratory Work Areas

The monitoring of environmental conditions and general housekeeping is maintained to avoid any influence on the testing activities performed and to provide an assured and continued safe environment. The separation of analytical sections is vitally important such as in the Microbiological-Bioassay and VOC departments. Environmental tests are stopped when any environmental condition affecting the results of a test is encountered. Good housekeeping is the

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responsibility of all personnel. Each person is responsible for assuring clean and unrestricted work areas.

7.3 Security

WA provides a secure environment for its employees, guests, clients, samples and analytical data. Security procedures require that all exterior doors remain locked unless manned internally. Access to the laboratory is limited to employees and contractors. All visitors are required to sign in and out using the Visitors Log and must be accompanied by a laboratory employee at all times within the appropriate areas.

All doors are locked after hours and require a key or key card for entry. The security alarm continuously monitors for smoke and fire related heat. When the alarm is activated, the appropriate emergency response departments are notified. The local emergency departments have the emergency contact list for the laboratory. Likewise, the laboratory posts emergency numbers in each area.

There are high-resolution security cameras placed strategically within the buildings in the complex. The cameras continuously monitor their respective areas with digital recording at all times.

Access to specific electronic databases is controlled by the IT Department. Prior authorization is required to obtain access to laboratory databases. Once authorized and access is allowed, further security control is enhanced by password protection. Each person who uses the laboratory's LMS, email system and other supporting electronic highways is pre-assigned by their supervisor. Passwords are changed on a periodic basis. All changes for access by individuals must be authorized before access is granted.

Samples are maintained securely to avoid deterioration, cross-contamination, loss or damage during sampling, storage, handling, preparation and analysis.

In the event special procedures regarding environmental conditions or security are needed the laboratory will prepare and implement where necessary.

Electronic and physical data is held securely. Consult the LMS Update and Change Control and Document Control SOPs for additional details.

8 Instrumentation and Equipment

8.1 Instrumentation

WA maintains a full complement of state-of-the-art instrumentation for the proper performance of analytical services. All instrumentation and equipment is selected to meet method specific sensitivity requirements. All laboratory equipment is purchased through an approved vendor. WA maintains a purchase order system that allows the use of approved vendors only. This system tracks the ordering, receipt and approval of all equipment and supplies utilized by the laboratory.

The installation and verification process of new instrumentation occurs according to the following schedule:

- Receipt of equipment and assignment of unique instrument ID
- Installation by a vendor approved service engineer
- General operation verification
- Sensitivity Check
- Initial Calibration
- Method Detection Limit Study
- Demonstration of Performance Study

A listing of the major equipment used for testing is available upon request. The equipment list details the unique identification and a summary of the configuration information. The unique identification number is listed on the equipment, in the maintenance record book and in the calibration records. Instrument manuals are maintained in order to provide instruction on use. The laboratory does not use equipment outside of its permanent control.

8.2 Support Equipment

The laboratory performs analyses using state of the art equipment. In addition to the major equipment, the most common support equipment used in the laboratory are: ovens, analytical balances and top loaders, autopipettors, water baths, hot blocks, autoclaves, pH/DO/ISE meters, conductivity meters, 8-position floor shakers, and a variety of lab wares. The SOP lists the calibration and verification requirements for all laboratory equipment used in measurements.

Laboratory reagent water is purified using ion exchange resin bed which is monitored daily with digital in-line meters. The reagent water resistivity normally is greater than 10 megohms. Water quality is monitored on a routine basis.

Reference materials include: Ultra and Class 1 weights, NIST-traceable thermometers and reference standards. A logbook records the calibration verification. The quality control staff maintains any certificates received with the reference materials. Laboratory personnel record in LMS the reference standards including date received, assignment of a unique identification number, and expiration date. Each laboratory area, records the unique identifier on the reference standard certificate when provided. The certificates are scanned and archived by the Client Services Department and or the Purchasing Agent. Alternatively, COAs are requested and obtained from the vendor.

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8.3 Maintenance

The laboratory has a proactive instrument and equipment maintenance program to minimize downtime in analytical work. The laboratory maintains service contracts for major equipment, which include routine preventative maintenance visits by the service provider. Personnel perform manufacturer-specified maintenance on a routine basis to ensure equipment operates at peak performance. All equipment is routinely inspected, maintained and cleaned.

Routine maintenance procedures are detailed within the applicable standard operating procedure (SOP). All instrument preventative and corrective maintenance are recorded in a maintenance logbook assigned to the equipment or electronically. After instrument maintenance or repair, the instruments must successfully calibrate following the method SOP. Laboratory personnel are trained in operational and routine maintenance procedures for all major instrumentation and must demonstrate quality control performance before sample analysis.

The laboratory maintains a stock of replacement parts and consumables for analytical equipment. Instrumentation contingency plans are available for use in case of major equipment failure. In the event of equipment maintenance problems or failures, equipment is taken out of service, tagged with a sign until repaired or it meets quality control.

Maintenance logbooks and or electronic records are kept for all major laboratory instrumentation and equipment. These logbooks may include manufacturer-recommended maintenance procedures, specific cleaning procedures, comments on calibration and replacement of worn or damaged parts and any work by outside contractors. When repairs are necessary, the equipment is taken out of service, repairs performed by either trained staff or trained service engineers, and an evaluation of the impact on previous calibrations or tests performed are recorded in the appropriate logbook with analyst’s initials and date. If an instrument is down for maintenance, a complete record of all corrective actions taken to reinstate the instrument back into operational service is recorded including reference to the new calibration and quality control checks. Maintenance contracts are maintained on all major analytical instruments. Work conducted by service providers is noted in the logbook and reference is made to the service report. Service reports are also kept on file by the supervisor.

Minimally, the maintenance records shall include:

- Equipment name or unique identity
- Manufacturer's name, type identification, serial number or other unique identification and instructions for use
- Date received, service date and condition
- Current location
- Details of past maintenance and future scheduling of maintenance
- A history of any damage, malfunction, modification or repair
- Dates and results of calibration or verification
- Records of maintenance performed by an outside contractor

9 Measurement Traceability and Calibration

9.1 General Requirements

All measuring devices and testing equipment have an effect on the accuracy and validity of tests. These devices and equipment are calibrated and/or verified before put into service and are monitored on a continuing basis. The results are recorded in a calibration verification logbook. The laboratory has a program for the calibration and verification of its measuring and testing equipment. The program includes all major instrumentation and support equipment such as balances, thermometers, variable pipettors and quality control standards. The SOP for Calibration of Supporting Equipment describes this calibration program including frequency and acceptance criteria. These procedures and policies are required by the 2016 TNI Standard.

9.2 Reference Standards and Reagents Program

WA maintains a Solution Validation Quality Assurance Program, SVQAP for the reagents and standards used. This SVQAP assures that all solutions and reagents purchased are of appropriate quality, traceable and accurate to a national standard. Standards are purchased as certified solutions or made in the laboratory from neat materials. All reagents, standards and solvents used within the laboratory must be traceable to the original source. All chemicals and reagents are stored in appropriate storage areas. All flammable stock solvents are stored in OSHA and NFPA approved cabinets. Acids are stored in acid cabinets.

Upon receipt, chemicals, reagents and neat standards are logged into the LMS automated inventory system that allows traceability of chemicals, standards and reagents, and manufacturer's lot number by assigning a unique identification number. Receipt date is also documented. On the corresponding Certificates of Analysis (when supplied), the unique identification number assigned for that standard or reagent is documented. Certificates of Analysis are archived by the Client Services Department or Purchasing Agent in the LMS Inventory Database. Upon depletion of the chemical, the container is removed from the inventory and the inventory is updated.

Once the chemicals/reagents or standards are properly logged in, they are identified with a label generated by LMS including the name of the chemical, standard or reagent, unique laboratory identification number, expiration date, and date received. The open date must be documented when the analyst physically opens standards or reagents. The chemicals are stored in the secure chemical stockroom until use in the preparation of reagents or standards. Chemicals used directly in the laboratory are assigned a reagent number before use in the laboratory area.

When secondary standards are to be generated, the analyst shall locate in the appropriate automated inventory system the name of the secondary standard to be generated. This database generates a programmed formula, which outlines the specific reagents and standards to be used, and the quantity of the standards or reagents and the preparation schedule. Upon the determination of quantity required, the analyst shall generate a bench sheet that summarizes the aforementioned formula.

Secondary standards are generated and maintained within the specific area of use. The analyst will record preparation of standards in LMS. Each secondary standard is identified as to test method, quantities and identification of reagents and standards used in preparing the standard solution. The documents shall include the analyst's initials, date received, date opened, and expiration date. When required, standards are verified using a second source or lot number different from that calibration standard.

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The purchase, receipt and storage of consumable materials used for the technical operations of the laboratory include the following;

a) The laboratory retains records of manufacturer's statement of purity, of the origin, purity and traceability of all chemical and physical standards.

b) Original reagent and standard containers are labeled with the date opened and the expiration date. When the manufacturer does not specify the day of the month in the expiration date, the container expiration date defaults to the last day of the month.

c) Detailed records are maintained on reagent and standards preparation. These records indicate traceability to purchased stocks or neat reagents. The following are also recorded for purchased and prepared standards as applicable: The manufacturer, lot number, LMS unique identifier, chemical name, expiration date, purity or concentration, reagents used for preparation including source, lot number and expiration date, person recording or preparing the standard/reagent and the date of preparation or receipt of stock.

d) All prepared reagents and standards are uniquely identified and the contents are clearly identified with prepared/expiration date, concentration and preparer's initials.

9.3 Traceability of Calibration

The policy of internal calibration and/or verification and validation of equipment shall be maintained by implementing the following:

The laboratory shall maintain documented procedures for in-house calibrations as evidenced by a calibration report and shall be retained for an appropriate determined time;

The laboratory shall maintain training records for calibration personnel and demonstrate technical competence for performing the calibration;

The laboratory shall demonstrate traceability to national or international standards of measurement by procuring calibration services from appropriately accredited calibration laboratories and/or purchasing reference materials that are traceable to national standards provide information of purity, and associated uncertainty of measurement and/or a statement of compliance with identified metrological specifications. The laboratory must maintain documentation of all such certificates of analyses and calibration reports;

The laboratory shall have and apply procedures for evaluating measurement uncertainty. Measurement uncertainty shall be calculated for each type of calibration and records of such calibrations be maintained. Measurement uncertainty shall be taken into account when notations of compliance with specifications are made;

Reference standards shall be re-verified at appropriate intervals to ensure that the reference value is reliable and meets the requirements of the test method. The procedure for establishing and changing calibration intervals shall be based on the historical behavior of the reference standard or as dictated by the manufacturer or reference method.

Calibrations performed by an external calibration provider must ensure measurement traceability and be accredited to a nationally approved authority. This policy shall include those calibrations and verifications provided and must be recorded in a calibration certificate or report and may be endorsed by the recognized Accreditations Body's symbol or otherwise make reference to accreditation status by a documented recognized accreditation body. The certificate must contain

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an indication of the type of entity that is accredited or endorsed by an accreditation number, with symbol or endorsed by the National Metrology Institute.

9.4 General Calibration Procedures

Essential to the Quality System, calibration procedures are in place that ensures measurements of traceability for each phase of the analytical system. Such calibrations are required in instrument calibrations and the use of calibration standards such as initial and continuing calibrations. Minimally, each calibration record is dated and labeled with method, instrument, analysis date, analyst(s), analyte name, concentration and response(s). The data processing system shall compute the calibration curve for each analyte. The curve may be derived from linear or nonlinear models. For an average response curve a minimum of 4 calibration points shall be used. For a linear fit 5 calibration points must be used and for quadratic fit, a minimum of 6 points is required. The curves generated are traceable to a database file and the unique filename shall be recorded on the appropriate batch worksheet. Criteria for acceptance of a calibration curve is established and documented in method standard operating procedures.

The following instrumentation shall undergo the following general calibration procedures.

a) Purge & Trap Gas Chromatography/Mass Spectrometry (GC/MS)

b) Purge & Trap Gas Chromatography (GC)

c) Automated Direct Injection GC/MS

d) Automated Direct Injection GC

e) High Pressure Liquid Chromatography (HPLC)

9.4.1 General Instrumentation Calibration Procedures

The following instrument calibration procedures are used in the laboratory's daily analytical procedures where applicable:

a) Initial Calibration, ICAL

The calibration of instruments is required to ensure that the analytical system is operating correctly and functioning at the proper precision, bias (accuracy), and sensitivity. The frequencies of calibration and calibration verification are presented in the following sections and are based upon the various analytical methods and industry standards.

An instrument is considered calibrated when an instrumental response can be related to the concentration of an analyte. This relationship can be depicted graphically and is termed a calibration curve. Refer to SW 846 Method 8000 for details on calibration models and calibration options.

ICALs are based on a requisite number of standards identified within the individual method for each target analyte. The MQL shall be established at a low standard for each target analyte. See individual method SOPs for details on concentrations, number of standards used, and evaluation of the ICAL.

All samples analyzed and quantitated must be associated with a valid initial calibration.

b) Initial Calibration Verification, ICV

The ICAL is verified as accurate with a standard purchased or prepared from an independent source. This procedure involves the analysis of a standard containing all of the target analytes (usually at the middle level of the curve). Refer to individual method SOPs for details on the concentration and evaluation of the ICV.

c) Continuing Calibration Verification, CCV

The initial calibration is verified on each day of testing through the analysis of a continuing calibration standard. The concentration and frequency of use of the continuing calibration standard is performed in compliance with the requirements of the specific method. The relative response factors for all analytes of interest are calculated and verified against the initial calibration mean relative response factors. The percent difference (%D) or percent drift (%X) for each analyte is calculated and must be less than the acceptance criteria stated in the method.

This standard is analyzed to determine whether the analytical system is working properly and/or if a new ICAL is required. Refer to individual method SOPs for details on the frequency and evaluation of CCVs. Calibration Verification verifies compliance with the initial calibration curve, but does not overwrite the response factors used for the quantitation, nor allows re-sloping of the calibration curve.

d) Initial Calibration Blank, ICB and CCB, Continuing Calibration Blank

These QC samples are required for inorganic metals analyses to verify the system is free of contamination.

The found concentrations for each target analyte in the ICB/CCB must be less than or equal to the MDL/MQL as defined by project specific requirements.

9.5 Instrument Calibration

WA performs the following instrument calibration procedures. Instrument calibration and calibration options are discussed in SW 846 Method 8000D and in individual reference SOPs.

Calibration is defined as the determination of response versus concentration of an analyte. This relationship is referred to as a calibration curve. Initial calibration curves are established utilizing a prescribed number of standards for each target analyte. The initial calibration curve is established as specified in the individual methods.

Linearity is determined using linear regression analysis for each target analyte by calculating the correlation coefficient (r) or the squared correlation coefficient, r^2 (coefficient of determination). In the generation of the calibration curve, the origin is not used as a calibration point, unless allowed by the method. Refer to individual SOPs for minimum r or r^2 values. Verification frequency is established by the reference method. For drinking water methods calibrations are evaluated using correlation coefficient or coefficient of determination and the laboratory shall evaluate relative error using either Relative Error (%RE) or Relative Standard Error (%RSE) at the mid-point and lowest calibration level. The RE shall meet the criteria specified by the applicable method. If no criterion for the low level is specified by the reference method the criterion and the procedure for deriving the criterion shall be specified in the laboratory SOP.

Alternatively, for chromatographic methods, the average calibration factor (CF) or response factors (RF) are calculated for each target analyte. Linearity is evaluated by calculating the percent relative standard deviation (%RSD) of the CFs/RFs from the initial calibration standards

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for each target analyte. The individual reference SOPs indicate minimum acceptance criteria for %RSD.

Linearity is presumed if the correlation coefficient (r) is >= 0.995 or the coefficient of determination (r^2) is >=0.99. The RSD criteria for linearity is specified in the applicable method. Analysis will not proceed until the method specific initial calibration evaluation criteria are met.

9.5.1 GC/MS Methods

GC/MS methods have additional specific evaluations that must be performed to validate the initial calibration:

a) System Performance Check Compounds (SPCCs). These compounds are designated within the analytical method (e.g. 8260B, 8270D.) and are used to verify compound stability and to check for degradation caused by contaminated lines or active sites in the system. The SPCCs are evaluated for minimum response factors as specified in the method. Analysis of samples is not to proceed unless this criterion is met.

b) Calibration Check Compounds (CCCs). The purpose of the CCCs is to evaluate the calibration from the standpoint of the integrity of the system. High variability for these compounds is indicative of system leaks or reactive sites on the column. The CCCs are evaluated for %RSD maximums as specified in the method. Analysis of samples is not to proceed unless this criterion is met.

9.5.2 GC and HPLC Methods

GC and HPLC initial calibrations are performed.

a) Multi-Component Pesticides. For each multi-component pesticide (e.g. Chlordane and Toxaphene), a mid-level standard is analyzed each sequence to aid in pattern recognition. If a multi-component pesticide is identified in a sample, the system may be re-calibrated for that pesticide with a minimum of three (3) standards. The extract is re-analyzed with the new calibration. Calibrations for the multicomponent pesticides are based on five (5) major characteristic peaks or area sum in the case of Toxaphene.

b) PCBs – Initial calibrations are maintained for Aroclors 1260 and 1016 (unless otherwise specified, the LCS and MS/MSD will be spiked with a mixture of 1260/1016). Mid-level standards of the other Aroclors are analyzed each analytical batch to aid in pattern recognition. If another Aroclor is identified in a sample, the system may be calibrated for that Aroclor with a minimum of three (3) standards or diluted to a concentration similar to the mid-level calibration standard. The extract may be re-analyzed with the new calibration or re-injected at a dilution with the calibration standard. Calibrations for the Aroclors are based on five major characteristic peaks.

For multiple component pesticides, PCBs or hydrocarbons the quantitation consists of the average of selected peaks or the integration of the area defined by a reference standard. The SOP details the integration criteria for each compound.

Internal standard calibration or external standard calibration is utilized for analysis by GC. The method-specified number of calibration standards is used. Each solution is analyzed once and the analyte relative response factors or calibration factors are calculated. The mean relative response factor for each analyte is then obtained by using the expression in the formula listed in the SOP. Integrated areas or heights are used for these expressions. Retention time windows for

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peak responses are calculated in compliance with the method requirements or established as default values.

The initial calibration is verified as accurate by the analysis of an independent calibration verification standard. This standard is prepared independently of the ICAL from a second source or different lot number. The ICV standard must meet method continuing calibration verification (CCV) criteria in order to validate the initial calibration.

CVs are analyzed to determine if the analytical system is operating properly and to validate that the current initial calibration remains valid. The CV is typically the analysis of a single, mid-level standard at method specified intervals. Typically, a calibration verification (CV) is analyzed at the beginning of the sequence; continuing CVs are dispersed throughout the sequence and at the end of the sequence.

The calibration verification process does not overwrite the original response factors from the initial calibration. Calibration verification is used for all organic analytical methods.

Initial CVs are evaluated based on method specific criteria. If a CV does not meet the evaluation criteria requirements specified by the method, a second CV is analyzed. If the CV remains unacceptable, corrective action must be taken (e.g. instrument maintenance). The CV must meet method evaluation criteria prior to the analysis of samples or a new initial calibration must be performed.

Method performance is monitored by the introduction of various internal quality control checks and samples. These checks allow the evaluation of data on a method, matrix and sample basis. In general, each extraction batch requires, at a minimum, a laboratory blank (LB), laboratory control sample (LCS) and a matrix spike/matrix spike duplicate (MS/MSD). Additionally,

a) Batch QC evaluation is based on the analysis of laboratory control sample(s) and laboratory blank(s).

b) Matrix QC evaluation is based on the fortification of an environmental sample with known amounts of target analytes (matrix spike, matrix spike duplicate).

c) Sample evaluation is performed with the assistance of surrogate recoveries.

9.5.3 Additional Organic Calibration Procedures

Retention Time Windows

Retention time windows are crucial to the identification of target analytes. Absolute retention times are used for compound identification in all GC and HPLC methods that do not employ internal standard calibration. Retention time windows are established to compensate for minor shifts in absolute retention times as a result of sample loading and normal chromatographic variability. The width of the retention time window is established to minimize the occurrence of both false positive and false negative results. Tight retention time windows may result in false negatives and/or may cause unnecessary reanalysis of samples when surrogates or spiked compounds are erroneously not identified. Overly wide retention time windows may result in false positive results that cannot be confirmed upon further analysis.

WA establishes the majority of retention time windows based on the default standard deviation criteria of 0.01 minutes listed in *Method 8000D Section 11.6.3 of SW-846*. RTWs are established and monitored using the following procedure:

a) Make three injections of all single component standard mixtures, including surrogate standards and multi-component analytes (such as PCBs) over the course of a 72-hour period. Typically, working standards analyzed the previous week are used to generate the retention time window report.

b) The mean and standard deviation of the absolute retention times for each single component analyte and surrogate are calculated.

c) For multi-component analytes (e.g. chlordane, PCBs), three to five major peaks are chosen. The mean and standard deviation of those peaks are calculated.

d) According to *Section 11.6.3 of SW-846 method 8000D*, "If the standard deviation of the retention times for a target compound is 0.000 (i.e., no difference between the absolute retention times), then the laboratory must either collect data from additional injections of standards or use a default standard deviation of 0.01 minutes."

e) The width of the retention time window for each analyte, surrogate, and major constituent in multicomponent analytes is defined as ± 3 times the standard deviation of the mean absolute retention time established during the RTW study. If the default standard deviation of 0.01 minutes is employed, the width of the window will be 0.03 minutes.

Instrument Performance Checks

Several methods outline additional QC procedures to verify the instrumentation is in good working condition. These QC samples must be analyzed and meet method-specified acceptable limits prior to commencing sample analyses.

Mass Spectrometer Tuning – GC/MS Methods

The GC/MS is hardware tuned before performing the initial and continuing calibrations. Results must meet the peak ratio specifications of the analytical methods. Volatiles analyses use Bromofluorobenzene (BFB) and Semivolatiles analyses use Decafluorotriphenylphosphine (DFTPP) for instrument tuning.

Prior to the analyses of any standard or samples, the MS standard mass spectral abundance criteria must be evaluated. BFB (4-Bromofluorobenzene) tune standard is analyzed for GC/MS volatiles (e.g. method 8260) and DFTPP (Decafluorotriphenylphosphine) for GC/MS semi-volatiles (e.g. method 8270). The tune standard must be analyzed at the beginning of the analytical shift/sequence and every 12 hours of continuous analysis. The 12-hour clock starts at the time of injection of the tune standard. Tune standards evaluation reports are generated by the data processing software. Analysis will not proceed until tune standard meets method specific acceptance criteria.

Injection Port Inertness - GC/MS Semi-Volatiles

To verify column condition and injection port inertness, the DFTPP tune standard also contains 4'4'-DDT, Benzidine and Pentachlorophenol. Analysis will not proceed until tune standard meets method specific acceptance criteria.

a) Injection Port Inertness

The injection port inertness of the GC portion of the GC/MS is evaluated by the % breakdown of 4,4'- DDT. This procedure is done to verify acceptable instrument performance, regardless of whether DDT is a target analyte. The % breakdown of 4,4'-DDT to 4,4'-DDE and 4,4'-DDD must not exceed method specific acceptance criteria in order to proceed.

b) Column Performance Check

The condition of the GC column is evaluated by the tailing of Benzidine and Pentachlorophenol (PCP). Benzidine and Pentachlorophenol must be present at their normal responses, with no visible peak tailing, as demonstrated by the peak tailing factors. The acceptance criteria for the peak tailing factor for Benzidine and Pentachlorophenol is specified in the applicable method. Breakdown and tailing factor reports are generated by the data processing software.

Injection Port Inertness Check – GC Pesticides

The inertness of the GC system must be checked prior to beginning the analytical sequence. A mid-range standard of 4,4'-DDT and Endrin is analyzed and monitored for breakdown. If the combined breakdown exceeds specified criteria, corrective action must be performed. Analysis will not proceed until the breakdown standard meets method specific acceptance criteria.

Additional quality control surveillances are part of the GC and GC/MS analyses. These may include internal standards, surrogates, laboratory blanks, instrument blanks, laboratory control samples, matrix spikes and matrix spike duplicates. The frequency and control criteria are defined in the laboratory SOP.

9.5.4 Analytical Methods – Metals Laboratory

Analyses for metallic analytes utilize the following instrumentation:

a) ICP – Inductively Coupled Plasma-atomic-emission Spectroscopy

b) ICP-MS – Inductively Coupled Plasma-Mass Spectroscopy

c) CVAA – Cold Vapor Atomic Absorption Spectroscopy

d) FAAS – Flame Atomic Absorption Spectroscopy

Calibration Procedures

Initial Calibration (ICAL)

For metals analyses, unless otherwise specified, an initial calibration must be performed at the beginning of each analytical shift and when a CCV fails or significant instrument maintenance is performed. In general, linearity is acceptable only if the linear regression coefficient r is >= 0.995 or if the squared correlation coefficient r^2 is >=0.99. If r < 0.995 or r^2 < 0.99, take corrective action and recalibrate.

ICP

ICP initial calibration is performed with four (4) standards and an initial calibration blank (ICB). The concentration of the highest standard establishes the linear calibration range and the linear dynamic range of the method. To ensure accuracy of concentrations at the MQL, a low-level check (LLC) standard is prepared from the primary source standard and analyzed after initial calibration. Results for the LLC must meet method specific acceptance criteria.

CVAA

CVAA initial calibration requires a minimum of five (5) standards and a calibration blank. The low standard is at or below the MQL.

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Linearity is acceptable only if the linear regression coefficient r is >= 0.995 or r^2 is >=0.99. If the calibration criterion does not meet any of the above requirements, corrective action is required prior to the analysis of any samples.

Initial Calibration Verification (ICV)

ICP

The initial calibration is verified as accurate prior to the continuation of the analytical sequence. The verification is performed based on the following:

a) Read-Back Analysis

Standards used for the initial calibration are re-analyzed as samples. The read-back results must meet method specific acceptance criteria to proceed. Corrective action is taken when this criterion is not met.

b) Initial Calibration Blank (ICB)

The ICB is analyzed as a sample. All analytes must be below the MQL unless otherwise specified in the analytical SOP.

c) Initial Calibration Verification Standard (ICV)

The ICV is a standard prepared independently (e.g. second source) of the initial calibration standards.

The ICV must meet method specific acceptance criteria.

d) Interference Check Sample (ICS)

Standards ICS-A (majors) and ICS-A/B (majors/minors) are analyzed. The results must meet method specific acceptance criteria.

e) Low Level Check (LLC)

The LLC standard is analyzed and must meet method specific acceptance criteria.

CVAA

The initial calibration is validated based on the analysis of the Initial Calibration Verification Standard (ICVS). The ICVS is a standard prepared independently (e.g. second source) of the initial calibration standards. The ICVS must meet method specific acceptance criteria.

Continuing Calibration Verification (CCV)

ICP

To verify the initial calibration throughout the analytical sequence, a series of checks are performed every 10th sample and at the end of the sequence.

a) Continuing Calibration Blank (CCB). Analyze after every 10 production/QC samples and at the end of the sequence. All results must be less than the MQL unless otherwise specified in the analytical SOP.

b) CCV standards. Analyze after every 10 production/QC samples and at the end of the sequence and must meet method specific acceptance criteria.

c) ICS-A and ICS-AB. The ICS-A is analyzed at the beginning and the ICS-AB is analyzed at the end of the sequence and must meet method specific acceptance criteria.

CVAA

To verify the initial calibration throughout the analytical sequence, a series of checks are performed after 10 production/QC samples and at the end of the sequence.

a) Continuing Calibration Blank (CCB). Analyze after 10 production/QC samples and at the end of the sequence. All results must be less than the MQL unless otherwise specified in the analytical SOP.

b) CCV standards. Analyze every 10th and at the end of the sequence and must meet method specific acceptance criteria.

ICP-MS and FAAS

Consult Methods EPA 200.8 and SW 846 Method 6020B and 7000B for details on calibration procedures.

Quality Control Procedures

Quality control procedures (e.g. sample batching, batch QC requirements) are detailed in Section 6.8 of this document. In general, each sample batch requires the digestion and analysis of a laboratory blank (LB), laboratory control sample (LCS) and a matrix spike/matrix spike duplicate (MS/MSD).

Method performance is monitored by the introduction of various internal quality control checks and samples. These checks allow the evaluation of data on a method and matrix basis. Method QC evaluation is based on the analysis of laboratory control samples and laboratory blanks. Matrix QC evaluation is based on the analysis of matrix spikes, matrix spike duplicates).

Refer to method SOPs for details on quality control procedures and their evaluation.

MS/MSD Failures – ICP Corrective Action

When MS/MSD recoveries are flagged as outside QC limits, the following corrective action is required:

Dilution Test (DT)

This test is generally performed when analytes are present at high levels in the parent sample when compared to the spike levels of the target analytes. If the result of the parent sample is at least 25 times the detection limit, then the digestate is diluted 1:5. The diluted and undiluted results of the failing analyte(s) should agree within 10%.

Post Digestion Spike (PDS)

If the results of the sample are less than 25 times the detection limit, then the parent sample digestate is spiked with a known amount of the failing analyte(s). The recovery should be within 75% to 125% of the expected value.

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MS/MSD Failures – CVAA Corrective Action

Dilution Test (DT)

This test is generally performed when analytes are present at high levels in the parent sample when compared to the spike levels of the target analytes. If the result of the sample is at least 25 times the detection limit, then the parent sample digestate is diluted 1:5. The diluted and undiluted results of the failing analyte(s) should agree within 10%.

Post Digestion Spike (PDS)

If the results of the sample are less than 25 times the detection limit, then the parent sample digestate is spiked with a known amount of the failing analyte(s). The recovery should be within 85% to 115% of the expected value.

Preliminary Method Set-Up for ICP

a) Linear Dynamic Range.

The linear dynamic range is checked initially, whenever there is a significant change in instrumental hardware or operating conditions or annually.

WA has established the upper limit for the ICP analytes as the concentration of the highest calibration standard used to perform the initial calibration. These values are well under the manufacture's recommendation of upper dynamic range for each analyte. Any sample results above these calibration values are diluted to bring the concentration of the analyte below the highest initial calibration concentration. This ensures that no sample result is reported that is above the initial calibration range of the instrument.

b) Interference Check Standard (ICS)

Spectral interferences can be caused by background emission interference from several sources (e.g. recombination phenomena, stray light or overlap). These factors are compensated for by the use of Interelement Spectral Correction Factors (IECs). IECs must be verified prior to the analysis of samples using ICS-A and ICS-A/B QC solutions and are updated at a minimum, annually.

9.5.5 Analytical Methods – Inorganic Laboratory

Instrumentation/Techniques

The inorganic laboratory employs a variety of wet chemistry techniques. Inorganic analyses generally refer to wet (classical) chemistry methods which fall into the following categories:

a) Colorimetric - UV/VIS Analyses

b) Titration

c) Gravimetric

d) Ion-specific Electrode

e) Instrumental

1) Ion Chromatography

2) Total Organic Carbon

Total organic carbon calibration is obtained by analyzing a set of five or more initial calibration solutions. The concentrations must bracket the expected concentration range of the samples analyzed. Procedures for verifying the calibration curve are method specific. The calibration curve is verified at least every 20 samples.

f) Spectrophotometric

g) Flow Injection Analyzers

Analytical worksheets have been developed for each method. The worksheet is method specific and is designed to record all necessary information, QA/QC requirements and sample results for each analytical batch. Data reduction procedures are presented within the analytical SOP. Sample preparation is generally included within the analytical method SOP.

Calibration

Initial Calibration (ICAL):

Analytical systems for wet chemistry methods are calibrated to define the working range by use of a series of standard solutions. A minimum of three (3) to six (6) standards is typically used depending on the specific method requirements or type of curve. The concentrations and responses are used to generate a calibration curve using linear regression. The correlation of coefficient, r must be >= 0.995 or the coefficient of determination r^2 must be >=0.99 to validate the curve. Calibration curves are generated and documented.

Initial Calibration Verification (ICV):

When feasible, a second source is utilized to verify the ICAL. The ICV is analyzed and evaluated using the calibration verification criteria. Refer to individual SOPs for evaluation criteria. Also, instrumental read back of initial calibration solutions may be applicable.

Continuing Calibration Verification (CCV):

Prior to the analysis of samples and periodically throughout the analytical sequence, the calibration must be verified to ensure that the system is performing properly. Typically, CCVs are analyzed at the beginning, every 10 to 20 samples and at the end of an analytical sequence. Evaluation criteria are specified within the analytical SOP.

9.5.6 Analytical Methods – Bioassay

The Bioassay Laboratory is a self-contained lab maintained at a constant temperature with a regulated light cycle and dedicated heating and air conditioning systems. The laboratory is designed to meet criteria as outlined in EPA document EPA/600/4-91/002. The bioassay department maintains certifications in several states including Arkansas, Louisiana, and Kentucky and participates in the annual DMR-QA study as part of NPDES Program.

This facility routinely performs testing required by NPDES permits for both industrial and municipal clients. This testing includes both Acute and Short Term Chronic testing in freshwater for *Ceriodaphnia dubia* and *Pimephales promelas* (fathead minnow) and acute testing for *Daphnia pulex*. In addition to regulatory testing, the Bioassay laboratory performs a variety of chemical product screen tests.

Bioassay procedures differ significantly from typical environmental analytical requirements. This department requires its own quality management plan and is therefore not specifically addressed here. Refer to the Quality Manual for Bioassay for further information.

9.5.7 Analytical Methods – Microbiology

The Microbiology Laboratory shares laboratory space with the Bioassay Laboratory and is a self-contained lab maintained at a constant temperature with a regulated light cycle and dedicated heating and air conditioning systems. The laboratory is designed to be separated from other analytical areas that use chemicals and reagents that may affect microbiological testing. The microbiology department maintains certifications in several states including Arkansas, Mississippi and Tennessee and participates in the annual DMR-QA study as part of NPDES Program. It also maintains limited accreditation under the Louisiana DEQ.

This facility routinely performs testing required by NPDES permits for both industrial and municipal clients. This testing includes but not limited to Total coliform, E. coli and Fecal coliform. In addition to regulatory testing, the microbiology laboratory performs a variety of food product tests.

Microbiology procedures differ significantly from typical environmental analytical requirements and have various quality control requirements. Due to this variability the specific quality control procedures are detailed in each analytical standard operating procedure.

9.6 Calibration-Verification of Laboratory Support Equipment

9.6.1 Thermometers

Thermometers are used in temperature-dependent equipment where the method or procedure requires the use of such. These include the monitoring of refrigerators, freezers, oven, incubators, water baths, hot blocks and pH meters.

On a daily basis, the QA Department checks and records the temperatures of working thermometers used at this laboratory. In aiding the monitoring of temperatures, thermometer bulbs are placed in sand for ovens and water or glycerin for water baths, freezers, refrigerators and incubators.

Laboratory thermometers are checked routinely for accuracy against certified, NIST- traceable thermometers. These calibrations are performed annually for mercury or alcohol in glass thermometers and digital thermometers. If a digital thermometer is used in support of drinking water analysis, it shall be calibrated quarterly. The temperature difference between the working thermometer and the NIST-traceable thermometer is known as the correction factor. Correction factors, derived from the calibrations, are applied to temperature readings where applicable. When warranted by state or program regulations, if the correction factor for drinking water methods exceeds ± 1.0ºC it shall be replaced (± 3.0°C for non-drinking water methods). The analyst records the corrected temperature for all observations.

NIST-traceable thermometers are calibrated by a certified agency and re-certified every three years. Such calibrations shall be performed according to the 2016 Standard and or the Manual for the Certification of Laboratories Analyzing Drinking Water. Such calibration shall also be documented on a calibration certificate and include the accrediting body’s symbol or statement of endorsement. Records of thermometer calibrations are retained in the QA Office. Working thermometers are identified according to location and serial number. All thermometers are tagged with the ID number, correction factor, and the date of the calibration check.

Thermometers are not used past the calibration expiration date or if the thermometer is not reading properly. Thermometers are replaced when a change occurs in a thermometer due to alcohol separation, breakage, damage, cracks or exhibit temperature fluctuations.

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9.6.2 Balances and Top Loaders

This laboratory routinely uses analytical balances and top loaders to weigh sample aliquots and reagents/standards.

This equipment is verified daily using pre-calibrated weights. Verification checks are performed on each day of use, for each balance. The weights used cover the range of the intended use for each balance/top loader. The verification consists of a minimum of three weights, which bracket the weight to be measured and individual readings are documented on verification log sheets which lists the acceptance criteria and performance criteria for the various balances used in the laboratory. The actual weight for each weight used is recorded on the Daily Balance Verification Log. The acceptance criterion for analytical balances is +/- 0.1% and +/- 1% for top loaders unless specific criteria is noted in an analytical method (i.e. EPA 1664B). Calibration weight measurements must meet the acceptance criteria listed on the record form.

Each balance and top loader is serviced and calibrated by an accredited service provider at least annually. The accuracy of the calibration weights used by WA are verified on a yearly basis by an accredited calibration service. Such calibrations shall be performed according to the2016 TNI Standard and the Manual for the Certification of Laboratories Analyzing Drinking Water. Such calibration shall also be documented on a calibration certificate and include the accrediting body's symbol or statement of endorsement. Certificates of Calibration are maintained by the QA Office. Balances are labeled with the balance number, date of calibration service and the expiration date for the annual service check. The balance number used for any measurements requiring traceability is recorded on the batch sheet. Balances are not used when the weight check is not within acceptable criteria.

9.6.3 Automatic Pipettes

Where applicable, variable pipettes are used to spike samples, make dilutions and generate standards. Where quantitative volume transfers are made, the delivery volumes are checked gravimetrically. Delivery volumes for the automatic pipettes are verified and recorded before use. The daily verification is performed three times at the volume of use. The average of the daily check must be within the criteria stated in the pipette calibration log sheet.

Where variable pipettes are used, calibration procedures are implemented daily. The QA Department maintains a variable pipette calibration record to document the multiple (3) weightings taken, based on the specific density of water at 20°C. The specific density of water at that temperature is determined to be 0.9982 g/ml. The established acceptance criteria is that accuracy must be within 2.5% of the expected volume for the average reading. Quarterly verification ranges for pipettes used for drinking water analysis include a low point, a high point that bracket the intended use of the variable pipette and at the mid-point.

9.6.4 pH Meters

pH meters are calibrated prior to each day of use. The meter is calibrated following the procedure for pH analysis. The records of the calibration are recorded in the instrument logbook or on the batch sheet for the analysis being performed. Three buffer solutions that bracket the measurement range for the analysis are used for calibration. An independent buffer is used daily to verify meter stability. Buffer solutions used for calibration are traceable. Standard buffer solutions are not retained or re-used. The standard reagent numbers of the buffer solutions are recorded on the applicable record to ensure traceability of the measurement.

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9.6.5 Conductivity Meters

Conductivity meters are calibrated daily as indicated in the appropriate analytical SOP. Calibration verification standards are used to verify instrument performance. The acceptance criteria are defined in the method SOP. Calibration verification standards are not retained or reused. Refer to the analytical SOP for details.

9.6.6 Autoclave

The date, pressure, time in/out, temperature, total cycle time and analyst's initials are recorded each time the autoclave is used. Maintenance is conducted annually by an authorized provider and recorded and maintained in the maintenance log. Routine maintenance includes cleaning the autoclave seal to ensure freedom of caramelized media and cleaning drain screens to remove any debris buildup. For the efficient operation of the unit, overcrowding is avoided. A copy of the pressure and temperature instrument printout is printed and kept with the analytical batch.

9.6.7 Spectrophotometer

WA utilizes spectrophotometers for various inorganic methods. In order to verify that the spectrophotometer readings are accurate, a calibration procedure is used. This calibration involves the use of a wavelength calibration check. This check requires the generation of a standard, Cobalt Chloride, upon which multiple reading are taken at 505, 510, 515 and 520 nm. The instrument is in proper calibration when maximum absorbance (minimum transmittance) occurs between 505 and 515 nm. The specific absorbance values are unimportant. This calibration is performed annually and recorded in the instruments maintenance log.

9.6.8 Turbidimeter

A turbidimeter is used for various inorganic methods. In order to verify that the turbidimeter readings are accurate, a calibration procedure is used. Multiple primary standards are used for verifying that the turbidimeter is reading correctly. These primary standards are various concentrations of Formazin. The acceptance criteria are ± 5 percent of the concentration of the primary standard(s). Turbidimeter may also be checked for drinking water samples for metals. Consult the appropriate SOP for criteria.

9.6.9 Volumetric Glassware

WA utilizes volumetric glassware appropriate for the applicable method. All glassware is routinely inspected for damage. All glassware found to be structurally compromised is removed from service and replaced. All calibration certificates are maintained and filed in the respective department utilizing the device(s). In instances where a certificate is not available, the department supervisor or their designate shall conduct a Volumetric Glassware/Device Calibration Check. WA employs *ASTM E 542-01* and *ASTM E 969-95* procedures for the verification of volumetric devices.

9.6.10 Calibration Verification Weights

WA utilizes multiple NIST-Traceable weights for verifying the calibration of the laboratory's analytical balances and top loaders. The verification is performed using three weights over the intended weighing range of the analytical balance or top loader. These weights are calibrated annually by a calibration laboratory according to ISO/IEC 17025. Such calibration shall also be documented on a calibration certificate and include the accrediting body's symbol or statement of endorsement. Certificates of Calibration are maintained by the QA Office.

Glass micro liter syringes are considered Class A when they come with a certificate attesting to established accuracy or if the laboratory initially demonstrates accuracy. These syringes are replaced on an annual basis or more frequently if problems are encountered.

Generally, calibration verification is performed on a designated schedule or if the most previous calibration has expired. This verification is performed for analytical systems that have a calibration verification requirement.

Internal reference materials, when used, shall be checked as technically as possible.

Consult the SOP, *Calibration Verification of Supporting Equipment* for details.

10 Test Methods and Standard Operating Procedures

10.1 Test Methods

The laboratory uses appropriate methods and procedures for all tests and related administrative activities. The method and procedures are consistent with the accuracy required, and with any standard specification relevant to the calibrations or tests concerned. When the use of mandated methods for a sample matrix is required, only those methods are used. Where methods are employed that are not required (e.g. a Performance Based Measurement System), the methods are fully documented and validated and are available to the client and applicable recipients. Refer to Appendix D Table 3 for a list of certified analytical methods accredited under the TNI Program. The laboratory derives its methods from current published or national standards. Based on the most current Method Update Rule the lab defaults to the most current versions of Standard Methods where applicable unless otherwise noted. Some microbiological methods may indicate a different version. Consult the most current CRF for guidance.

10.2 Methods Documentation

Methodology documentation is a vital component in the Quality System. This document allows for an analytical pattern to exist that allows reproducibility in analytical procedures. Test method SOPs describe the sample analysis procedures, quality control frequencies and acceptance criteria. EPA accepted methods, nationally recognized methods or client-specified methods are the basis for performance criteria, instrument conditions and the steps of the procedure. The method performance requirements of the published methods are followed unless otherwise specified by the client in writing.

The reference methods define the operating conditions. In many of the reference methods a range or general guidance on the operating conditions are defined. Documented modifications to the operating conditions clarify the reference methods or improve the quality of the results. In all cases where the method modifications are adopted, the performance criteria from the reference method must be met. Modifications to the operating conditions are stated in the SOP. Minor changes in the operating conditions are documented in the appropriate document revision form and attached to the current document. A complete revision to a SOP takes place on a scheduled basis, when a change in the operating condition improves performance and/or as required by regulation or accrediting authority.

10.3 Standard Operating Procedures (SOPs)

WA maintains SOPs that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, sample receipt and storage, purchasing of all materials, and all test methods. These documents include reference to equipment manuals provided by the manufacturer, internally referenced documents, and published promulgated methods.

Controlled copies of all SOPs are accessible to all personnel in either electronic or hard copy. The SOPs are organized in a standard format with the signatures of the approving authorities. Each SOP is uniquely identified by its effective date. Uncontrolled copies may be distributed to agencies outside of the laboratory. Likewise, antiquated SOPs are removed from circulation and appropriately archived to preclude their use. A master list of current and antiquated SOPs is maintained by the QA Office. Analytical SOPs are reviewed minimally every two years using the same process performed at the original review to ensure compliance with applicable requirements

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or standards. Employees shall read and acknowledge the most current SOPs. Pertinent information to designated personnel is available upon which to base the review and approval.

10.3.1 Laboratory Analytical Methods SOP(s)

Each laboratory area maintains a Laboratory Methods Manual containing SOPs utilized in this area. Manuals consist of copies of method and administration SOPs prepared by the laboratory. Each test method includes or references where applicable:

1) identification of the test method;
2) applicable matrix or matrices;
3) method detection limit;
4) scope and application;
5) summary of method;
6) definitions;
7) interferences;
8) safety;
9) equipment, maintenance, and supplies
10) reagents and standards
11) sample collection, preservation, shipment and storage;
12) quality control;
13) calibration and standardization;
14) procedure;
15) calculations;
16) method performance;
17) pollution prevention;
18) data assessment and acceptance criteria for quality control measurements;
19) corrective actions for out-of-control data;
20) contingencies for handling out-of-control or unacceptable data;
21) waste management;
22) references; and
23) any tables, diagrams, flowcharts and validation data.
24) revision history of the standard operating procedure

In cases where modifications to the published method have been made by the laboratory or where the referenced method is ambiguous or provides insufficient detail, these changes or clarifications are clearly described in the SOP. All SOPs include a unique title with revision identification number, total number of pages, effective date and approved signatories. Likewise, any minor hand amendments are marked, initialed and dated. Document Revision Forms may be issued for minor

updates to an SOP. All SOPs are organized and a master list of SOPs is maintained by the QA Office. Additionally, Method manuals housing current SOPs are located in the laboratory areas.

All standard analytical methods are validated prior to use.

10.3.2 Laboratory Administrative SOP(s)

Administrative SOPs are generated in support of analytical and non-analytical operating procedures. These SOPs maintain the framework and directives of all administrative duties required by the accrediting authorities. Both management and support staff undergo the appropriate training and such verification of compliance is documented on a Document Acknowledgement Form. Administrative SOPs are reviewed minimally every two years.

Administrative SOPs must include at least the following headings. Additional headings are added based on procedural requirements.

1) scope and application

2) definitions

3) procedure

4) corrective action

5) references

10.4 Computers and Electronic Data Related Requirements

Computers or automated equipment are used for the capture, processing, management, recording, reporting, storage or retrieval of test data. The laboratory ensures that computer software is documented and adequate. The goals of the software development methodology, existing system validations and the change control system are to ensure that:

the software systems perform the required functions accurately,

the users understand how to use the system, and

the automated system can demonstrate data traceability and validity even after changes have been implemented (i.e. original data is captured).

The Laboratory Management System (LMS) used at WA is proprietary, internally developed and controlled. A coordinated effort is made to assure that computer operations meet the laboratory requirements for data integrity. WA has a formal validation program of its computer systems. The validation program is a comprehensive program to ensure data transmitted, reported or manipulated by electronic means is correct and free of errors. The validation and verification approach is separated into three areas.

1. New software is developed and validated using test data. Records of validation include the test data report, date and initials. Where formulas are part of the program, documentation includes manual verification of the final calculated values. New software includes the development of macros for spreadsheets and other tools using commercial software packages.
2. Request for changes to software are documented.
3. Verification of system integrity is through routine maintenance, protection from unauthorized access and electronic verification programs. Routine maintenance including system backups is performed on a scheduled basis.

The backup process, password and access protections are defined in the computer specific standard operating procedures. Electronic verification is used to assure the commercially purchased software is performing at its original specifications. This includes virus checking of all network operations on an ongoing basis. Documentation of all verification, updates and maintenance operations is retained for the computer network.

Where computers, automated equipment, or microprocessors, are used for the capture, processing, manipulation, recording, storage or retrieval of test data, WA ensures that:

a) Computer software is tested and documented to be adequate for use (e.g., internal audits, personnel training, focus point of QA and QC)

b) Procedures are established and implemented for protecting the integrity of data; such procedures include, but are not limited to, integrity of data entry or capture (e.g. instrument interface), data storage and archival (e.g. tape backup and off-sight storage), data transmission, data processing and virus detection

c) Computer and automated equipment are maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data

d) Appropriate procedures are implemented for the maintenance of security of data including, but not limited to, the prevention of unauthorized access to, and the unauthorized amendment of, computer records

Data generated both electronically or physically is stored and archived using several methods of traceability. All raw data, documentation, and records generated are archived in a manner that is orderly and facilitates retrieval. Conditions of storage minimize potential deterioration of documents or magnetic media in accordance with the requirements for the retention period. Maintenance of this media includes electronic computer backup of all in-house servers, scanning of final reports and raw data onto discs and storage of physical raw data. Raw data is archived and stored on site.

Consult the SOPs, LMS Update and Change Control and Document Control Procedures for further information.

11 Sample Handling Protocols

WA supports a sample management program designed to provide proper sample custody. A system of checks and balances are implemented to ensure that samples are received, handled, and maintained. The goal of this program is to protect the interest of the client and the laboratory.

The sample management personnel check for proper sample labeling, preservation and handling at the time of arrival at the laboratory. Table 1 in Appendices specifies laboratory requirements for the proper sample preservation, containers, and holding times. Additional client specific criteria are documented on the Shipment Receipt Form. Sample management staff records all observations and immediately notifies the Environmental Services or Project Manager of any discrepancies or questions arising during sample receipt. Records of the sample condition including deviations and non-compliances are documented on the Shipment Receipt Form and/or Chain of Custody. In the event of noncompliance, the Project Manager or Login Coordinator contacts the client for instructions and documents the directive requested by the client.

Clients or courier services deliver samples to the laboratory during normal business hours. Sample receiving occurs in the sample management area.

11.1 Sample Receipt and Acceptance Policy

A sample is physical evidence collected from a facility or site. Sample Login procedures detail sample control and the maintaining of sample integrity from receipt at the laboratory until disposal.

Samples arrive by common courier, e.g. UPS, Federal Express, other special courier or are delivered directly by the client. All samples are routed through the Login area of the laboratory. Iced samples which are hand delivered immediately after collection are considered acceptable.

Samples arriving at the laboratory must be properly identified, logged in and assigned appropriate analyses. Sample Chain of Custody (COC) procedure must be maintained during the receiving process. The COC document is designed to provide documentation that samples were received by and maintained. The COC is designed to pass pertinent information to the laboratory to ensure that samples are analyzed for the appropriate methods. The COC minimally contains client's name, contact information, client sample ID, date/time sampled, matrix, analytical testing requested, signature and date/time of relinquishment to the laboratory and signature and date/time of receipt by the laboratory.

The Login Coordinator (LC) will inspect the samples and COC and record any discrepancies encountered on the Shipment Receipt Form. The following items are inspected:

1) Condition of shipping container/cooler
2) Temperature of shipment
3) Condition and number of sample containers
4) Receipt of special safety warnings or MSDS with samples
5) Sample container information
6) Test analysis requested
7) Sample chemical preservation

8) Chain of Custody correlation with field ID samples received

11.1.1 Preservation and Container Verification

If temperature preservation is required for the analyses requested, the cooler temperature is monitored using a calibrated digital thermometer. The temperature is taken by using one of the following procedures:

Temperature Blank

A container filled with DI water is provided specifically for the monitoring of temperature.

Note: WA recommends the use of a temperature blank. Sample kits provided by WA will contain a temperature blank.

Direct Monitoring

Insertion of the temperature probe in an area adjacent to the samples. This method generally applies to samples arriving preserved with Blue Ice type ice packs. WA does not recommend the use of Blue Ice.

Samples arriving on crushed ice (not melted) are checked by the insertion of the temperature probe in an area adjacent to the samples. Under no circumstances will the temperature probe be inserted into a sample. Reference the SOP for Sample Receipt and Log In for details. This area also uses calibrated infrared thermometers for taking temperatures.

Exception: The State of Arkansas requires that the temperature of all Bioassay samples be taken directly from the sample being analyzed.

Chemical Preservation

Sample labels are reviewed for proper preservation indication. Sample pH is verified at this time as an indication of proper chemical preservation unless prohibited by the reference method or verified just prior to specific methodology.

Containers

Proper container types are verified. Refer to Appendix Table 1 for approved containers and preservations.

When samples are received outside the temperature preservation requirements of ≤ 6°C, or have been improperly preserved upon collection, or samples are in improper containers documentation of their condition is noted on the Shipment Receipt Form. The client is also contacted for notification and further directives.

Holding Time Verification

a) The COC is reviewed to compare method holding times to sample dates. If samples are approaching holding times, the LC will issue RUSH requests via the current e-mail system to each laboratory to ensure that the samples are extracted/analyzed within method holding times.

b) If upon arrival to the laboratory a sample is found to be reaching its specified holding time and extraction/analysis may not be performed in time to meet this requirement, the client is contacted and a directive shall be taken. All correspondences and instructions are noted in the clients file associated with the samples in question.

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c) Samples arriving outside of method specified holding times will be documented on the Shipment Receipt Form and the client is called. All directions by the client are documented.

d) Holding times are evaluated based on the following:

1) Holding times begin on the day of sample collection.

2) Holding times are measured in days, unless specified differently (e.g. hours) within the analytical method.

3) Samples that require a preparation step are said to be within holding time when the preparation is initiated within holding time.

4) Sample analyses are said to be within holding time when the analysis (introduction into the instrument), including dilutions, is initiated within holding time.

COC Verification

The LC signs the COC forms, as well as documenting the date and time of sample receipt. Sample labels are compared to those listed on the COC. Any discrepancy will be noted on the Shipment Receipt Form and the client contacted.

The analyses requested on the COC shall be verified by one of the following:

a) Client specific job requirements

b) State specific analytical requirements

c) Method specific analytical requirements

If any discrepancy is identified, or if the LC has any doubt as to the analyses requested, clarification is requested from the client and documented on the Shipment Receipt Form or in LMS or the client shall forward a revised chain of custody. When possible, a written change to the COC is required. COCs are scanned and maintained electronically.

Noncompliance/Corrective Action/Client Contact

Login corrective action is designed to identify problems or potential problems that may result in noncompliant analytical data. The overall objective is to ensure that the client is provided with information that will allow evaluation as to the effect on the quality of the associated analytical data. Some projects may require a Shipment Receipt Form, which details observances when the cooler arrives at the laboratory. If generated, the Shipment Receipt Form accompanies the final report.

WA utilizes Laboratory Project Managers (LPM) and Client Service Representatives (CSR). The LC shall inform the LPM or the CSR of any noncompliance and shall direct them to contact the client. However, the LC has the authority to contact the client directly should time be of the essence. When a potentially non-compliant situation arises or questions arise as to the requests made on the COC, the login process does not proceed without notifying the client.

a) When contact is made with the client, the LC, LPM or CSR records their conversation in the customer log. At this time, the situation is discussed and options presented to the client.

b) Changes or modifications resulting from this conversation to the original COC request must be done so in writing (fax or e-mail). Likewise, changes made to the

original COC are initialed by the LC. These changes are also recorded in the LMS.

c) At the discretion of the LC, LPM or CSR, receipt of the client's written request may be required prior to the commencement of work.

d) If the client is being notified of a non-compliance situation, they will be given the option to re-sample and re-submit the sample. The client may also choose to proceed with the analysis with the understanding that a Non-Compliance Report will accompany the final report.

It is possible for samples or sample containers to be lost, damaged, or determined to be unsuitable, for whatever reason, after initial receipt at WA. Should this happen, the event is recorded on a Corrective Action Report. The problem is brought to the attention of the Environmental Services Manager who reports it to the client. Plans for disposition of the affected samples are agreed upon with the client and recorded on the Corrective Action Report. Consult the SOP on Implementing Corrective Actions.

11.1.2 Sample Login

Once verification procedures have been completed and any necessary corrective action implemented, the samples are logged into the current LMS. Samples received by WA are assigned a unique identifier by LMS which follows the life of the sample in the laboratory.

11.2 Sample Tracking and Storage

The entire building at WA is maintained as a secure area. Once login is complete, samples are distributed to the proper storage area. All refrigerated storage area temperatures are monitored daily by the QA Department for compliance.

Samples are stored in the central walk-in refrigerator or other designated refrigerators until preparation or analysis. Samples are separated by department (e.g., inorganic, organic), arrival date and preservation.

Samples for same day testing (e.g. Chlorine, coliforms, and BOD) are analyzed on the same day that they arrive. These samples are transferred directly to the appropriate laboratory for immediate processing.

Samples designated for VOC analyses are transferred directly to the VOC laboratory refrigerators regardless of any other analyses being performed. Samples leave the volatile laboratory only after the VOC analyses are complete.

All samples for metals analyses are transferred to the metal’s digestion area. Samples for metals analyses do not require refrigerated storage (Chromium VI requires refrigeration and is treated as an inorganic same day test.)

Samples for Bioassay testing are stored in the main refrigerator until transfer to the laboratory. Samples that are to be setup the same day and Microbiology are taken directly to the lab.

Samples classified as RUSH analyses are transferred directly to the appropriate laboratory for immediate processing.

Extracts from organic extractions are stored in a dedicated refrigerator. Samples are removed from the storage areas as needed by each department. Extracts are transferred for analysis directly to the Instrumentation Laboratory for analysis. All extracts maintain their parent IDs.

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WA maintains records documenting all phases of sample handling from sample receipt to final analysis. The 2016 TNI Standard identifies two record-keeping events: those related to evidentiary samples and non-evidentiary samples. WA does not maintain samples for evidentiary purposes.

WA's document control system allows historical reconstruction of all laboratory activities that produced the analytical data. The history of the sample can be readily tracked through the documentation.

WA supplies laboratory grade water for field QC blanks. Water used for volatile organics must be free of volatile compounds below the method detection limit. The quality of the laboratory water is monitored for resistivity/conductivity once per day. Additional water quality criteria are monitored based on client specific requests or as applicable for drinking water regulations.

Sample management personnel transfer samples to the sample storage areas after analysis. All samples are stored in the designated storage area until all requested testing is complete. Sample removal from the process storage occurs after release of the final report. The sample management staff places the samples in the archive storage area for thirty days after report release. Upon written client request samples are held for up to three months in an uncontrolled area. Requests for controlled sample storage or extended sample storage periods must be arranged at the time of contractual commitment. Based on State or Federal regulations, samples are properly disposed or may be returned to the client.

11.3 Sample Kits

Sample containers provided by WA include labels, preservatives and a blank COC Form. When requested by the client, records of container traceability to the original Certificates of Compliance are maintained. Chain of Custody Forms accompanies all samples received by laboratory personnel. The COC Form indicates the sample origin and arrival at the laboratory and identifies the analyses requested.

EPA methods require that samples be collected in specific type containers. Some methods require additional chemical and/or temperature preservation to ensure that sample integrity is maintained from sampling through arrival at the laboratory.

Based on project requirements, WA will provide sample kits designed for each specific sampling event. At a minimum, sample kits will contain the following items:

a) Pre-preserved containers are color-coded and types of preservations are indicated.

b) Temperature Blank

c) Field or Trip Blank (by request)

d) Coolers

e) Chain-of-Custody (COC) documents

f) Sample Labels

g) Sampling Instructions

h) Sample Kit Request Form to summarize the provided containers and appropriate analysis.

i) Shipping/Packing Materials

Sample kits are assembled and tracked by the shipping department. Vendor's analytical certificates for bottles that are provided by WA are maintained. Reagent Reference Numbers of chemicals

used as preservatives are recorded. Consult the Generation of Bottle Kits and Preservation Activities SOP for details.

11.4 Sample Aliquots

In the scheme of the sampling process, an aliquot of a submitted sample may be required in any part of analytical phase. The laboratory uses documented and appropriate procedures and techniques to obtain representative sub-samples. Sample aliquots removed for analysis are homogenized and representative portions removed from the sample container. Evidence of sub sampling is documented and recorded on the test method worksheets. See SOP on Subsampling.

11.5 Waste Minimization and Disposal

11.5.1 Waste Management

The Laboratory's Waste Management Plan has established a “cradle to grave” system for the disposal of hazardous waste, generated from the daily process activities at this facility.

WA actively practices the following waste management and pollution control procedures:

a) Reducing the quantity of waste generated (reference Waste Reduction Plan)

b) Reducing the amount of sample material used for analysis/preparation

c) Offer to an approved Treatment Storage and Disposal Facility, TSDF for incinerating, fuels blending, or land filling

d) Separating hazardous waste from non-hazardous waste in order to better provide a proper route of disposal.

e) Change in technologies to reduce or eliminate hazardous waste

11.5.2 EPA Identification Number

WA has obtained an EPA Identification number as mandated by 40 CFR 263.11 and is currently classified as a large quantity generator, LQG. Without this EPA ID number, this facility would be barred from storing, transporting, or offering for transportation, treating and disposing of any hazardous waste. Likewise, as a generator, we are barred from offering any hazardous waste to any transporter or TSDF that does not have an EPA ID number. Presently, the CQO is responsible for ensuring that the Waste Management Plan is followed and the applicable RCRA regulations are fulfilled. The laboratory is responsible for assuring that all applicable employees are trained in the laboratory requirements for waste management and that all procedures are performed in accordance with the rules for safely handling lab materials.

11.5.3 Lab Packing

The laboratory’s overall procedure for waste management is the lab packing of hazardous sample retains and extracts. Because of the various wastes that are generated, WA has established multiple waste profiles. These profiles have been verified by the TSDF and are active. Consult the Waste Management Plan for details.

11.5.4 Documentation Required for Disposal

For the proper disposal of waste, EPA requires several documents. These documents and their relevance are summarized in the following sections:

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Uniform Waste Manifest Form

US EPA Form 8700-22A is required of generators, transporters of hazardous waste and owners/operators of hazardous waste treatment, storage and disposal facilities for both interstate and intrastate transportation.

Land Ban Forms

The Land Disposal Restriction/Land Ban Forms A/B is notification of restrictions of land disposal for certain hazardous waste. Both the Generator and TSDF are affected by such restrictions.

Placarding and Labeling

To transport hazardous waste off-site, this facility must ensure proper packaging, labeling, marking and placarding of the packaged waste (40 CFR 262.30-.33). Labeling, marking and placarding of the packaged waste is done to inform the transporter, firefighter and emergency responders about the characteristics and dangers associated with the waste being transported. This information is vital in case of an emergency situation. No waste leaves WA without the proper labeling. For this purpose, the following labels and placards are required:

a) Hazardous Waste Identification Label and Placard

b) PCB Caution Waste Notification Label (PCB waste only)

Records, Reporting and Record keeping

WA maintains records for all its waste management activities in order to demonstrate cradle to grave disposal. The documents used at this facility indicate the process of traceability. The following procedure and associated logbooks are used in the lab-packing activities utilized at this facility:

a) Lab Packing Logbooks- Per Profile

b) Manifested Drum Inventory Log

c) Manifest Logs to record individual shipments:

1) Manifest Summary Sheets
2) Uniform Manifest Forms
3) Land Ban Forms A and B
4) Certificate of Disposals (when provided)

d) Waste Generation Record

e) Waste Shipping Record

f) Waste Accumulation Record

g) Off-Site Shipping History

h) Lab Packing Notices and Miscellaneous Support Documents

i) Drum Inspection Log

These records allow the step-by-step process that traces individual samples/solvent waste to a specific drum. These drums in turn are manifested and disposed by an approved TSDF. Records of disposal are kept for a minimum of three years.

By March 1 of each year an annual report is forwarded to the State of TN summarizing waste activities for the previous year.

Records are maintained for three years.

Waste Reduction Plan

The laboratory maintains a waste reduction plan for the waste activities of the laboratory. The goal is to formulate waste reduction strategies for implementation by the laboratory. These strategies can be found in the Waste Reduction Plan. As per regulations, this Plan is reviewed annually. Consult this document for additional information.

Tier II Reporting

In response to providing state and local officials and the public with specific information on potential hazards found at the laboratory, a Tier II Report is filed by March 1 of each year.

12 Data Capture, Reduction, Review and Validation

Data reduction procedures, whether performed by an instrument or manually, follow methodologies outlined within the laboratory SOP/analytical method. Automated procedures are verified as required by EPA's guidance on GALP (EPA 2185) where all software is tested with a sample set of data to verify its correct operation via accurate capture, processing, integration, transfer, recording, and reporting of data.

All analytical data captured by laboratory instruments are reviewed prior to report release to assure the validity of the reported data. This internal data evaluation process covers the areas of data generation, reduction, and ultimately three levels of documented review. For each level, the review process is documented using an appropriate sequence checklist or worksheet that is signed and dated by the reviewer.

Chromatography data requiring manual integration of peak areas or heights must follow defined protocol. The analyst must perform manual integration when software does not properly integrate or identify the peak. Manual integration must not occur for the purpose of achieving acceptable quality control or calibration. The analyst must minimize and avoid manual integration whenever possible. Additionally, the establishment of the proper integration parameters in the software reduces the number of manual integration occurrences. Consult the Procedure for Manual Integration SOP.

The SOP for each test presents the formula used for data reduction for the individual method. These SOPs present the procedures to be used for calculating and documenting procedures such as linear regression, absolute retention times, relative retention time windows, and reporting of the results from second column confirmations.

Analytical data reduction/review/documentation occurs under the direction of the laboratory managers. The laboratory project managers are responsible for informing clients of any data that are considered unacceptable or require caution on the part of the data user in terms of its reliability. The CTO is responsible for the overall assessment of the laboratories ability to generate quality data.

Data will be reduced, evaluated, and reported as described in this QA plan. Additional requirements specific to a particular laboratory section or method will be detailed in the appropriate SOP. Data reduction, review, and reporting by the laboratory will be conducted as follows:

12.1 Level 1 - Analyst Review

Level 1 - Raw data are produced by the analyst who has primary responsibility for the correctness and completeness of the data. All data will be generated and reduced following the QA Manual defined methods and implementing laboratory SOP.

- Sample preparation information is correct and complete
- Analysis information is correct and complete
- The analytical SOP(s) have been followed
- Analytical results and calculations are correct and complete
- Raw data, including all manual integrations, have been correctly interpreted and flagged
- QC samples are within established control limits

- Any special sample preparation and analytical requirements have been met
- Data transfers were verified
- Documentation is complete (e.g., all anomalies in the preparation and analysis have been documented and addressed)
- Review shall be documented by using a checklist or worksheet and by the signature or initials of the reviewer and date

12.2 Level 2 – Supervisor/Peer Review

Level 2 - Technical data review is completed relative to an established set of guidelines by a supervisor, peer analyst or qualified data review specialist. The review will ensure the completeness and correctness of the data while ensuring all method QC measures have been implemented and were within appropriate criteria. Any outliers must be documented.

The following are items that are typically reviewed as part of the Level II review. Method specific check lists are used to document the Level 1 and Level 2 reviews. Note that not all items apply to all methods.

- Holding times
- Instrument Blanks
- Calibration Blanks
- Instrument tunes
- Initial Calibration
- Calibration Verification
- Method Blanks
- MS/MSDs
- LCS/LCSDs
- Duplicates
- Second-column confirmation results
- Surrogate recovery
- Internal standards
- Inductively coupled plasma (ICP) or atomic absorption QC
- Sample reanalysis
- Secondary dilutions
- Appropriate data qualifiers (See below)
- Laboratory case narrative

Note: Level 1 and Level 2 reviews are conducted for each preparatory and/or analytical batch of samples.

12.3 Level 3 – Laboratory Project Manager Review

Level 3 – Once all testing is completed for a set of samples (report), the data is reviewed (i.e. preliminary report generation) by the laboratory project manager for Level 3 administrative data review. The review will ensure consistency and completeness and to ensure that any issues encountered that affect data quality are properly detailed in a Case Narrative. The report is also reviewed for compliance with all laboratory instructions, client specific instructions and/or an available statement of work.

Final reports are generated and signed by a Laboratory Project Manager.

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The laboratory retains full analytical and QC documentation for all samples analyzed. This allows the laboratory to recreate the analyses conducted in the event that questions arise regarding the final report from the client.

12.4 QA Review

QA review is performed by the CQO or his designate. This review is not part of the normal production data review process. The QA Office reviews a percentage of the data produced by the laboratory which includes performance testing studies. Additional technical details may be assessed in this QA review, similar to Levels 1 and 2, along with a total package review, i.e., correlation of results from differing but related chemical parameters. Typically, the QA Office selects the data packages reviewed at random as part of internal audits. Nonconformance and/or corrective action reports would be required for any issues noted.

An additional independent review may be performed by the QA Office. A LMS Raw Data audit is conducted on the generation of the initial calibration response factors generated by the Target DB Server. The Target generated average response factors and percent relative standard deviations are compared to those generated by an independent source. The independent source utilized for verification is Excel©. These audit reports are scanned and become part of the initial calibration data package.

Records of independent QA reviews are documented in internal audit records.

Internal audits also function as a tool for QA reviews at different levels of data generation and laboratory operations. Such reviews are documented in individual internal audit reports.

Data Qualifiers

The laboratory uses data qualifiers during the data generation/ review process as warranted. These qualifiers are applied when data quality objectives are not met or outside the noted acceptance criteria. All flags used are defined completely within the final data report packages.

The following data qualifiers are currently in use:

* QC failure - percent recovery/RPD for analyte was outside QC Limits

I Recoveries affected by interferences or high background

J Estimated value - Presence of the compound was confirmed but less than the Method Quantitation Limit (MQL) but about the Method Detection Limit (MDL)

E Concentration exceeds the established method calibration range but is within the working range of the instrument

B Analyte detected in the associated method blank

U Reported result was unconfirmed

C Result reported from GC/MS confirmation analysis

M Result reported represents a minimum value due to low recovery in associated calibration verification or laboratory control sample

NC Result reported from Primary Column. Result did not confirm or was not analyzed by secondary column.

Q RPD >40% between primary and confirmation columns

H Holding time exceeded

G GGA standard fails acceptance criteria

Project specific or program specific data qualifiers will be detailed in any project specific statement of work (SOW).

13 Laboratory Report Format and Contents

The SOP on Data Reduction and Review and project files details the recording and reporting of data as required by the client and in accordance with relevant environmental regulations. The results of each test or series of tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively. The results are reported in a test report and include all the information necessary for the interpretation of the test results and all information required by the method used. Any client requested deviations shall also be included. Clients specify the report delivery and deliverables required for the work submitted. Report delivery includes standard turnaround and rush turnaround. Clients specify the delivery address or multiple addresses and method of delivery such as U.S. Mail, facsimile or electronic at the start of the project. WA provides data deliverables in hardcopy or electronic format. At the start of any project, the electronic deliverable formats required must be received before sample arrival.

The final report data package contains the client required and relevant information to demonstrate that the project Data Quality Objectives has been fulfilled.

Refer to Appendix Table 2 for a list of standard WA's data package contents.

All reported data packages are retained by the laboratory for a minimum of five (5) years, or as dictated by project requirements, if longer than five years, or drinking water requirements (6 years).

Reporting packages are available for routine regulatory reporting requirements. Regulatory reporting packages include only the information requested by the regulatory agency. In additional to regulatory report packages, WA prepares a standard report format. The standard report format includes:

1) a title, "Report of Analysis";

2) name and address of laboratory, and location where the test was carried out if different from the address of the laboratory and phone number with name of contact person for questions;

3) unique report number (a serial number) and of each page, and the total number of pages;

4) name and address of client and project name, if applicable;

5) description and unambiguous identification of the tested sample including the client identification code;

6) identification of test results derived from any sample that did not meet sample acceptance requirements such as improper container, holding time, or temperature violations are flagged;

7) date of receipt of sample, date and time of sample collection, date(s) of performance of test, and time of sample preparation and/or analysis;

8) identification of the test method used, or unambiguous description of any non-standard method used. The method(s) include but are not limited to the EPA, Standard Methods for the Examination of Water and Wastewater, Manual for the Certification of Laboratories Analyzing Drinking Water and Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW-846);

9) non-compliance or corrective action reports, where applicable;

10) a case narrative discussing any deviations (such as failed quality control), client-required amendments or additions to or exclusions from the test method (such as environmental conditions), and any non-standard conditions that have an affected on the quality of results, and including the use and definitions of data qualifiers flagged;

11) measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified, whether data was calculated on a dry weight or wet weight basis and identity of the reporting units;

12) data qualifiers are added by the laboratory during the data generation/ review process. These qualifiers are applied when data quality objectives are not met. All qualifiers used are defined completely within the final data report packages.

13) a statement of the estimated uncertainty of the test result when requested by the client; The laboratory currently monitors performance based on the LCS recovery limits;

14) a signature and title, or an equivalent electronic identification of the person(s) accepting responsibility for the content of the certificate or report, and date of issue. This individual attest to the accuracy of the data documented on the reports based on scientific knowledge derived from the use of known, promulgated and accepted national standards;

15) a statement to the effect that the results relate only to the items tested or to the sample as received by the laboratory;

16) a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory;

17) clear identification of all test data provided by outside sources, such as subcontracted laboratories, clients, etc;

18) clear identification of any numerical results with values outside of quantitation limits;

19) The laboratory shall provide certification that the tests results meet the applicable TNI standard or appropriate regulation. Modifications to regulatory requirements are documented.

After issuance of the report, the report shall remain unchanged. Amendments to an analytical report after issue shall be made in the form of an amended document.

The amended or modified report includes a narrative that lists the change and the reason for the change. When it is necessary to issue an amended report, the new report will be uniquely identified making it different from the original report. This is done by changing the first number (typically “0”) in the last four digits of the original report number to “9”.

Reports are designed to accommodate each test performed and to reduce the possibility of misunderstanding, misuse or misinterpretation.

Results transmitted by facsimile or other electronic means include a statement of confidentiality.

14 Outside Support Services and Supplies

When WA purchases outside services and supplies in support of tests, the laboratory uses only those outside services and supplies that are of adequate quality to maintain confidence in the tests.

The laboratory reviews suppliers and services for quality of the materials and supplies. Where no independent assurance of the quality of outside support services or supplies are available, the laboratory ensures that purchased equipment, materials, and services comply with specifications by evaluating method performance before routine use.

The laboratory checks shipments upon receipt as complying with purchase specifications. The use of purchased equipment and consumables is only after the evaluation and compliance to the specifications is complete. The laboratory supervisors purchase supplies and materials based on the quality specified in the laboratory technical SOPs. The laboratory purchasing procedure defines the process for documenting purchases and receiving materials and supplies.

Purchases from suppliers must be approved by the Laboratory Director or other management personnel. The Purchaser maintains records of all suppliers and vendors from whom it obtains support services or supplies required for tests. Refer to the SOP on the Selection and Purchasing of Supplies.

14.1 Subcontracting

Analytical tests not routinely performed by WA are subcontracted. In such cases, the sample(s) are sent to a laboratory that meets client and regulatory requirements. WA's policy is to advise the client of intention to subcontract any portion of the testing to another party. The laboratory approves testing and sampling subcontractors by review of current state, national or other external parties' certifications or approvals. The laboratory will maintain subcontractor certifications or approval documents. When available, these records are kept to indicate current approval for the subcontracted work. Subcontracting laboratories must maintain validations, certifications or approvals commiserate with the type or work being sub-contracted (e.g., NELAP). For the parameters accredited by NELAP, the laboratory must use a NELAP accredited laboratory, unless the parameters are clearly noted as not requiring NELAP accreditation or the client specifies the subcontractor in writing.

The process for sample handling when subcontracting samples must include the use of a Chain of Custody Form. The client must be notified of subcontracted work and approval is in writing before releasing samples to the subcontractor.

The Environmental Services Coordinator and the Laboratory Director reviews the subcontractor documents for completeness and meeting the specifications defined for the project. Documented report reviews and any requested corrections are written on the Corrective Action Report Form.

The laboratory performing the subcontracted analysis is clearly indicated in the final report. Additionally, the laboratory shall be clearly identified as either NELAP or non-NELAP accredited. Reports received by the subcontracting laboratory may be a physical report or electronic and may be made available to the client upon request.

Consult the SOP on Subcontracting Procedures for further details.

15 Client Relations

15.1 Client Services

Majority of the client services occur from personnel in the administration and laboratory services areas. The Client Service Department acts as the liaison between the laboratory and client. The client service goal is to ensure that the client's expectations are met on a consistent basis. The client service department acts as the client's representative within the laboratory to ensure that adequate priority is assigned to each project. Client service/marketing involves inquiries into services offered, technical consulting, placing orders, and receiving orders, providing updates on the status of orders and completing orders. Client Service Representatives (CSRs) offer the client a single source within the laboratory for the following types of activities or requests:

a) Current status on in-house samples/projects

b) Support for questions and inquiries relating to analytical methods used and results

c) Support for questions related to reporting issues

d) Verification of analytical regulatory requirements (e.g. UST, wastewater)

e) Request for sample kits

f) Customer complaints resolution

g) Sample tracking and custody procedures

h) Sample containers – containers, preservation and holding time

i) Field QC sample requirements

j) General sampling procedures

k) Focal point for issuing directives regarding the project

Personnel interacting with clients must document and review client specific project requirements. Personnel must document client interactions following the appropriate laboratory procedures in the LMS automated system, via email and or telephone logs as applicable. Each person must communicate deviations, modifications and client requests to the Laboratory Director. The CSR operates under the premise that client's needs come first. CSR's work closely with Project Managers and report directly to the President or VP.

The reference method applied for sample analysis is usually based on the regulatory program. The Chief Technical Officer and/or Environmental Services Manager may assist the client with method selection when the client specifies the regulatory program. The CTO recommends methods for regulatory programs. In all cases, recommendation of methods is based on client-defined method performance criteria as long as the client specifications are more stringent than the reference method criteria. The Environmental Services Manager handles the process for inquiry receipt and actions taken of inquiries, processing sales orders and process for requesting sample containers.

15.2 Project Management

The laboratory Project Managers reviews requests, tenders and contracts for new work and notifies supervisors during staff meetings. The CTO and COO address all capacity and capability issues. Where conflicts in workload arise, client notification is immediate. Project files contain the documentation of all project information and any subsequent changes to a contract based on unforeseen issues. Cooperation between laboratory and client services staff allows direct

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communication and scheduling with the client. Management arranges scheduling and coordination between departmental areas. Refer to the SOP, Review of Requests, Tenders and Contracts for details.

The Project Manager documents all clients' complaints, amendments or concerns regarding data quality or laboratory operations. The Corrective Action Report records complaints and laboratory correction action with the client. The process uses the same form and process as the corrective action process. Customer service representatives may document customer complaints in the LMS Customer Log screen, in the Feedback Complaints Data Issues file in GroupWise, in emails and or telephone logbooks. The customer log program in LMS records customer requests, concerns, and complaints. In the event that a complaint or concern is filed, a systemic approach is conducted in order to identify, investigate and ultimately rectify when applicable. Because the nature of this facility is in producing quality analytical data, the majority of complaints or concerns are directly or indirectly related to client analytical results. This may include any associated quality control or quality assurance issues. In the scope of this the following procedure is undertaken in order to address any complaint:

Identification of complaint;

Nature of complaint;

Investigate procedures for retrieval of data;

Investigate procedures for data reviewed materials;

Investigate procedures for review process; and

Investigate report attached to a corrective action.

Additionally, the Project Manager may inform a client of potential conflicts, deficiencies observed at the laboratory, lack or loss of accreditation status, deviations or amendments from the contract or difficultly on the laboratory's part to complete the work. Further, any amendments to the contract will also be recorded in the project files and communicated to the appropriate laboratory personnel. Refer to the document on Procedures for Dealing with Complaints and the SOP on the Review of Requests, Tenders and Contracts for details.

All client data is held secure and confidential at all times. Consult the Client Proprietary Rights and Confidentiality document for details.

16 Safety Program

WA is totally committed to employee safety and loss control. It is this company's intention that:

a) All employees work under the safest conditions possible with a proactive attitude toward safety

b) A workplace and equipment, which are free from recognized hazards, are provided

c) Information, training, and supervision are offered to enable employees to perform their jobs safely

The Laboratory Safety Plan documents vital safety rules and procedures that are to be followed by all company employees. While this plan will help the employee recognize and avoid obvious hazards, it cannot possibly cover all situations. When in doubt, consult the supervisor or Safety Officer for guidance. WA endeavors to comply with safety regulations implemented by federal, state, and local agencies. It is company policy that every employee and all property be protected from controllable hazards. This laboratory believes that accidents can be avoided using good training methods, common sense, and personal initiative. Therefore, each employee is responsible for complying with all safety regulations. The laboratory will supply employees with the applicable personal protective equipment in response to their work environment and or provide surveillance monitoring where applicable.

Laboratory safety and emergency equipment is inspected quarterly and records are maintained. This equipment includes eye wash stations, emergency showers, fume hood and fire extinguishers. Periodic checks are also conducted on non-standard equipment such as tank supports and restraints and noise monitoring. All laboratory areas are supplied with first aid kits. Annually a contractor inspects fire extinguishers, recharges them as applicable and tags them.

As part of the Laboratory Safety Plan the laboratory maintains an Egress Plan for Evacuation. In the event that a fire or other potentially harmfully event shall occur, the laboratory has a written plan indicating the roles and responsibilities of all employees. Consult the Egress Plan for Evacuation for details.

Additionally, as part of the internal audit process, the QA Department will assess and report near-miss events observed or encountered as part of the lab' effort in improving the laboratory safety program.

16.1 Chemical Hygiene Plan

In accordance with the OSHA Laboratory Standard, (29 CFR 1910.1450), WA has implemented a written Chemical Hygiene Plan, CHP, and is made accessible to all employees. The document is intended to familiarize employees with a basis for Chemical Hygiene. The employee should bear in mind that the plan is not and is not intended to be a comprehensive plan, since situations could arise to amend any part of the plan. However, it provides basic guidelines and information regarding the practice of safe laboratory operations and prudence with the use of laboratory chemicals. The employee should at all times be cautious when working with potentially dangerous chemicals and take every step to protect themselves, others in their work area, the facility, and the equipment that encompasses the range of this concern. Consult the Chemical Hygiene Plan for further information.

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17 Appendix A – Acronyms and Definitions

17.1 Acronyms

AE	Automatic Entry
ASQ	American Society for Quality
ASQC	American Society for Quality Control
CBI	Confidential Business Information
CCC	Calibration Check Compounds
CCV	Continuing Calibration Verification
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
CLP	Contract Laboratory Program
COC	Chain of Custody
CRDL	Contract Required Detection Limit
CRQL	Contract Required Quantitation Limit
CRM	Certified Reference Material
CSR	Client Service Representatives
CV	Coefficient of Variation
CVAA	Cold Vapor Atomic Absorption
CWA	Clean Water Act
DQA	Data Quality Assessment
DQO	Data Quality Objective
EDL	Environmental Detection Limit
EPA	Environmental Protection Agency
GC	Gas Chromatograph
GC-MS	Gas Chromatography - Mass Spectrometer (interfaced together)
GPC	Gel Permeation Chromatography
HPLC	High Performance Liquid Chromatography
IC	Ion Chromatography
ICB	Initial Calibration Blank
ICP	Inductively Coupled Plasma (Atomic Emission Spectroscopy)
ICP/MS	Inductively Coupled Plasma/Mass Spectrometry
ICV	Initial Calibration Verification
IR	Installation Restoration
ISO	International Standards Organization
LB	Laboratory Blank
LC	Liquid Chromatograph
LCS	Laboratory Control Sample
LCSD	Laboratory Control Sample Duplicate
LD	Analytical Detection Limit
LMS	Laboratory Management System
MDL	Method Detection Limit
MQL	Method Quantitation Limit
MRL	Method Reporting Limit
MS	Matrix Spike
MSD	Matrix Spike Duplicate
NELAP	National Environmental Laboratory Accreditation Program
NIST	National Institute of Standards and Technology
OSHA	Occupational Safety and Health Administration

PDS	Post Digestion Spike
PQL	Practical Quantitation Limit
PT	Proficiency Testing
PBMS	Performance Based Measurement System
QA	Quality Assurance
QMS	Quality Management System
QC	Quality Control
R	Recovery
RCRA	Resource Conservation and Recovery Act
RL	Reporting Limit
RSD	Relative Standard Deviation
RTW	Retention Time Window
S	Standard Deviation
SAP	Sampling and Analysis Plan
SARA	Superfund Amendments and Reauthorization Act
SDWA	Safe Drinking Water Act
SOP	Standard Operating Procedure
SOW	Statement of Work
SPCC	System Performance Check Compound
SQL	Sample Quantitation Limit
TCLP	Toxicity Characteristic Leaching Procedure
TIC	Tentatively Identified Compounds
TNI	The NELAC Institute
TSDF	Treatment Storage and Disposal Facility
USDA	U. S. Department of Agriculture
UST	Underground Storage Tanks
WP	Water Pollution
WS	Water Supply

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17.2 Definitions of Terms

The definitions presented here have been compiled using the following reference materials: definitions developed by the NELAC Institute, TNI. The source of each definition is noted. When more than one source is indicated the original source document is the first reference presented.

Terms may have more than one definition due to the multiple documents used for project planning. Each project should define the term as used for the site-specific project.

Acceptance Criteria: specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQC) (TNI)

Accreditation: the process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. In the context of the National Environmental Laboratory Accreditation Program (NELAP), this process is voluntary. (TNI)

Accrediting Authority: the Territorial, State, or federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation (TNI)

Accrediting Authority Review Board (AARB): five voting members from Federal and State Accrediting Authorities and one non-voting member from USEPA, appointed by the NELAP Director, in consultation with the TNI Board of Directors, for the purposes stated in this standard.

Accuracy: the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. (QAMS)

Assessor Body: the organization that actually executes the accreditation process, i.e., receives and reviews accreditation applications, reviews QA documents, reviews proficiency testing results, performs on-site assessments, etc., whether EPA, the State, or contracted private party. (TNI)

Analyst: the designated individual who performs the “hands-on” analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality. (TNI)

Applicant Laboratory or **Applicant:** the laboratory or organization applying for NELAP accreditation. (TNI)

Assessment: the evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of TNI).

Assessment Criteria: the measures established by TNI and applied in establishing the extent to which an applicant is in conformance with TNI requirements.

Assessment Team: the group of people authorized to perform the on-site inspection and proficiency testing data evaluation required to establish whether an applicant meets the criteria for NELAP accreditation. (TNI)

Assessor: one who performs on-site assessments of accrediting authorities and laboratories' capability and capacity for meeting TNI requirements by examining the records and other physical evidence for each one of the tests for which accreditation has been requested.

Audit: a systematic evaluation to determine the conformance to quantitative *and qualitative* specifications of some operational function or activity. (EPA-QAD)

Batch: environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one to 20 environmental samples of the same TNI-defined matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An **analytical batch** is composed of prepared environmental samples (extracts, digestates or concentrates), which are analyzed together as a group. An analytical batch can include prepared samples originating from various environmental matrices and can exceed 20 samples. (TNI Quality Systems Committee)

Blank: a sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. Blanks include:

> **Equipment Blank:** a sample of analyte-free media, which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures.
>
> **Field Blank:** blank prepared in the field by filling a clean container with pure de-ionized water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA-OSWER)
>
> **Instrument Blank:** a clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD)
>
> **Laboratory Blank:** a sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses. (TNI)
>
> **Reagent Blank:** (method reagent blank): a sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps. (QAMS)

Blind Sample: a sub-sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process. (TNI)

Calibration: to determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument, or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements. (TNI)

Calibration Curve: the graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response. (TNI)

Calibration Method: a defined technical procedure for performing a calibration. (TNI)

Calibration Standard: a substance or reference material used to calibrate an instrument. (QAMS)

Certified Reference Material (CRM): a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body. (ISO Guide 30 - 2.2)

Chain of Custody Form: record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; the collector; time of collection; preservation; and requested analyses. (TNI)

Clean Air Act: the enabling legislation in 42 U.S.C. 7401 *et seq*., Public Law 91-604, 84 Stat. 1676 Pub. L. 95-95, 91 Stat., 685 and Pub. L. 95-190, 91 Stat., 1399, as amended, empowering EPA to promulgate air quality standards, monitor and to enforce them. (TNI)

Combined Standard Uncertainty: is the standard uncertainty of the result of a measurement when that result is obtained from the values of a number of other quantities, equal to the positive square root of a sum of terms, the terms being the variances or covariance's of these other quantities weighed according to how the measurement result varies with changes in these quantities.

Comprehensive Environmental Response, Compensation and Liability Act (CERCLA/Superfund)**:** the enabling legislation in 42 U.S.C. 9601-9675 *et se*q., as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), 42 U.S.C. 960*1et seq*., to eliminate the health and environmental threats posed by hazardous waste sites. (TNI)

Confidential Business Information (CBI): Information that an organization designates as having the potential of providing a competitor with inappropriate insight into its management, operation or products. TNI and its representatives agree to safeguard identified CBI and to maintain all information identified as such in full confidentiality.

Confirmation: verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to:

Second column confirmation

Alternate wavelength

Derivatization

Mass spectral interpretation

Alternative detectors or

Additional cleanup procedures. (TNI)

Conformance: an affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements. (ANSI/ASQC E4-1994) (TNI)

Contributor: a participant in TNI who is not a Voting Member. Contributors include representatives of laboratories, manufacturers, industry, business, consumers, academia, laboratory associations, laboratory accreditation associations, counties, municipalities, and other

political subdivisions, other federal officials not engaged in environmental activities, and other persons who are interested in the objectives and activities of TNI.

Corrective Action: the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence. (ISO 8402)

Coverage Factor: is the numerical factor used as a multiplier of the combined standard uncertainty in order to obtain expanded uncertainty. (NIST)

Data Audit: a qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality (i.e., that they meet specified acceptance criteria). (NELAC)

Data Reduction: the process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useable form. (EPA-QAD)

Deficiency: an unauthorized deviation from acceptable procedures or practices, or a defect in an item. (ASQC)

Delegate: any environmental official of the States or the Federal government not sitting in the House of Representatives, who is eligible to vote in the House of Delegates. (TNI)

Demonstration of Capability: a procedure to establish the ability of the analyst to generate acceptable accuracy. (TNI)

Denial: to refuse to accredit in total or in part a laboratory applying for initial accreditation or resubmission of initial application. (TNI)

Detection Limit: the lowest concentration or amount of the target analyte that can be identified, measured, and reported with confidence that the analyte concentration is not a false positive value. See Method Detection Limit. (TNI)

Document Control: the act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed. (ASQC)

Environmental Laboratory Advisory Board (ELAB): a Federal Advisory Committee, with members appointed by EPA and composed of a balance of non-state, non-federal representatives, from the environmental laboratory community, and chaired by an ELAB member. (TNI)

Environmental Monitoring Management Council (EMMC): an EPA Committee consisting of EPA managers and scientists, organized into a Policy Council, a Steering Group, *ad hoc* Panels, and work groups addressing specific objectives, established to address EPA-wide monitoring issues. (TNI)

Expanded Uncertainty: is a quantity defining an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand. (NIST)

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA): the enabling legislation under 7 U.S.C. 135 *et seq.,* as amended, that empowers the EPA to register insecticides, fungicides, and rodenticides. (TNI)

Federal Water Pollution Control Act (Clean Water Act, CWA): the enabling legislation under 33 U.S.C. 1251 *et seq*., Public Law 92-50086 Stat. 816, that empowers EPA to set discharge limitations, write discharge permits, monitor, and bring enforcement action for non-compliance. (TNI)

Field of Accreditation: (previously Field of Testing) TNI's approach to accrediting laboratories by matrix, technology/method and analyte/analyte group. Laboratories requesting accreditation for a matrix-technology/method –analyte/analyte group combination, or for an updated/ d method are required to submit only that portion of the accreditation process not previously addressed. (TNI)

Field of Proficiency Testing: TNI's approach to offering proficiency testing by matrix, technology, and analyte/analyte group.

Finding: an assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding is normally a deficiency and is normally accompanied by specific examples of the observed condition. (TNI)

Governmental Laboratory: as used in these standards, a laboratory owned by a Federal, state, or tribal government; includes government-owned contractor-operated laboratories. (TNI)

Holding Times (Maximum Allowable Holding Times): the maximum times that samples may be held prior to analysis and still be considered valid or not compromised. (40 CFR Part 136)

Inspection: an activity such as measuring, examining, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformance is achieved for each characteristic. (ANSI/ASQC E4-1994)

Interim Accreditation: temporary accreditation status for a laboratory that has met all accreditation criteria except for a pending on-site assessment which has been delayed for reasons beyond the control of the laboratory. (TNI)

Internal Standard: a known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method. (TNI)

Laboratory: a body that calibrates and/or tests. (ISO 25)

Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample): a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (TNI)

Laboratory Duplicate: aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently. (TNI)

Legal Chain of Custody Protocols: procedures employed to record the possession of samples from the time of sampling until analysis and are performed at the special request of the client.

These protocols include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples by the laboratory. **In addition, these protocols document all handling of the samples within the laboratory.** (TNI)

Manager (however named): the individual designated as being responsible for the overall operation, all personnel, and the physical plant of the environmental laboratory. A supervisor may report to the manager. In some cases, the supervisor and the manager may be the same individual. (TNI)

Matrix: the substrate of a test sample.

Field of Accreditation Matrix: these matrix definitions shall be used when accrediting a laboratory (see Field of Accreditation).

Drinking Water: any aqueous sample that has been designated a potable or potential potable water source.

Non-Potable Water: any aqueous sample excluded from the definition of Drinking Water matrix. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts.

Solid and Chemical Materials: Includes soils, sediments, sludges, products and by-products or an industrial process that results in a matrix not previously defined.

Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Air and Emissions: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device. (TNI)

Quality System Matrix: These matrix definitions are an expansion of the field of Accreditation matrices and shall be used for purposes of batch and quality control requirements (see Appendix D of Chapter 5). These matrix distinctions shall be used:

Aqueous: any aqueous sample excluded from the definition of Drinking Water matrix of Saline/Estuarine source. Includes surface water, ground water effluents, and TCLP or other extracts.

Drinking Water: any aqueous sample that has been designated a potable or potential potable water source.

Saline/Estuarine: any aqueous sample from an ocean or estuary, or other salt-water source such as the Great Salt Lake.

Non-aqueous Liquid: any organic liquid with <15% settleable solids.

Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Solids: includes soils, sediments, sludges and other matrices with >15% settleable solids.

Chemical Waste: a product or by-product of an industrial process that results in a matrix not previously defined.

Air and Emissions: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device. (TNI)

Matrix Spike (spiked sample or fortified sample): a sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of Target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency. (QAMS)

Matrix Spike Duplicate (spiked sample or fortified sample duplicate): a second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte. (QAMS)

May: denotes permitted action, but not required action. (TNI)

Measurement Uncertainty: a non-negative parameter characterizing the dispersion of the values attributed to a measured quantity. All measurements are subject to uncertainty and a measured result is complete only when it is accompanied by a statement of the associated uncertainty. (NIST)

Method Detection Limit: the minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. (40 CFR Part 136, Appendix B, MDL Procedure Revision 2)

Must: denotes a requirement that must be met. (Random House College Dictionary)

National Accreditation Database: the publicly accessible database listing the accreditation status of all laboratories participating in NELAP. (TNI)

National Institute of Standards and Technology (NIST): an agency of the US Department of Commerce’s Technology Administration that is working with EPA, States, TNI, and other public and commercial entities to establish a system under which private sector companies and interested States can be accredited by NIST to provide NIST-traceable proficiency testing (PT) to those laboratories testing drinking water and wastewater. (NIST)

National Environmental Laboratory Accreditation Conference (NELAC): a voluntary organization of State and Federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP. This organization is NOW superseded by The NELAC Institute, TNI.

National Environmental Laboratory Accreditation Program (NELAP): the overall National Environmental Laboratory Accreditation Program of which TNI oversees.

National Voluntary Laboratory Accreditation Program (NVLAP): a program administered by NIST that is used by providers of proficiency testing to gain accreditation for all

compounds/matrices for which NVLAP accreditation is available, and for which the provider intends to provide NELAP PT samples. (TNI)

Negative Control: measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results. (TNI)

NELAP Recognition: the determination by the NELAP Director that an accrediting authority meets the requirements of the NELAP and is authorized to grant NELAP accreditation to laboratories. (TNI)

Non-Governmental Laboratory: any laboratory not meeting the definition of the governmental laboratory. (TNI)

Performance Audit: the routine comparison of independently obtained *qualitative and* quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory. (TNI)

Performance Based Measurement System (PBMS): a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified and serve as criteria for selecting appropriate test methods to meet those needs in a cost-effective manner. (TNI)

Positive Control: measures taken to ensure that a test and/or its components are working properly and producing correct or expected results from positive test subjects. (TNI)

Precision: the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms. (TNI)

Preservation: refrigeration and/or reagents added at the time of sample collection (or later) to maintain the chemical and/or biological integrity of the sample. (TNI)

Primary Accrediting Authority: the agency or department designated at the Territory, State or Federal level as the recognized authority with responsibility and accountability for granting NELAC accreditation for a specified field of testing. (TNI)

Proficiency Testing: a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. (TNI)

Proficiency Testing Oversight Body/Proficiency Testing Provider Accreditor (PTOB/PTPA): an organization with technical expertise, administrative capacity and financial resources sufficient to implement and operate a national program of PT provider evaluation and oversight that meets the responsibilities and requirements established by the TNI Standard.

Proficiency Testing Program: the aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories. (TNI)

Proficiency Testing Study Provider: any person, private party, or government entity that meets stringent criteria to produce and distribute PT samples, evaluate study results against published

performance criteria and report the results to the laboratories, primary accrediting authorities, PTOB/PTPA, and TNI.

Proficiency Test Sample (PT): a sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria. (QAMS)

Protocol: a detailed written procedure for field and/or laboratory operation (e.g., sampling, analysis), which must be strictly followed. (EPA-QAD)

Quality Assurance: an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. (QAMS)

Quality Assurance [Project] Plan (QAPP): a formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EPA-QAD)

Quality Control: the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. (QAMS) (TNI)

Quality Control Sample: an uncontaminated sample matrix spiked with known amounts of analytes from a source independent from the calibration standards. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (EPA-QAD)

Quality Manual: a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users. (TNI)

Quality System: a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC. (ANSI/ASQC E-41994)

Quantitation Limits: levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported at a specified degree of confidence. (TNI)

Range: the difference between the minimum and the maximum of a set of values. (EPA-QAD)

Raw Data: any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g., tapes which have been transcribed verbatim, data and verified accurate by signature), the exact copy or exact transcript may be submitted. (EPA-QAD)

Recognition: previously known as reciprocity. The mutual agreement of two or more parties (i.e., States) to accept each other's findings regarding the ability of environmental testing laboratories in meeting the TNI Standard.

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Reference Material: a material or substance with one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. (ISO Guide 30-2.1)

Reference Method: a method of known and documented accuracy and precision issued by an organization recognized as competent to do so. (TNI)

Reference Standard: a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. (VIM-6.08)

Reference Toxicant: the toxicant used in performing toxicity tests to indicate the sensitivity of a test organism and to demonstrate the laboratory's ability to perform the test correctly and obtain consistent results (see Chapter 5, Appendix D, section 2.1f). (TNI)

Replicate Analyses: the measurements of the variable of interest performed identically on two or more sub-samples of the same sample within a short time interval. (TNI)

Requirement: denotes a mandatory specification; often designated by the term "shall". (TNI)

Resource Conservation and Recovery Act (RCRA): the enabling legislation under 42 USC 321 *et seq.* (1976), that gives EPA the authority to control hazardous waste from the "cradle-to-grave", including its generation, transportation, treatment, storage, and disposal. (TNI)

Revocation: the total or partial withdrawal of a laboratory's accreditation by the accrediting authority. (TNI)

Safe Drinking Water Act (SDWA): the enabling legislation, 42 USC 300f *et seq.* (1974), (Public Law 93-523), that requires the EPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations. (TNI)

Sample Tracking: procedures employed to record the possession of the samples from the time of sampling until analysis, reporting, and archiving. These procedures include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples to the laboratory. In addition, access to the laboratory is limited and controlled to protect the integrity of the samples. (TNI)

Secondary Accrediting Authority: the Territorial, State or federal agency that grants accreditation to laboratories, based upon their accreditation by a NELAP-recognized Primary Accrediting Authority. See also **Reciprocity** and **Primary Accrediting Authority**. (TNI)

Selectivity: (Analytical chemistry) the capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances. (EPA-QAD)

Sensitivity: the capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. (TNI)

Shall: denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled. (ANSI)

Should: denotes a guideline or recommendation whenever noncompliance with the specification is permissible. (ANSI)

The Quality Manual has been prepared for the sole use of Waypoint Analytical, LLC.

Spike: a known mass of target analyte added to a blank sample or sub-sample; used to determine recovery efficiency or for other quality control purposes. (NELAC)

Standard: the document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of NELAC and meets the approval requirements of the TNI procedures and policies. (ASQC)

Standard Operating Procedures (SOPs): a written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks. (QAMS)

Standardized Reference Material (SRM): a certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method. (EPA-QAD)

Statistical Minimum Significant Difference (SMSD): the minimum difference between the control and a test concentration that is statistically significant; a measure of test sensitivity or power. The power of a test depends in part on the number of replicates per concentration; the significance level selected, e.g., 0.05, and the type of statistical analysis. If the variability remains constant, the sensitivity of the test increases as the number of replicates is increased. (TNI)

Supervisor (however named)**:** the individual(s) designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees, supply and instrument adequacy and upkeep, quality assurance/ quality control duties and ascertaining that technical employees have the required balance of education, training and experience to perform the required analyses. (TNI)

Surrogate: a substance with properties that mimic the analyte of interest. It is unlikely to be found in environment samples and is added to them for quality control purposes. (QAMS)

Suspension: temporary removal of a laboratory's accreditation for a defined period of time, which shall not exceed six months, to allow the laboratory time to correct deficiencies or area of non-compliance with the TNI Standard. (TNI)

Technical Director: individual(s) who has overall responsibility for the technical operation and quality of data of the environmental testing laboratory. (TNI)

Test: a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate. (ISO/IEC Guide 2-12.1, amended)

Test Method: an adoption of a scientific technique for a specific measurement problem, as documented in a laboratory SOP or published by a recognized authority. (TNI)

Testing Laboratory: a laboratory that performs tests. (ISO/IEC Guide 2-12.4)

Test Sensitivity/Power: the minimum significant difference (MSD) between the control and test concentration that is statistically significant. It is dependent on the number of replicates per concentration, the selected significance level, and the type of statistical analysis (TNI)

Tolerance Chart: a chart in which the plotted quality control data is assessed via a tolerance level (e.g. +/- 10% of a mean) based on the precision level judged acceptable to meet overall

quality/data use requirements instead of a statistical acceptance criteria (e.g. +/- 3 sigma) (applies to radiobioassay laboratories). (ANSI)

Toxic Substances Control Act (TSCA): the enabling legislation in 15 USC 2601 *et seq*., (1976), that provides for testing, regulating, and screening all chemicals produced or imported into the United States for possible toxic effects prior to commercial manufacture. (TNI)

Traceability: the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons. (VIM-6.12)

Type A Evaluation of Uncertainty: is a method of evaluation of uncertainty by the statistical analysis of series of observations. (NIST)

United States Environmental Protection Agency (EPA): the federal governmental agency with responsibility for protecting public health and safeguarding and improving the natural environment (i.e., the air, water, and land) upon which human life depends. (US-EPA)

Validation: the process of substantiating specified performance criteria. (EPA-QAD)

Verification: confirmation by examination and provision of evidence that specified requirements have been met. (TNI)

> NOTE: In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.
>
> The result of verification leads to a decision either to restore in service, to perform adjustment, to repair, to downgrade, or to declare obsolete. In all cases, it is required that a written trace of the verification performed shall be kept on the measuring instrument's individual record.

Voting Member: officials in the employ of the Government of the United States, and the States, the Territories, the Possessions of the United States, or the District of Columbia and who are actively engaged in environmental regulatory programs or accreditation of environmental laboratories. (TNI)

Work Cell: a well-defined group of analysts that together perform the method analysis. The members of the group and their specific functions within the work cell must be fully documented.

Sources:

40 CFR Part 136, April 16, 2024

American Society for Quality Control (ASQC), Definitions of Environmental Quality Assurance Terms, 1996

American National Standards Institute (ANSI), Style Manual for Preparation of Proposed American National Standards, Eighth Edition, March 1991

ANSI/ASQC E4, 1994

ANSI N42.23-1995, Measurement and Associated Instrument Quality Assurance for Radiobioassay Laboratories

A2LA, American Association for Laboratory Accreditation

International Standards Organization (ISO) Guides 2, 30, 8402

International Vocabulary of Basic and General Terms in Metrology (VIM): 1984. Issued by BIPM, IEC, ISO and OIML

National Institute of Standards and Technology (NIST)

The NELAC Institute, 2016 TNI Standard

Random House College Dictionary

US EPA Quality Assurance Management Section (QAMS), Glossary of Terms of Quality Assurance Terms, 8/31/92 and 12/6/95

US EPA Quality Assurance Division (QAD)

Webster's New World Dictionary of the American Language

ISO/IEC 17025

18 Appendix B – Table 1 Sample Preservation, Containers, and Holding Time Table

A partial list of sample preservation, containers, and holding time requirements for the test parameters most commonly performed by the laboratory are listed in the following table:

Sample Preservation, Containers, and Holding Time Table

Parameter	**Matrix A = Aqueous S = Solids**	**Container P= Polyethylene G= Glass**	**Preservation**	**Maximum Holding Time If preservation conditions are met**
Ammonia	A	P, G	Cool ≤ 6°C, H_2SO_4 pH < 2	28 days
BOD	A	P, G	Cool ≤ 6°C	48 hours
Chemical Oxygen Demand	A	P, G	Cool ≤ 6°C, H_2SO_4 pH < 2	28 days
Cyanide	A	P, G	Cool ≤ 6°C, NaOH pH > 12, 0.6 g ascorbic acid (Note 1)	14 days
Nitrate	A	P, G	Cool ≤ 6°C	48 hours
Nitrate-Nitrite	A	P, G	Cool ≤ 6°C, H_2SO_4 pH < 2	28 days
Boron	A	P, PFTE, Quartz	HNO_3 pH < 2	6 months
Chromium VI	A	P, G	Cool ≤ 6°C	24 hours
Mercury	A	P, G	HNO_3 pH < 2	28 days
Mercury	S	P, G	Cool ≤ 6°C	28 days
Metals (except boron, mercury, Cr VI)	A	P, G	HNO_3 pH < 2	6 months
Metals (except Boron, Mercury, Cr VI)	S	P, G	Cool, ≤ 6°C	6 months
Phenols	A	G	Cool ≤ 6°C H_2SO_4 pH < 2	28 days
Total Solids	A	P, G	Cool ≤ 6°C	7 days
Total Dissolved Solids	A	P, G	Cool ≤ 6°C	7 days
TSS	A	P, G	Cool ≤ 6°C	7 days
TVS	A	P, G	Cool ≤ 6°C	7 days
Total Phosphorus-ICP analysis	A	P, G	Cool ≤ 6°C HNO_3 pH < 2	28 days
Oil & Grease	A	G	Cool ≤ 6°C HCl pH < 2	28 days
Total Organic Carbon	A	P, G	Cool < 6°C H_3PO_4 pH < 2	28 days
Diesel Range Organics (DRO)	A	G, Teflon-lined cap	Cool, 4°C 0.008% $Na_2S_2O_3$ (Note 1)	7 days extraction, 40 days after extraction
Diesel Range Organics (DRO)	S	G, Teflon-lined cap	Cool, 4°C	14 days extraction, 40 days after extraction
Gasoline Range Organics (GRO)	A	G, Teflon-lined septum	Cool, 4°C HCl pH < 2	14 days

Parameter	**Matrix A = Aqueous S = Solids**	**Container P= Polyethylene G= Glass**	**Preservation**	**Maximum Holding Time If preservation conditions are met**
Gasoline Range Organics (GRO)	S	G, Teflon-lined cap	Cool, 4°C	14 days
Volatile Organic Compounds (VOC)	A	G, Teflon-lined septum	Cool, 4°C HCl pH < 2, 10% $Na_2S_2O_3$ (Note 1)	14 days
Volatile Organic Compounds (VOC)	S	G, Teflon-lined cap	Cool, 4°C	14 days
Semivolatiles Organic Compounds (SVOC)	A	G, Teflon-lined cap	Cool, 4°C 0.008% $Na_2S_2O_3$ (Note 1)	7 days extraction, 40 days after extraction
Semivolatiles Organic Compounds (SVOC)	S	G, Teflon-lined cap	Cool, 4°C	14 days extraction, 40 days after extraction
Pesticides/PCBs	A	G, Teflon-lined cap	Cool, 4°C 0.008% $Na_2S_2O_3$ (Note 1)	7 days extraction, 40 days after extraction; PCB – 1 yr
Pesticides/PCBs	S	G, Teflon-lined cap	Cool, 4°C	14 days extraction, 40 days after extraction; PCB 1 yr
Herbicides	A	G, Teflon	Cool	7 days extraction, 40 days after extraction
Herbicides	S	G, Teflon	Cool	14 days extraction, 40 days after extraction
Nitroaromatics and Nitroamines	A	G, Teflon	Cool	7 days extraction, 40 days after extraction
Nitroaromatics and Nitroamines	S	G, Teflon	Cool	14 days extraction, 40 days after extraction
Polynuclear aromatic Hydrocarbons	A	G, Teflon	Cool	7 days extraction, 40 days after extraction
Polynuclear aromatic Hydrocarbons	S	G, Teflon	Cool	14 days extraction, 40 days after extraction

(Note 1) The use of a dechlorinating agent is only required when residual chlorine is present in the sample.

Reference: 40 CFR 136 Table II and SW 846 Current Revision and Updates.

A complete listing of parameters and preservation requirements can be found as a separate document.

19 Appendix C – Table 2 Data Packages

Data Packages

QC Level I – Results Only **QC Report**	**QC Form or Equivalent**
Case Narrative – When problems are encountered.	CN Summary
Non-Conformance Report, when applicable	NCR
Corrective Action Report, when applicable	CAR
Surrogate Recoveries (Organics Only)	WA Report Format
Sample Results	WA Report Format

QC Level II QA/QC – Minimum QC Report	**QC Form or Equivalent**
Level I requirements	
Laboratory Blank Summary	Form 4
Laboratory Blank Results	Form 1 or equivalent
Laboratory Control/Laboratory Control Sample Dup	Form 3 or equivalent
Matrix Spike/Matrix Spike Duplicate	Form 3 or equivalent
Post Digestion Spike Recovery (Metals only)	WA Format
Dilution Test RPD (Metals only)	WA Format
Post Digestion Spike Recovery (Metals only)	WA Format
Dilution Table (Inorganics and Metals only)	WA Format

QC Level III QA/QC Report	**QC Form or Equivalent**
Level II requirements	
Tune Evaluation Report (SVOC and VOC)	Mass Hunter Form
Initial Calibration	Form 6
Calibration Verification (Narrative Only)	Form 7, or equivalent
Internal Standard Summary	Form 8
Sample TIC Summary Reports (GC/MS only)	Form 1 TIC

QC Level IV QA/QC **QC Report**	**QC Form or Equivalent**
Level III requirements	
Raw Data	Worksheets, Prep Logs, Instrument Printouts, Chromatograms, etc.

20 Appendix D – Table 3 NELAP- Accredited Analytical Methods – Program Specific

NELAP Fields of Accreditation (CWA-SCM): LELAP – Primary AB			
Method	**Parameter - Analyte**	**CWA**	**SCM**
Texas 1006	Total Petroleum Hydrocarbons (TPH)	Y	Y
ASTM D93	Flashpoint	Y	Y
TKN + NO3-NO2	Total Nitrogen	Y	Y
TKN - Ammonia	Organic Nitrogen	Y	Y
200.7 – 3500 CrB	Chromium(III)	Y	
6010B - 3500 CrB	Chromium(III)	Y	
200.8 - 3500 CrB	Chromium(III)	Y	
6010C - 3500 CrB	Chromium(III)	Y	
6010D - 3500 CrB	Chromium(III)	Y	
6020B - 3500 CrB	Chromium(III)	Y	
6010C – 7196A	Chromium(III)		Y
6010D-7196A	Chromium(III)		Y
6020B-7196A	Chromium(III)		Y
8260D	1,3-Butadiene	Y	Y
7.3.3.2	Reactive Cyanide	Y	Y
7.3.4.2	Reactive Sulfide	Y	Y
160.4	Residue-Volatile	Y	
1010A/B	Ignitability		Y
1311	TCLP		Y
1312	SPLP		Y
3005A	Acid Digestion for Metals	Y	Y
3050B	Acid Digestion for Solids	Y	Y
3060A	Cr VI Digestion		Y
3510C	Separatory Funnel Extract	Y	Y
3540C	Soxhlet Extraction		Y
3546	Microwave Extraction	Y	Y
3550B	Ultrasonic Extraction		Y
3550C	Ultrasonic Extraction	Y	Y
3580A	Waste Dilution	Y	Y
3665A	Sulfuric/Permanganate		Y
5021/A	VOC Headspace Analysis		Y
5030A	PT for Aqueous Samples	Y	Y
5030B	PT for VOC Samples	Y	Y
5035	Closed System PT	Y	Y
5035	Solid-Phase PT		Y
5050	Bomb Preparation		Y
6010B/C/D	Aluminum	Y	Y
6010B/C/D	Antimony	Y	Y
6010B/C/D	Arsenic	Y	Y
6010B/C/D	Barium	Y	Y

6010B/C/D	Beryllium	Y	Y
6010B/C/D	Boron	Y	Y
6010B/C/D	Cadmium	Y	Y
6010B/C/D	Calcium	Y	Y
6010B/C/D	Chromium	Y	Y
6010B/C/D	Cobalt	Y	Y
6010B/C/D	Copper	Y	Y
6010B/C/D	Iron	Y	Y
6010B/C/D	Lead	Y	Y
6010B/C/D	Magnesium	Y	Y
6010B/C/D	Manganese	Y	Y
6010B/C/D	Molybdenum	Y	Y
6010B/C/D	Nickel	Y	Y
6010B/C/D	Potassium	Y	Y
6010B/C/D	Selenium	Y	Y
6010B/C/D	Silica as SiO2	Y	Y
6010B/C/D	Silver	Y	Y
6010B/C/D	Sodium	Y	Y
6010B/C/D	Strontium	Y	Y
6010B/C/D	Thallium	Y	Y
6010B/C/D	Tin	Y	Y
6010B/C/D	Titanium	Y	Y
6010B/C/D	Total Phosphorus	Y	Y
6010B/C/D	Vanadium	Y	Y
6010B/C/D	Zinc	Y	Y
6020/A/B	Aluminum	Y	Y
6020/A/B	Antimony	Y	Y
6020/A/B	Arsenic	Y	Y
6020/A/B	Barium	Y	Y
6020/A/B	Beryllium	Y	Y
6020/A/B	Boron	Y	Y
6020/A/B	Cadmium	Y	Y
6020/A/B	Calcium	Y	Y
6020/A/B	Chromium	Y	Y
6020/A/B	Cobalt	Y	Y
6020/A/B	Copper	Y	Y
6020/A/B	Iron	Y	Y
6020/A/B	Lead	Y	Y
6020/A/B	Magnesium	Y	Y
6020/A/B	Manganese	Y	Y
6020/A/B	Molybdenum	Y	Y
6020/A/B	Nickel	Y	Y
6020/A/B	Potassium	Y	Y
6020/A/B	Selenium	Y	Y
6020/A/B	Silver	Y	Y
6020/A/B	Sodium	Y	Y

6020/A/B	Strontium	Y	Y
6020/A/B	Thallium	Y	Y
6020/A/B	Tin	Y	Y
6020/A/B	Titanium	Y	Y
6020/A/B	Total Phosphorus	Y	Y
6020/A/B	Vanadium	Y	Y
6020/A/B	Zinc	Y	Y
7000B	Lithium	Y	Y
7196A	Chromium VI		Y
7470A	Mercury	Y	Y
7471A/B	Mercury		Y
8011	DBCP	Y	
8011	EDB	Y	
8015C	DRO	Y	Y
8015B/C	GRO	Y	Y
8015B/C	Methanol	Y	Y
8015C	Diethylene glycol	Y	Y
8015C	Ethylene glycol	Y	Y
8015C	Propylene glycol	Y	Y
8015C	Triethylene glycol	Y	Y
8081B	4,4-DDD	Y	Y
8081B	4,4-DDE	Y	Y
8081B	4,4-DDT	Y	Y
8081B	Aldrin	Y	Y
8081B	Chlordane (tech.)	Y	Y
8081B	Chlorobenzilate		Y
8081B	Dieldrin	Y	Y
8081B	Endosulfan I	Y	Y
8081B	Endosulfan II	Y	Y
8081B	Endosulfan Sulfate	Y	Y
8081B	Endrin	Y	Y
8081B	Endrin Aldehyde	Y	Y
8081B	Endrin Ketone	Y	Y
8081B	Heptachlor	Y	Y
8081B	Heptachlor Epoxide	Y	Y
8081B	Hexachlorobenzene		Y
8081B	Hexachlorocyclopentadiene		Y
8081B	Isodrin		Y
8081B	Methoxychlor	Y	Y
8081B	Mirex		Y
8081B	Toxaphene	Y	Y
8081B	Alpha-BHC	Y	Y
8081B	Alpha-Chlordane	Y	Y
8081B	Beta-BHC	Y	Y
8081B	Delta -BHC	Y	Y
8081B	Gamma-BHC	Y	Y

8081B	Gamma-Chlordane	Y	Y
8081B	trans-Nonachlor		Y
8082	PCB 1016		Y
8082	PCB 1221		Y
8082	PCB 1232		Y
8082	PCB 1242		Y
8082	PCB 1248		Y
8082	PCB 1254		Y
8082	PCB 1260		Y
8082A	PCB 1016	Y	Y
8082A	PCB 1221	Y	Y
8082A	PCB 1232	Y	Y
8082A	PCB 1242	Y	Y
8082A	PCB 1248	Y	Y
8082A	PCB 1254	Y	Y
8082A	PCB 1260	Y	Y
8082A	PCB 1016 in Oil		Y
8082A	PCB 1221 in Oil		Y
8082A	PCB 1232 in Oil		Y
8082A	PCB 1242 in Oil		Y
8082A	PCB 1248 in Oil		Y
8082A	PCB 1254 in Oil		Y
8082A	PCB 1260 in Oil		Y
8151A	2,4,5-T	Y	Y
8151A	2,4-D	Y	Y
8151A	2,4-DB	Y	Y
8151A	Acifluorfen		Y
8151A	Bentazon		Y
8151A	Dalapon	Y	Y
8151A	Dicamba	Y	Y
8151A	Dichloroprop	Y	Y
8151A	Dinoseb	Y	Y
8151A	MCPA	Y	Y
8151A	MCPP	Y	Y
8151A	Pentachlorophenol	Y	Y
8151A	Picloram	Y	Y
8151A	2,4,5-TP (Silvex)	Y	Y
8260B/D	1,1,1,2-Tetrachloroethane	Y	Y
8260B/D	1,1,1-Trichloroethane	Y	Y
8260B/D	1,1,2,2-Tetrachloroethane	Y	Y
8260B/D	1,1,2-Trichloro-1,2,2-trifluoroethane Freon 113		Y
8260B/D	Freon 113a		Y
8260B/D	1,1,2-Trichloroethane	Y	Y
8260B/D	1,1-Dichloroethane	Y	Y
8260B/D	1,1-Dichloroethylene	Y	Y
8260B/D	1,1-Dichloropropene	Y	Y

8260B/D	1,2,3-Trichlorobenzene	Y	Y
8260B/D	1,2,3-Trichloropropane	Y	Y
8260B/D	1,2,4-Trichlorobenzene	Y	Y
8260B/D	1,2,4-Trimethylbenzene	Y	Y
8260B/D	DBCP	Y	Y
8260B/D	EDB	Y	Y
8260B/D	1,2-Dichlorobenzene	Y	Y
8260B/D	1,2-Dichloroethane	Y	Y
8260B/D	1,2-Dichloropropane	Y	Y
8260B/D	1,3,5-Trichlorobenzene		Y
8260B/D	1,3,5-Trimethylbenzene	Y	Y
8260B	1,3-Butadiene	Y	Y
8260B/D	1,3-Dichlorobenzene	Y	Y
8260B/D	1,3-Dichloropropane	Y	Y
8260B/D	1,4-Dichlorobenzene	Y	Y
8260B/D	1,4-Dioxane		Y
8260B/D	2,2,4-Trimethylpentane	Y	Y
8260B/D	2,2-Dichloropropane	Y	Y
8260B/D	2-Butanone (MEK)	Y	Y
8260B/D	2-Chloroethanol		Y
8260B/D	2-Choroethyl vinyl ether	Y	Y
8260B/D	2-Chlorotoluene	Y	Y
8260B/D	2-Hexanone	Y	Y
8260B/D	2-Methylaniline		Y
8260B/D	2-Nitropropane		Y
8260B/D	2-Pentanone		Y
8260B/D	2-Picoline		Y
8260B/D	3-Chloropropionitrile		Y
8260B/D	4-Chlorotoluene	Y	Y
8260B/D	4-Isopropyltoluene	Y	Y
8260B/D	4-Methyl-2-Pentanone, MIBK	Y	Y
8260B/D	Acetone	Y	Y
8260B/D	Acetonitrile	Y	Y
8260B/D	Acrolein	Y	Y
8260B/D	Acrylamide	Y	
8260B/D	Acrylonitrile	Y	Y
8260B/D	Allyl Alcohol		Y
8260B/D	Allyl Chloride (3-Chloroprene)		Y
8260B/D	Benzene	Y	Y
8260B/D	Bromobenzene	Y	Y
8260B/D	Bromochloromethane	Y	Y
8260B/D	Bromodichloromethane	Y	Y
8260B/D	Bromoform	Y	Y
8260B/D	Carbon Disulfide	Y	Y
8260B/D	Carbon Tetrachloride	Y	Y
8260B/D	Chloral Hydrate		Y

8260B/D	Chloroacetonitrile		Y
8260B/D	Chlororbenzene	Y	Y
8260B/D	Chlorodibromomethane	Y	Y
8260B/D	Chloroethane	Y	Y
8260B/D	Chloroform	Y	Y
8260B/D	Di-isopropylether	Y	
8260B/D	Chloroprene	Y	Y
8260B/D	Crotonaldehyde		Y
8260B/D	Dibromochloropropane		Y
8260B/D	Dibromofluoromethane		Y
8260B/D	Dibromomethane	Y	Y
8260B/D	Dichlorodifluoromethane	Y	Y
8260B/D	Diethyl ether		Y
8260B/D	Epichlorohydrin		Y
8260B/D	Ethanol	Y	Y
8260B/D	Ethyl acetate		Y
8260B/D	Ethyl-t-butyl ether	Y	
8260B/D	Ethyl Methacrylate		Y
8260B/D	Ethylbenzene	Y	Y
8260B/D	Hexachlorobutadiene	Y	Y
8260B/D	Hexachloroethane	Y	
8260B/D	Iodomethane		Y
8260B/D	Isobutyl Alcohol		Y
8260B/D	Isopropyl Alcohol		Y
8260B/D	Isopropylbenzene	Y	Y
8260B/D	Methacrylonitrile		Y
8260B/D	Methyl bromide	Y	Y
8260B/D	Methyl chloride	Y	Y
8260B/D	Methyl Methacrylate		Y
8260B/D	Methyl-tert-butyl ether	Y	Y
8260B/D	Methylene chloride	Y	Y
8260B/D	Naphthalene	Y	Y
8260B/D	Nitrobenzene	Y	
8260B/D	Pentachloroethane		Y
8260B/D	Pentafluorobenzene		Y
8260B/D	Propargyl Alcohol		Y
8260B/D	Propionitrile (Ethyl cyanide)		Y
8260B/D	Pyridine		Y
8260B/D	Styrene	Y	Y
8260B/D	T-amyl methyl ether	Y	
8260B/D	Tetrachloroethylene	Y	Y
8260B/D	Tetrahydrofuran		Y
8260B/D	Toluene	Y	Y
8260B/D	Total BTEX	Y	Y
8260B/D	Trichloroethene	Y	Y
8260B/D	Trichlorofluoromethane	Y	Y

8260B/D	Vinyl Acetate	Y	Y
8260B/D	Vinyl Bromide	Y	Y
8260B/D	Vinyl Chloride	Y	Y
8260B/D	Xylenes, total	D: Y	Y
8260B/D	Cis-1,2-Dichloroethylene	Y	Y
8260B/D	Cis-1,3-Dichloropropene	Y	Y
8260B/D	Cis,1-4,Dichloro-2-butene		Y
8260B/D	M+p-Xylene	D: Y	Y
8260B/D	m-Xylene	Y	Y
8260B/D	n-Butyl alcohol		Y
8260B/D	n-Butylbenzene	Y	Y
8260B/D	n-Propylamine		Y
8260B/D	n-Hexane	Y	D:Y
8260B/D	n-Propylbenzene	Y	Y
8260B/D	o-Xylene	Y	Y
8260B/D	p-Xylene	Y	Y
8260B/D	Sec-Butylbenzene	Y	Y
8260B/D	Tert-Butyl alcohol	Y	Y
8260B/D	Tert-Butylbenzene	Y	Y
8260B/D	Total 1,3-Dichloropropene	Y	Y
8260B/D	Trans-1,2-Dichloroethylene	Y	Y
8260B/D	Trans-1,3-Dichloropropylene	Y	Y
8260B/D	Trans-1,4-Dichloro-2-butene		Y
8270D	Leptophos		Y
8270D/E	Methyl methanesulfonate	Y	Y
8270D	Mevinphos		Y
8270D/E	Monocrotophos		Y
8270D/E	1,2,4,5-Tetrachlorobenzene	Y	Y
8270D/E	1,2,4-Trichlorobenzene	Y	Y
8270D/E	1-Methylnaphthalene	Y	
8270D/E	1,2-Dichlorobenzene	Y	Y
8270D/E	1,2-Dinitrobenzene	Y	Y
8270D/E	1,2-Diphenylhydrazine	Y	Y
8270D/E	1,3-Dichlorobenzene	Y	Y
8270D/E	1,4-Dichlorobenzene	Y	Y
8270D/E	1,4-Naphthoquinone	Y	Y
8270D/E	1-Chloronaphthalene	Y	Y
8270D/E	2,3,4,6-Tetrachlorophenol	Y	Y
8270D/E	2,4,5-Trichlorophenol	Y	Y
8270D/E	2,4,6-Trichlorophenol	Y	Y
8270D/E	2,4-Dichlorophenol	Y	Y
8270D/E	2,4-Dimethylphenol	Y	Y
8270D/E	2,4-Dinitrophenol	Y	Y
8270D/E	2,4-Dinitrotoluene	Y	Y
8270D/E	2,6-Dichlorophenol	Y	Y
8270D/E	2,6-Dinitrotoluene	Y	Y

8270D/E	2-Chloronapthalene	Y	Y
8270D/E	2-Chlorophenol	Y	Y
8270D/E	4,6-Dinitro-2-methylphenol	Y	Y
8270D/E	2-Methylnapthalene	Y	Y
8270D/E	2-Methylphenol	Y	Y
8270D/E	2-Nitroaniline	Y	Y
8270D/E	2-Nitrophenol	Y	Y
8270D/E	3,3-Dichlorobenzidine	Y	Y
8270D/E	3,3-Dimethylbenzidine	Y	Y
8270E	3+4-Methylphenol	Y	Y
8270D/E	3-Methylphenol	Y	Y
8270D/E	3-Nitroaniline	Y	Y
8270D/E	4-Bromophenyl phenyl ether	Y	Y
8270D/E	4-Chloro-3-methylphenol	Y	Y
8270D/E	4-Chloroaniline	Y	Y
8270D/E	4-Chlorophenyl phenyl ether	Y	Y
8270D/E	4-Methylphenol	Y	Y
8270D/E	4-Nitroaniline	Y	Y
8270D/E	4-Nitrophenol	Y	Y
8270D/E	Acenaphthene	Y	Y
8270D/E	Acenaphthylene	Y	Y
8270D/E	Acetophenone	Y	Y
8270D/E	Aniline	Y	Y
8270D/E	Anthracene	Y	Y
8270D/E	Aramite	Y	Y
8270D/E	Azinophos-methyl (Guthion)		Y
8270D/E	Benz(a)anthracene	Y	Y
8270D/E	Benzidine	Y	Y
8270D/E	Benzo(a)pyrene	Y	Y
8270D/E	Benzo(b)fluoranthene	Y	Y
8270D/E	Benzo(g,h,i)perylene	Y	Y
8270D/E	Benzo(k)fluoranthene	Y	Y
8270D/E	Benzoic Acid	Y	Y
8270D/E	Benzyl Alcohol	Y	Y
8270D/E	Butyl benzyl phthalate	Y	Y
8270D/E	Carbazole	Y	Y
8270D/E	Chlorobenzilate	Y	Y
8270/D	Chlorpyrifos		Y
8270D/E	Chrysene	Y	Y
8270D	Coumaphos	Y	Y
8270D	Demeton and isomers		Y
8270D/E	Bis(2-Ethylhexyl)phthalate	Y	Y
8270D/E	Di-n-butyl phthalate	Y	Y
8270D/E	Di-n-octyl phthalate	Y	Y
8270D	Diazinon		Y
8270D/E	Dibenz(a,h)anthracene	Y	Y

8270D/E	Dibenzofuran	Y	Y
8270D	Dichlorovos, DDVP	Y	Y
8270D/E	Diethyl phthalate	Y	Y
8270D/E	Dimethoate		Y
8270D/E	Dimethyl phthalate	Y	Y
8270D	Dioxathion		Y
8270D/E	Diphenylamine	Y	Y
8270D/E	Disulfoton		Y
8270D/E	EPN	Y	Y
8270D/E	Ethyl methanesulfonate	Y	Y
8270D/E	Famphur	Y	Y
8270D/E	Fensulfothion		Y
8270D/E	Fenthion		Y
8270D/E	Fluoranthene	Y	Y
8270D/E	Fluorene	Y	Y
8270D/E	Hexachlorobenzene	Y	Y
8270D/E	Hexachlorobutadiene	Y	Y
8270D/E	Hexachlorocyclopentadiene	Y	Y
8270D/E	Hexachloroethane	Y	Y
8270D/E	Hydroquinone	Y	Y
8270D/E	Indeno(1,2,3-cd)pyrene	Y	Y
8270D/E	Isophorone	Y	Y
8270D/E	Kepone	Y	Y
8270D	Leptophos		Y
8270D/E	Malathion		Y
8270D/E	Methyl Methanesulfonate	Y	Y
8270D/E	Parathion, methyl		Y
8270D	Mevinphos		Y
8270D/E	Monocrotophos		Y
8270D/E	Naled	Y	Y
8270D/E	Napthalene	Y	Y
8270D/E	Nitrobenzene	Y	Y
8270D/E	Parathion, ethyl		Y
8270D/E	Pendimethalin		Y
8270D/E	Pentachlorobenzene	Y	Y
8270D/E	Pentachloronitrobenzene	Y	Y
8270D/E	Pentachlorophenol	Y	Y
8270D/E	Phenacetin	Y	Y
8270D/E	Phenanthrene	Y	Y
8270D/E	Phenobarbital	Y	Y
8270D/E	Phenol	Y	Y
8270D/E	Phorate	Y	Y
8270D/E	Pyrene	Y	Y
8270D/E	Pyridine	Y	Y
8270D/E	Resorcinol	Y	Y

8270D/E	Total Cresols	Y	Y
8270D/E	Ronnel		Y
8270D/E	Sulfotepp		Y
8270D/E	Tetrachlorvinphos, Stirophos		Y
8270D/E	Trifluralin, (Treflan)	Y	Y
8270E	Bis(2-Chloroethoxy)methane	Y	Y
8270D/E	Bis(2-chloroethyl)ether	Y	Y
8270D/E	Bis(2-Chloroisopropyl)ether	Y	Y
8270D/E	N-Nitrosodi-n-butylamine	Y	Y
8270D/E	N-Nitrosodi-n-propylamine	Y	Y
8270D/E	Nitrosodiethylamine	Y	Y
8270D/E	N-Nitrosodimethylamine	Y	Y
8270D/E	N-Nitrodiphenylamine	Y	Y
8315A	Acetaldehyde	Y	Y
8315A	Formaldehyde	Y	Y
9010B	Amenable Cyanide		Y
9010B/C	Total Cyanide		Y
9014	Cyanide		Y
9014	Reactive Cyanide	Y	
9014	Total Cyanide		Y
9030	Sulfide		Y
9031	Sulfide		Y
9034	Sulfide		Y
9034	Reactive Sulfide		Y
9040B	pH		Y
9045C	pH		Y
9050/A	Conductivity		Y
9056/A	Bromide	A: Y	Y
9056/A	Chloride	A: Y	Y
9056/A	Fluoride	A: Y	Y
9056/A	Nitrate as N	A: Y	Y
9056/A	Nitrate-Nitrite	A: Y	Y
9056/A	Nitrite		Y
9056/A	Nitrite as N	A: Y	Y
9056/A	Sulfate	A: Y	Y
9056/A	Total Nitrate-Nitrite	A: Y	Y
9065	Phenol		Y
9065	Total Phenolics		Y
9071B R2	Oil and Grease		Y
9071B R2	Total Petroleum Hydrocarbons (TPH)		Y
9095A/B	Free Liquid		Y
1667A	Formaldehyde	Y	
AOAC 955.01	Calcium Carbonate Equivalent		Y
8270D/E SIM	1-Methylnaphthalene	D:Y	D:Y
8270D/E SIM	2-Methylnaphthalene	Y	D:Y
8270D/E SIM	Acenaphthene	Y	D:Y

8270D/E SIM	Acenaphthylene	Y	D:Y
8270D/E SIM	Anthracene	Y	D:Y
8270D/E SIM	Benzo(a)anthracene	Y	D:Y
8270D/E SIM	Benzo(a)pyrene	Y	D:Y
8270D/E SIM	Benzo(b)fluoranthene	Y	D:Y
8270D/E SIM	Benzo(g,h,i)perylene	Y	D:Y
8270D/E SIM	Benzo(k)fluoranthene	Y	D:Y
8270D/E SIM	Chrysene	Y	D:Y
8270D/E SIM	Dibenz(a,h)anthracene	Y	D:Y
8270D/E SIM	Fluoranthene	Y	D:Y
8270D/E SIM	Fluorene	Y	D:Y
8270D/E SIM	Indeno(1,2,3-cd)pyrene	Y	D:Y
8270D/E SIM	Naphthalene	Y	D:Y
8270D/E SIM	Phenanthrene	Y	D:Y
8270D/E SIM	Pyrene	Y	D:Y
9040C	pH		Y
9045D	pH		Y
9060/A	Total Organic Carbon		Y
3511	Microextraction	Y	Y
4500-NH3C-2011	Ammonia as N		Y
4500-NH3C-2011	Kjeldahl nitrogen - total	Y	Y
4500-Norg B-2011	Kjeldahl nitrogen - total	Y	Y
4500-Norg D-2011	Kjeldahl nitrogen - total	Y	Y
4500-P E	Total Phosphorus	Y	Y
Walkley Black	TOC		Y
MA VPH R 1.1/2.1	VPH Aliphatic C6-C8	Y	Y
MA VPH R 1.1/2.1	VPH Aliphatic C8-C10	Y	Y
MA VPH R 1.1/2.1	VPH Aliphatic >C8-C10	Y	Y
TNRCC 1005	TPH >C12-C28	Y	Y
TNRCC 1005	TPH >C28-C35	Y	Y
TNRCC 1005	TPH C6-C12	Y	Y
TNRCC 1005	TPH C6-C35	Y	Y
TNRCC 1005	Total Petroleum Hydrocarbons (TPH)	Y	Y
160.4	Residue-volatile	Y	
200.7R4.4	Aluminum	Y	
200.7R4.4	Antimony	Y	
200.7R4.4	Arsenic	Y	
200.7R4.4	Barium	Y	
200.7R4.4	Beryllium	Y	
200.7R4.4	Boron	Y	
200.7R4.4	Cadmium	Y	
200.7R4.4	Calcium	Y	
200.7R4.4	Chromium	Y	
200.7R4.4	Cobalt	Y	
200.7R4.4	Copper	Y	

200.7R4.4	Hardness	Y	
200.7R4.4	Iron	Y	
200.7R4.4	Lead	Y	
200.7R4.4	Magnesium	Y	
200.7R4.4	Manganese	Y	
200.7R4.4	Molybdenum	Y	
200.7R4.4	Nickel	Y	
200.7R4.4	Potassium	Y	
200.7R4.4	Selenium	Y	
200.7R4.4	Silica-dissolved	Y	
200.7R4.4	Silica as SiO2	Y	
200.7R4.4	Silver	Y	
200.7R4.4	Sodium	Y	
200.7R4.4	Strontium	Y	
200.7R4.4	Thallium	Y	
200.7R4.4	Tin	Y	
200.7R4.4	Titanium	Y	
200.7R4.4	Total Phosphorus	Y	
200.7R4.4	Total Hardness as CaCO3	Y	
200.7R4.4	Vanadium	Y	
200.7R4.4	Zinc	Y	
200.8 R5.4	Aluminum	Y	
200.8 R5.4	Antimony	Y	
200.8 R5.4	Arsenic	Y	
200.8 R5.4	Barium	Y	
200.8 R5.4	Beryllium	Y	
200.8 R5.4	Boron	Y	
200.8 R5.4	Cadmium	Y	
200.8 R5.4	Calcium	Y	
200.8 R5.4	Chromium	Y	
200.8 R5.4	Cobalt	Y	
200.8 R5.4	Copper	Y	
200.8 R5.4	Hardness (calc.)	Y	
200.8 R5.4	Iron	Y	
200.8 R5.4	Lead	Y	
200.8 R5.4	Magnesium	Y	
200.8 R5.4	Manganese	Y	
200.8 R5.4	Molybdenum	Y	
200.8 R5.4	Nickel	Y	
200.8 R5.4	Potassium	Y	
200.8 R5.4	Selenium	Y	
200.8 R5.4	Silver	Y	
200.8 R5.4	Sodium	Y	
200.8 R5.4	Strontium	Y	
200.8 R5.4	Thallium	Y	
200.8 R5.4	Tin	Y	

200.8 R5.4	Titanium	Y	
200.8 R5.4	Total Phosphorus	Y	
200.8 R5.4	Vanadium	Y	
200.8 R5.4	Zinc	Y	
245.1 R3	Mercury	Y	
300.0R2.1	Bromide	Y	
300.0R2.1	Chloride	Y	
300.0R2.1	Fluoride	Y	
300.0R2.1	Nitrate as N	Y	
300.0R2.1	Nitrate-Nitrite	Y	
300.0R2.1	Nitrite	Y	
300.0R2.1	Sulfate	Y	
365.4	Total Phosphorus	Y	Y
420.1	Total Phenolics	Y	
1664A/B	Total Petroleum Hydrocarbons	Y	
1664B SGT	Total Petroleum Hydrocarbons	Y	
1664A/B	Oil and Grease	Y	
1664A/B SGT-HEM	Oil and Grease	Y	
2120B-2011	Color	Y	
2130B-2011	Turbidity	Y	
2310B-2011	Acidity	Y	
2320B-2011	Alkalinity	Y	
2340B-2011	Hardness	Y	
2510B-2011	Conductivity	Y	
2540B-2015	TS	Y	
2540C-2015	TDS	Y	
2540D-2015	TSS	Y	
2540E-2015	TVS	Y	
2540F-2015	Settleable Solids	Y	
2540G-2011	Total Residue	Y	Y
2540G-2011	Total, Fixed and Volatile Residue	Y	Y
2540G 18th ED	TVS	Y	
2550B-2010	Temperature	Y	
3500 Cr B-2011	Hexavalent Chromium	Y	
4500 Cl G-2011	TRC, low level	Y	
4500 Cl G-2011	Total Residual Chlorine	Y	
4500 Cn C-2016	Cyanide	Y	
4500 Cn E-2016	Cyanide	Y	
4500 Cn G-2016	Amenable Cyanide	Y	
4500 Cn G-2011	Cyanide	Y	
4500 H B-2011	pH	Y	
4500NH3B-2011	Ammonia as N	Y	Y
4500NH3C-2011	Ammonia		Y
4500NH3D-2011	Ammonia	Y	
4500NH3D-2011	Ammonia as N	Y	
4500NO3F-2016	Nitrate-Nitrite	Y	Y

4500NO3I-2016	Nitrate-Nitrite	Y	Y
4500 OG-2016	Oxygen, dissolved	Y	
4500PB5-2011	Total Phosphorus	Y	
4500 PE-2011	Orthophosphate as P	Y	
4500 PE-2011	Total Phosphorus	Y	Y
4500 S2F-2011	Sulfide	Y	
4500 SO3B-2011	Sulfite	Y	
5210B-2016	BOD	Y	
5210B-2016	CBOD	Y	
5220D-2011	COD	Y	
5310C-2014	TOC	Y	
5540C-2011	MBAS	Y	
9223B-2016	Escherichia coli	Y	
9223B-2016	Total coliforms	Y	
Colilert-18	Fecal coliforms	Y	
504.1	1,2-Dibromo-3-chloropropane	Y	
504.1	1,2-Dibromoethane	Y	
608.3	4,4-DDD	Y	
608.3	4,4-DDE	Y	
608.3	4,4-DDT	Y	
608.3	Alachlor	Y	
608.3	Aldrin	Y	
608.3	PCB 1016	Y	
608.3	PCB 1221	Y	
608.3	PCB 1232	Y	
608.3	PCB 1242	Y	
608.3	PCB 1248	Y	
608.3	PCB 1254	Y	
608.3	PCB 1260	Y	
608.3	Butachlor	Y	
608.3	Chlordane	Y	
608.3	Chlorobenzilate	Y	
608.3	Chloroneb	Y	
608.3	Chlorothalonil	Y	
608.3	Chlorpyrifos	Y	
608.3	Dacthal	Y	
608.3	Dieldrin	Y	
608.3	Endosulfan I	Y	
608.3	Endosulfan II	Y	
608.3	Endosulfan Sulfate	Y	
608.3	Endrin	Y	
608.3	Endrin Aldehyde	Y	
608.3	Endrin Ketone	Y	
608.3	Heptachlor	Y	
608.3	Heptachlor Epoxide	Y	
608.3	Hexachlorobenzene	Y	

608.3	Isodrin	Y	
608.3	Kepone	Y	
608.3	Methoxychlor	Y	
608.3	Mirex	Y	
608.3	Permethrin (total)	Y	
608.3	Propachlor (Ramrod)	Y	
608.3	Simazine	Y	
608.3	Toxaphene	Y	
608.3	a-BHC	Y	
608.3	a-Chlordane	Y	
608.3	b-BHC	Y	
608.3	d-BHC	Y	
608.3	g-BHC (Lindane)	Y	
608.3	g-Chlordane	Y	
612	Hexachlorobenzene	Y	
615	2,4,5-T	Y	
615	2,4-D	Y	
615	2,4-DB	Y	
615	Dalapon	Y	
615	Dicamba	Y	
615	Dichloroprop	Y	
615	Dinoseb	Y	
615	MCPA	Y	
615	MCPP	Y	
615	Picloram	Y	
615	Silvex (2,4,5-TP)	Y	
624.1	1,1,1-Trichloroethane	Y	
624.1	1,1,1,2-Tetrachloroethane	Y	
624.1	1,1,2,2-Tetrachloroethane	Y	
624.1	1,1,2-Trichloroethane	Y	
624.1	1,1-Dichloroethane	Y	
624.1	1,1-Dichloroethene	Y	
624.1	1,2-Dichlorobenzene	Y	
624.1	1,2-Dichloroethane	Y	
624.1	1,2-Dichloropropane	Y	
624.1	1,3-Dichlorobenzene	Y	
624.1	1,4-Dichlorobenzene	Y	
624.1	2-Chloroethylvinyl ether	Y	
624.1	Acetonitrile	Y	
624.1	Acrolein (Propenal)	Y	
624.1	Acrylonitrile	Y	
624.1	Benzene	Y	
624.1	Bromodichloromethane	Y	
624.1	Bromoform	Y	
624.1	Carbon Tetrachloride	Y	
624.1	Chlorobenzene	Y	

624.1	Chlorodibromomethane	Y	
624.1	Chloroethane	Y	
624.1	Chloroform	Y	
624.1	Ethylbenzene	Y	
624.1	Methyl bromide	Y	
624.1	Methyl chloride	Y	
624.1	MTBE	Y	
624.1	Methylene Chloride	Y	
624.1	Naphthalene	Y	
624.1	Tetrachloroethene	Y	
624.1	Toluene	Y	
624.1	Total BTEX	Y	
624.1	Trichloroethene	Y	
624.1	Trichlorofluoromethane	Y	
624.1	Vinyl Chloride	Y	
624.1	Xylenes, total	Y	
624.1	Cis-1,2-Dichloroethylene	Y	
624.1	Cis-1,3-Dichhloropropene	Y	
624.1	Total 1,3-Dichloropropene	Y	
624.1	trans-1,2-Dichloroethene	Y	
624.1	trans-1,3-Dichloropropene	Y	
625.1	1,2,4-Trichlorobenzene	Y	
625.1	1,2-Dichlorobenzene	Y	
625.1	1,3-Dichlorobenzene	Y	
625.1	1,4-Dichlorobenzene	Y	
625.1	2,2-Oxybis (1-chloropropane)	Y	
625.1	2,3,4,6-Tetrachlorophenol	Y	
625.1	2,4,5-Trichlorophenol	Y	
625.1	2,4,6-Trichlorophenol	Y	
625.1	2,4-Dichlorophenol	Y	
625.1	2,4-Dimethylphenol	Y	
625.1	2,4-Dinitrophenol	Y	
625.1	2,4-Dinitrotoluene	Y	
625.1	2,6-Dichlorophenol	Y	
625.1	2,6-Dinitrotoluene	Y	
625.1	2-Chloronaphthalene	Y	
625.1	2-Chlorophenol	Y	
625.1	2-Methyl-4,6-Dinitrophenol	Y	
625.1	2-Methylphenol	Y	
625.1	2-Nitrophenol	Y	
625.1	3,3-Dichlorobenzidine	Y	
625.1	4-Bromophenyl phenyl ether	Y	
625.1	4-Chloro-3-methylphenol	Y	
625.1	4-Chlorophenyl phenyl ether	Y	
625.1	4-Methylphenol	Y	
625.1	4-Nitrophenol	Y	

625.1	Acenaphthene	Y	
625.1	Acenaphthylene	Y	
625.1	Anthracene	Y	
625.1	Benzo(a)anthracene	Y	
625.1	Benzidine	Y	
625.1	Benzo(a)pyrene	Y	
625.1	Benzo(b)fluoranthene	Y	
625.1	Benzo(g,h,i)perlyene	Y	
625.1	Benzo(k)fluoranthene	Y	
625.1	Benzyl butyl phthalate	Y	
625.1	Carbazole	Y	
625.1	Chrysene	Y	
625.1	Bis(2-ethylhexyl)phthalate	Y	
625.1	Di-n-butyl phthalate	Y	
625.1	Di-n-octyl phthalate	Y	
625.1	Dibenz(a,h)anthracene	Y	
625.1	Diethyl phthalate	Y	
625.1	Dimethyl phthalate	Y	
625.1	Fluoranthene	Y	
625.1	Fluorene	Y	
625.1	Hexachlorobenzene	Y	
625.1	Hexachlorobutadiene	Y	
625.1	Hexachlorocyclopentadiene	Y	
625.1	Hexachloroethane	Y	
625.1	Indeno(1,2,3-cd)pyrene	Y	
625.1	Isophorone	Y	
625.1	Napthalene	Y	
625.1	Nitrobenzene	Y	
625.1	Pentachlorophenol	Y	
625.1	Phenanthrene	Y	
625.1	Phenol	Y	
625.1	Pyrene	Y	
625.1	Total Cresols	Y	
625.1	Bis(2-Chloroethoxy)methane	Y	
625.1	Bis(2-chloroethyl)ether	Y	
625.1	n-Decane	Y	
625.1	N-Nitrosodi-n-propylamine	Y	
625.1	N-Nitrosodimethylamine	Y	
625.1	N-Nitrosodiphenylamine	Y	
625.1	n-Octadecane	Y	
6200B-2011	1,1,1,2-Tetrachloroethane	Y	
6200B-2011	1,1,1-Trichloroethane	Y	
6200B-2011	1,1,2,2-Tetrachloroethane	Y	
6200B-2011	1,1,2-Trichloroethane	Y	
6200B-2011	1,1-Dichloroethane	Y	
6200B-2011	1,1,-Dichloroethylene	Y	

6200B-2011	1,1-Dichloropropene	Y	
6200B-2011	1,2,3-Trichlorobenzene	Y	
6200B-2011	1,2,3-Trichloropropane	Y	
6200B-2011	1,2,4-Trichlororbenzene	Y	
6200B-2011	1,2,4-Trimethylbenzene	Y	
6200B-2011	1,2-Dibromoethane, EDB	Y	
6200B-2011	1,2-Dichlorobenzene	Y	
6200B-2011	1,2-Dichloroethane	Y	
6200B-2011	1,2-Dichloropropane	Y	
6200B-2011	1,3,5-Trimethylbenzene	Y	
6200B-2011	1,3-Dichlorobenzene	Y	
6200B-2011	1,3-Dichloropropane	Y	
6200B-2011	1,4-Dichlorobenzene	Y	
6200B-2011	2,2-Dichloropropane	Y	
6200B-2011	2-Butanone, MEK	Y	
6200B-2011	2-Chlorotoluene	Y	
6200B-2011	2-Hexanone	Y	
6200B-2011	4-Chlorotoluene	Y	
6200B-2011	4-Isopropyltoluene	Y	
6200B-2011	4-Methyl-2-pentanone, MIBK	Y	
6200B-2011	Acetone	Y	
6200B-2011	Benzene	Y	
6200B-2011	Bromobenzene	Y	
6200B-2011	Bromochloromethane	Y	
6200B-2011	Bromodichloromethane	Y	
6200B-2011	Bromoform	Y	
6200B-2011	Carbon tetrachloride	Y	
6200B-2011	Chlorobenzene	Y	
6200B-2011	Chlorodibromomethane	Y	
6200B-2011	Chloroethane	Y	
6200B-2011	Chloroform	Y	
6200B-2011	Di-isopropylether, DIPE	Y	
6200B-2011	Dichlorodifluoromethane	Y	
6200B-2011	Ethanol	Y	
6200B-2011	Ethyl-tert-butyl ether	Y	
6200B-2011	Ethylbenzene	Y	
6200B-2011	Isopropylbenzene	Y	
6200B-2011	Methyl bromide	Y	
6200B-2011	Methyl chloride	Y	
6200B-2011	MTBE	Y	
6200B-2011	Methylene chloride	Y	
6200B-2011	Naphthalene	Y	
6200B-2011	Styrene	Y	
6200B-2011	t-amyl methyl ether, TAME	Y	
6200B-2011	Tetrachloroethylene	Y	
6200B-2011	Toluene	Y	

6200B-2011	Total BTEX	Y	
6200B-2011	Trichloroethene	Y	
6200B-2011	Trichlorofluoromethane	Y	
6200B-2011	Vinyl acetate	Y	
6200B-2011	Vinyl Chloride	Y	
6200B-2011	Xylenes, total	Y	
6200B-2011	Cis-1,2-Dichloroethylene	Y	
6200B-2011	Cis-1,3-Dichloropropene	Y	
6200B-2011	M+p-Xylene	Y	
6200B-2011	n-Butylbenzene	Y	
6200B-2011	n-Propylbenzene	Y	
6200B-2011	o-Xylene	Y	
6200B-2011	sec-Butylbenzene	Y	
6200B-2011	Tert-Butyl alcohol	Y	
6200B-2011	Tert-Butylbenzene	Y	
6200B-2011	Trans-1,2-Dichloroethylene	Y	
6200B-2011	Trans-1,3-Dichloropropylene	Y	
6640B-2006	2,4,5-T	Y	
6640B-2006	2,4-D	Y	
6640B-2006	Silvex (2,4,5-TP)	Y	
ASTM D93-80	Flash Point	Y	Y
MA EPH R 1.1	Aliphatic C19-C36	Y	Y
MA EPH R 1.1	Aliphatic C9-C18	Y	Y
MA EPH R 1.1	Aromatic C11-C22 Unadjusted	Y	Y
MA EPH R 1.1	Extractable Petroleum Hydrocarbons (EPH)	Y	Y
LDNR 29-B	Acid Digestion of Sludges		Y
LDNR 29-B	Cation Exchange Capacity		Y
LDNR 29-B	Electrical Conductivity		Y
LDNR 29-B	Exchangeable Sodium %		Y
LDNR 29-B	Moisture %		Y
LDNR 29-B	Oil and Grease		Y
LDNR 29-B	Sample Prep Procedure		Y
LDNR 29-B	Saturated Paste Procedure		Y
LDNR 29-B	Saturation %		Y
LDNR 29-B	Sodium Absorption Ratio		Y
LDNR 29-B	Soluble Cation Exchange		Y
LDNR 29-B	Soluble Cations (Na, Ca, Mg)		Y
LDNR 29-B	True Total Barium		Y
LDNR 29-B	pH		Y
2000.0	FHM 48-Hr Acute 20% DMW 25°C	Y	
1000.0	FHM 7-D Chronic 20% DMW 25°C	Y	
2002	C. dubia Acute 20% DMW 25°C	Y	
1002.0	C.dubia 7-D Chronic 20% DMW 25°C	Y	
2021	D. pulex 7-D Chronic 20% DMW 25°C	Y	

Other State certifications can be found in the lab's Statement of Qualifications available upon request. Consult the lab's current LELAP scope for further clarification.

Quality Manual Revision History

Date	Revision	Comments
09/01/04	QA.QM.01	Initial Document
10/01/06	QA.QM.02	Updates
08/29/08	QA.QM.03	Annual Review and Audit Response Update
09/15/09	QA.QM.04	NELAC and A2LA Audit Response Update
01/03/11	Quality Manual 010311	NELAC Audit Update
04/04/12	Quality Manual 040412	Annual Update
04/02/13	Quality Manual 040213	Annual Update
04/01/14	Quality Manual 040114	Annual Review and Update
04/01/15	Quality Manual 040115	Annual Review and Update
07/20/15	Quality Manual 040115A	DRF Notification Name Change
07/20/15	Quality Manual 072015	Name Change Update
07/08/16	Quality Manual 070816	Annual Review and Update
03/17/17	Quality Manual 070816A	Update to Appendix D and Appended Sec. 9.5.7
08/08/17	Quality Manual 080817	Annual Review and Update
04/05/18	Quality Manual 080817A	Update to Appendix D
08/30/19	Quality Manual 082819	Annual Review and Update
05/01/19	Quality Manual 082819A	Update to include ISO 17025:2017 and Addendum
08/30/19	Quality Manual 083019	Minor Updates to accredited methodologies
01/28/20	Quality Manual 083019A	Appended DRF 012580A to QM: Updates to Sections 6.8.2-6.8.3, 9.6.1,15.2-15.3.
06/03/20	Quality Manual 060320	Updates based on FDOH DW audit: Added verbiage to include 2016 TNI Standard; Adding the requirement for mid-point check for variable pipettes, relative error evaluation at low and mid-point standards of curve and clarification of minimum number of points for linear calibrations, et al. Updates based on SC DHEC review to Sections 9.6.1, 9.6.3 and 9.6.5. Updates to Section 10.3 and 10.3.2on document review frequency.
06/10/21	Quality Manual 062725	Updates to Appendix D based on 3 scope amendment applications submitted to LELAP and processed simultaneously. Reference scope dated 04/30/2021. Added statement regarding near-miss assessment and recording. Revised Appendix D as applicable.
12/14/21	Quality Manual 061021A	Reference DRF 121421A: Delete ISO 17025:2017 and ALACC 2018 in reference to accreditation; Updated methods listing based on EPA MUR 05/19/21 and scope amendment; Remove Kim Presley as QA Supervisor.
06/27/22	Quality Manual 062722	Updated body of document as noted above; Add Beau Simpson as QA Supervisor; Added provision for notifying LA DEQ to Section 4: Updated instrumentation listing.

6/30/23	Quality Manual 063023	Annual review and updates: Section5.1: Updates to personnel information; 6.3: Addition of safety and near miss review; 6.5: PT frequency update; 6.7: Update to verbiage; 6.7.1: Update to listing; 6.8: Added 40 CFR 141 to language; 6.8.1: Added project requirements verbiage; 7.0 Update lab areas; 7.1: Clarification of environments; 7.3: Update to building and facility complex; 8.2: Added Purchasing agent; 9.5.4: Added FAAS reference; 9.5.5: Removed TOX reference; 11.1.1: Added reference to IR thermometers.
06/28/24	Quality Manual 062824	Annual review and updates: Update to MUR reference to publish date 04/16/24; Update to titles of Ag and Environmental Division Presidents; Updated 10.1 to replace 2011 version to read most current version; Update to Sources regarding current MUR date; Added the following to 20 Appendix Table 3: 7000B/5021A/Silica as SiO2 by 200.7; Update of Freon 113a chemical name by LELAP on scope.
06/27/25	Quality Manual 062725	Annual review and updates: Removed reference to 2009 TNI Standard; Updated personnel change of QA Supervisor: Added information regarding QA Administration Coordinator; Updated Section 7.0 on administrative information; Added Tier II information; Updated Section 12.4 on QA Reviews; Updated Section 13.0 on Drinking Water requirements for data retention; Updated Appendix D Table 3 with target analyte/method/matrix additions based on scope amendments by LELAP since last QM update.



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EMSL Analytical, Inc. Management

EMSL Analytical, Inc.

LABORATORY
QUALITY MANAGEMENT SYSTEM
(QMS) MANUAL

REVISION 26 – Dec. 15, 2023

For laboratory located at:

Lab specific Cover Pages can be found on E-link:
Quality Assurance>Quality Management System Manual>Lab Cover Pages

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Approved by:

Laboratory Manager	Date
	12/15/2023
Nicholas Straccione Vice President of Quality Assurance	Date

Issued by: EMSL Analytical, Inc.
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(800) 220-3675

Contains: QMS Manual Main Section

Mod A: Asbestos	Mod G: Food Sci.
Mod B: Env. Lead	Mod H: Molec. Biol.
Mod C: Env. Micro	Mod I: Materials Sci.
Mod D: IH	Mod K: Chemistry
Mod E: Radiochem	Mod L: Air Toxics
Mod F: Radon	

Authorized for use by Dr. Peter Frasca/President

COMPLIANCE and COMMITMENT AGREEMENT / SIGNATURE and INITIALS LOG

In executing this Agreement, I attest and confirm that I have read and understand the entire contents of this document. My signature represents that I agree to fully comply with, implement, and enforce all requirements, procedures, and protocols specified in these procedures set forth in this document and any supporting referenced materials or methodologies by the effective date. I acknowledge the proprietary nature of this document. Furthermore, I understand that this document is the most recent version and any revisions, modifications, additions, or amendments to this document will only be recognized and executed upon review, final approval, and reissue of this document by the Quality Assurance Department management.

Those individuals who have checked the column labeled "Lab Management Commitment" are further acknowledging they approve the document for use in their lab and are committed to enforcing the requirements stated herein. Those individuals holding positions of Laboratory, Department and/or Quality Manager, or who have been named to a position of authority for the purposes of state or independent accreditations shall mark this column.

After reviewing the main QMS Manual section and modules appropriate to the work you perform, sign, initial, date and check off those modules which you are acknowledging. **Print this page as many times as needed. A copy of this completed page shall be maintained as a Signature and Initials Log as per the requirements of Section 4.13.5 of this Manual.**

Print Name	*Signature*	*Initials*	*Lab Management Commitment*	*Date*	*Main Manual*	*A (Asb)*	*B (Lead)*	*C (Micro)*	*D (IH)*	*E (RadChem)*	*F (Radon)*	*G (Food)*	*H (MolecBiol)*	*I (MatSci)*	*K (Chem)*	*L (AirTox)*

QMS Manual Signatures/Initials Log, Page __ of __ (reprint page as necessary)

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PLEASE NOTE: This QMS Manual contains 86 pages of content, each page numbered as Page xx of 86. The initial six pages of the QMS Manual are uniquely identified using Roman numerals, as they contain information guiding the reader through the document.

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Section 1.0: Scope

1.1 Scope of EMSL Quality Management System (QMS) Manual

Note: *Prior to Rev. 16 of this manual, the name of this manual was "EMSL Quality Assurance Manual." References to this term or the acronym (QAM) may appear on other management system documents but shall be read to reference this document. Out of date references will be updated as documents are revised.*

EMSL Analytical, Inc.'s commitment to providing quality services to our customers is embodied in EMSL's corporate policy on quality assurance (QA). The aims of the EMSL quality assurance program are to ensure the following:

- Quality, accuracy, and integrity of analytical results to minimize risk
- Conformance with analytical methodologies
- Conformance with corporate mandated QA/QC requirements
- Delivery of the highest quality of professional services and technical excellence to our customers
- Fulfillment of the requirements as set forth by of the American Industrial Hygiene Association Laboratory Accreditation Program (AIHA LAP, LLC), the National Voluntary Laboratory Accreditation Program (NVLAP), The NELAC Institute (TNI), A2LA, CALA, NYS ELAP, NJDEP, PALA, and other independent, state, and local accrediting authorities as relevant to the laboratories' qualifications. Test methods under which our laboratories perform accredited testing are listed on our certificates of accreditation found on the EMSL website – www.emsl.com.

To achieve these goals, this QMS Manual directs the implementation and maintenance of the quality management program, describes responsibilities and duties of personnel as related to quality, and establishes the required policies of the quality management system. This QMS Manual covers analytical services offered in the EMSL laboratories, Inc. (hereafter referred to as EMSL), which include asbestos, lead, environmental microbiology, industrial hygiene organics and inorganics, radon, food microbiology and chemistry, materials science, environmental chemistry metals, radiochemistry, and other developing service areas. General policies applicable to analytical areas are addressed in the main section of the QMS Manual, while policies, procedures and requirements for each specific service area are addressed in the program specific modules. These modules are organized as follows:

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Module	Program Description
A	Asbestos
B	Environmental Lead
C	Environmental Microbiology
D	Industrial Hygiene
E	Radiochemistry
F	Radon
G	Food Microbiology and Chemistry
H	Molecular Biology (PCR)
I	Materials Science
K	Chemistry
L	Air Toxics

EMSL laboratories shall comply with the requirements detailed in this manual and the additional program

requirements specified in Modules A – L as applicable to the laboratory operations. This manual is posted to the EMSL E-link SharePoint site, and is accessible by all employees. Employees are responsible for being familiar with, and adhering to, its contents.

This manual is the property of EMSL and may not be used for any purposes other than those related to EMSL work. Under no circumstances, will this manual be removed from the laboratory facility, nor will any of its contents be disclosed to any outside entity unless prior approval has been granted by EMSL corporate management. Requests for copies of this manual must be made to the EMSL National Quality Assurance Department.

1.2 Quality Management System (QMS) Manual Maintenance and Update Procedures

As defined in the EMSL Control of Documents SOP (QA-SOP-301), the QMS Manual will be reviewed at least annually for continued suitability. Review will be conducted by the QA Department with assistance from national technical management and select others with appropriate knowledge and background in each area. Any revisions shall be reviewed and approved by the Vice President of Quality Assurance. Prior to publication, the QMS Manual revision will be authorized by the EMSL president. The revisions made to the QMS Manual are recorded in a Revision History in Section 6. A 'Notice from the Quality Assurance Department' may also be provided with the QMS Manual at distribution summarizing the additions and changes to the manual.

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Section 2.0: Normative References

The EMSL's Quality Management System (QMS) has been developed to comply with the requirements of the following current references as well as those of several other state and local accrediting agencies:

- ISO/IEC 17025:2017
- The NELAC Institute (TNI) standards, 2016 (or latest revision)
- A2LA General Requirements: Accreditation of 17025 Laboratories (R101), November 2021 (or latest revision)
- AIHA LAP, LLC Accreditation Policies, June 2022 (or latest revision)
- NIST Handbook 150:2020, August 2020, NVLAP Procedures and General Requirements (or latest revision)
- PALA, Analytical Laboratory Accreditation Program
- CALA, Canadian Association for Laboratory Accreditation, Inc.
- Applicable State Quality Policies

Section 3.0: Terms and Definitions

See *Appendix A – Glossary*

Section 4.0 - Management Requirements

4.1 Organization

4.1.1 Quality Policy Statement

EMSL is committed to providing a high standard of service and producing dependable, accurate and technically defensible test results in order to best serve our customers. EMSL will avoid involvement in activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity. Our experienced and qualified technical personnel are committed to providing data of the highest quality achievable.

The senior management of EMSL is committed to adopting the quality standards utilized by the various accrediting agencies and those requirements documented in the ISO/IEC 17025, TNI standards and PALA, and continually improving the management system efficiency. Management ensures scientific rigor and professionalism for our customers for the parameters specified in DR-12-CDA. The major goal of the laboratory and its personnel will be toward constant improvement in the quality management system, which has been designed with the purpose of ensuring consistent operations leading to quality data.

The senior management staff of EMSL acknowledges and accepts the responsibility for the commitment towards the quality of the data produced by the laboratory, and makes a commitment toward continual improvement of the final product and the management system. In doing so, management provides the laboratory manager and the Quality Assurance Department with full authority to accomplish this end. Management is committed to providing the necessary resources to provide high quality analytical data.

EMSL Analytical, Inc. is committed to address any complaints about the quality of the reported analytical results. Any complaint about the quality of report results may be referred to the accrediting body if such complaints cannot be resolved directly with the customer.

Personnel concerned with testing within the laboratory must familiarize themselves with the quality documentation, and implement the policies and procedures addressed in this manual.

Commitment to ISO Standard

Starting with corporate management and extending to regional and local laboratory management, EMSL is committed to ensuring that the standards documented in ISO/IEC 17025:2017 (or the most recent revision of the 17025 standard) are upheld in the applicable aspects of company affairs. The range of activities include, but are not limited to:

- Organization of management system in accordance with Option A of ISO 17025:2017
- Management system - definition, establishment, and maintenance
- Document control
- Review of requests for work (contracts, etc.)
- Subcontracting services/inter-laboratory exchange of samples
- Purchasing supplies
- Service to the customer
- Complaints
- Control of non-conforming work
- Corrective and preventative action
- Control of records
- Internal audits
- Management reviews
- Personnel qualifications
- Method validation
- Traceability
- Assuring quality
- Reporting results
- Risk management

By way of authority, it is corporate management that implements, maintains, and monitors compliance.

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This statement is issued under the authority of company president, Peter Frasca, Ph.D.

4.1.2 Relevance of Personnel Activities and Communication by Management

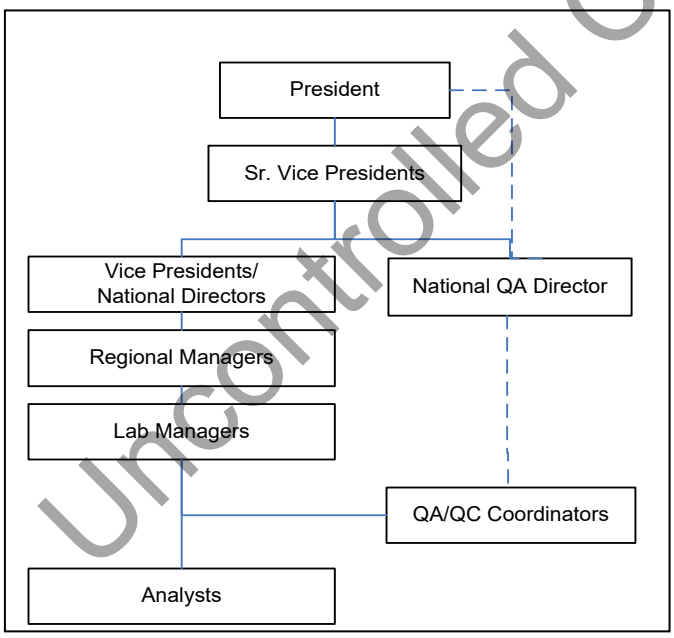
Management communicates to the staff the importance of their role in customer needs, regulatory requirements and involvement, to the achievement of the objectives of the management system through this QMS Manual, newsletters, management meetings and telephone and video conferences and periodic phone conversations.

Correspondence is also performed through the monthly quality control reports, the quarterly quality control reports, and the annual management review.

Management ensures employees are aware of their role in the achievement of the objectives of the quality management system by requiring employees to sign an acknowledgment of understanding of this QMS Manual, as well as relevant policies and procedures.

The management of EMSL Analytical, Inc. accepts legal responsibility for its actions associated with the analysis and reporting of samples in accordance with its Quality Management System.

4.1.3 General Organization Chart – Quality Management Structure



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Individual Lab Organizational Charts are available on E-Link in Quality Assurance>QMS Manual>Org Charts.
Note: The terms 'Sr. Vice President,' 'Vice President,' 'National Director,' 'Regional Manager,' and 'Lab Manager,' wherever they appear in this document and its Modules shall be understood and read to mean 'Sr. Vice President(s),' 'Vice President(s),' 'National Director(s),' 'Regional Manager(s),' and 'Lab Managers(s),' where applicable.

4.1.4 Corporate Organization

The corporate headquarters of EMSL operates out of the Cinnaminson, New Jersey office location. The corporate headquarters oversee the laboratory operations located there, as well as the branch laboratory locations. Organizational charts for each laboratory are maintained by the corporate QA Department and are available on the company's intranet (E-link).

Corporate headquarters are responsible for the management of the company activities. These include:

- Fiscal management
- Personnel management
- Human resources
- Information technology (IT)
- Credit and collections
- Accounting
- Sales
- Customer service
- Contracts review
- Business development
- Quality assurance/quality control management systems
- Legal counsel
- Purchasing

The corporate laboratory and the branch laboratories perform the company's analytical services. They report to the corporate headquarters on quality control, productivity, staffing and marketing/sales matters.

4.1.4.1 EMSL Analytical, LA Testing, MPL Laboratories and Advanced MicroAnalytical

EMSL Analytical goes by three additional DBA names: LA Testing, operating in Southern California; MPL Laboratories, a GMP-microbial lab in Sparta, New Jersey; and Advanced MicroAnalytical, a materials testing lab in Salem, New Hampshire. The policies and procedures documented in this manual apply to all facilities, including those doing business as LA Testing and Advanced MicroAnalytical. MPL Laboratories operates under its own QMS Manual, and is not covered by this manual.

4.1.4.2 Products Division

EMSL also operates a products division which supplies environmental sampling equipment. No key personnel in this division have direct involvement or influence on the testing activities of our laboratories and, therefore, present no conflict of interest.

4.1.4.3 Roles of Administrative Support Groups

This section describes the basic role of the corporate administrative support groups in the laboratory organization. Administrative support consists of:

- Information technology
- Human resources
- Corporate counsel
- Accounting
- Credit/collection
- Sales and marketing
- Corporate customer service
- Purchasing

The departments of the support group are located in the corporate headquarters. Each department has defined roles which provide the laboratories with the support needed to maintain the business. Laboratory managers have direct access to employees of the individual departments in the administrative support group.

4.1.4.3.1 Information Technology (IT)

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The IT Department is responsible for computer and technology services at EMSL including, but not limited to, servers, PCs, telecommunications, storage, security, web services, software licensing, repair, maintenance, support, and custom enhancement of EMSL's LIMS (Sample Master XP), LabConnect (report distribution engine) and all company databases. Requests for assistance are forwarded to IT through an e-mail help request system (itsupport@emsl.com). In addition, the IT Department is responsible for instructions for use of its products.

4.1.4.3.2 Human Resources

Human resource responsibilities are handled by EMSL's Human Resources Department. Responsibilities include, but are not limited to, employee recruitment and hiring, personnel record keeping, employee benefits and career development, as well as providing advice to laboratory management on topics such as employee discipline, conflicts of interest, and discrimination and harassment prevention.

4.1.4.3.3 Corporate Counsel

EMSL maintains an in-house corporate counsel. Corporate counsel advises EMSL corporate management on legal issues related to the business of EMSL.

4.1.4.3.4 Accounting

The Accounting Department has the fiduciary responsibility of ensuring the accuracy and timeliness of all accounting processes and financial reporting. This includes invoicing to customers, processing and payment of vendor bills, cash management, reconciliation of accounts, and satisfying financial reporting obligations to internal and external entities. The department ensures accounting transactions are recorded, flow through the general ledger, and are properly summarized to produce financial statements for management in accordance with Generally Accepted Accounting Principles (GAAP).

4.1.4.3.5 Credit/Collections

This is a sub-department within Accounting. The responsibility of this department is to act on the outstanding accounts receivable sub-ledger, which lists customers with outstanding invoices. Contacts are made in an effort to ensure outstanding debt is collected in a timely fashion. This department deposits daily cash receipts and applies customer payments to their accounts. It also reviews accounts in consideration for outside collection assistance.

4.1.4.3.6 Sales and Marketing

The Sales and Marketing Department develops new business for EMSL through advertising, marketing, and contacting potential customers. Each sales employee is assigned customers for whom they are responsible for negotiating contract terms. Marketing is responsible for the development of marketing materials including fliers, advertising, and informational materials distributed via the web and through the laboratories, as well as in-person through EMSL's participation in conferences and exhibitions.

4.1.4.3.7 Corporate Customer Service

The Corporate Customer Service team assists Marketing, Sales, and EMSL laboratories nationwide. Their current duties include, but are not limited to, answering incoming calls to the customer service extension, assisting customers who are seeking information on capabilities and technical questions, researching invoice discrepancies, finding, and sending

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reports, assisting with LABConnect user issues, setting up LABConnect accounts, placing supply orders, and assisting with pricing inquiries.

4.1.4.3.8 Purchasing

The EMSL Purchasing Department is responsible for arranging for the procurement of supplies and services for the entire EMSL organization. Responsibilities include obtaining and reviewing suppliers for business-critical supplies and services, reviewing and approving service orders submitted by branch laboratories, and tracking performance of suppliers and service providers by being the main point of contact for complaints and supply/service problems. See § 4.6 for additional information.

4.1.5 Confidentiality, Ethics and Data Integrity Policy

4.1.5.1 Confidentiality (see also § 5.10.5)

It is understood that confidentiality and proprietary rights must be respected throughout the performance of services for any customer. Information will only be given to those for whom it is intended, and the proprietary rights of our customer shall be protected. EMSL does not place information related to our customers in the public domain. Data reports and/or other related information will not be given out to any person other than the customer, unless prior approval from the customer is received, or when EMSL is compelled to disclose records and/or information by law, subpoena, government entity, or other legal means. When the lab is contracted to notify the customer of the release of confidential information, it shall. Any information relayed to the laboratory by a third party (regulator, complainant, etc.) associated with the customer shall be kept confidential, unless agreed upon by the source.

This attention to confidentiality extends beyond the workplace. Employees, contractors, external assessors, and committee members shall be aware that revealing confidential information in a non-work social setting is still considered a breach of confidentiality requirements.

The laboratory manager is responsible for ensuring the sample results and related information is disseminated appropriately. In the event there is a question regarding applicability of confidentiality (including requests from government agencies or legal representatives), the vice president of quality assurance, national directors and/or vice presidents or Sr. vice presidents are to be consulted.

4.1.5.2 Ethics and Data Integrity Policies and Procedures

This section describes one of the key elements of this quality assurance program. A proper ethics and data integrity program establishes the principles which ensure the well-being of the company and its staff members. It presents the company values on honesty, integrity, excellence, and trust.

4.1.5.2.1 Ethics Policy

As a condition of hire, every employee (part-time or full-time, temporary, or permanent, including interns) is required to sign an acknowledgement of the Corporate Ethics Policy. The signed policy statement shall be maintained in the personnel files. This policy is as follows:

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EMSL Analytical, Inc.
Corporate Ethics Statement

In order to comply with The NELAC Institute and ISO 17025 standards and to provide the highest level of proper, honest, reliable, legal, and ethical service to EMSL Analytical, Inc.'s customers, EMSL requires that each employee comply with the following Corporate Ethics Statement ("Ethics Statement"). This Ethics Statement mandates that each EMSL employee performs his/her jobs honestly, properly, ethically, and legally, and that each EMSL employee performs his/her assigned responsibilities with the utmost regard for the standards set forth in this Ethics Statement and in the EMSL Employee Handbook. Under no circumstances will any EMSL employee act dishonestly, unreliably, unethically, or unprofessionally while engaged in employment with EMSL. Without limiting what EMSL may consider acts that violate this Ethics Statement, examples of prohibited acts are as follows:

1) *Fabrication of data of any kind, including, but not limited to,*
   - *Reporting data for samples not analyzed*
   - *Quality control or customer results*
   - *Training records*
   - *Calibration measurements*
   - *Maintenance records*

2) *Intentional misuse of company resources, including but not limited to:*
   - *Changing documents without proper authorization or embezzling documentation (Manuals, Standard Operating Procedures, company generated forms)*
   - *Performing unauthorized services for personal use or for use by an EMSL competitor, or for any other non-EMSL purpose or use*
   - *Misuse of office resources (phone, fax, internet, etc.) for any non-EMSL purpose or use*

3) *Back-dating data*

4) *Misrepresenting or fabricating performance (e.g., sample productivity, billing)*

5) *Signing acknowledgements of policies or procedures (e.g., QMS Manual, SOPs, work instructions, policy statements) without having read, understood, and committed to their contents*

6) *Knowingly failing to follow said policies and procedures for any reason including, but not limited to, for the sake of productivity*

7) *Misrepresenting qualifications (e.g., experience, academic training, etc.)*

8) *Disclosing information in contravention to, or in disregard of, customer confidentiality agreements*

EMSL prohibits these and any other act that violates the Ethics Statement or the EMSL Employee Handbook. The officers, managers, and employees of EMSL will not condone, tolerate, encourage, or ignore any unprofessional, illegal, or unethical actions directed towards or impacting a person's work at EMSL, EMSL customers or potential customers, or a person's co-workers; or any act that violates the Ethics Statement or the Employee Handbook. In addition, no officers, managers, or employees of EMSL shall be offered, given or accept any encouragement, monetary or otherwise, to perform acts which violate the Ethics Statement or the Employee Handbook.

The management of EMSL strives to ensure laboratory employees (especially analysts) are not exposed to undue pressures such as:

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- *Impossible time constraints (turnaround times)*
- *Customer influences that may affect analysis*
- *Pricing/marketing issues*
- *Productivity rates**

If employees feel they are exposed to any undue pressure, the situation should be brought to the attention of that staff member's immediate supervisor. If the supervisor is unable or unwilling to resolve the issue, or if the source of pressure originates with the supervisor and the staff member feels they cannot bring it to their attention, the situation may be reported to the Lab Manager or corporate management for review. These items may always be brought to the attention of the human resources department.

**NOTE: The corporate management of EMSL must monitor analyst's productivity rates as a normal course of business. Reasonable rates of analysis are used as guidelines to help determine analysts' ability. At no time are analysts given productivity goals that are unreasonable.*

Employees are required to report to managers located at EMSL branch offices, EMSL Corporate Officers/Managers or human resources department located in Cinnaminson, New Jersey, all acts by EMSL employees, managers or officers that may violate this Ethics Statement. The failure to report such actions may subject that person(s) to the punishments set forth below and in the Employee Handbook. Reporting unprofessional and/or unethical behavior will not negatively impact employment and will not jeopardize the employment status of any EMSL employee.

If an unfortunate event occurs where a customer or fellow employee asks a staff member to perform in an unethical manner, the situation will be brought to the attention of that staff member's immediate manager. If the cause of pressure comes from the immediate manager, or the immediate manager is unable to resolve the issue, the situation may be brought to the next level manager for resolution. At all times, an ethics issue may be brought to the human resources department or other corporate management by any staff member. Issues will be handled confidentially, whenever possible.

If a violation or potential violation of this ethics statement has been reported, it will be investigated by the laboratory manager and/or by corporate management. Investigations will be conducted confidentially until they are concluded. The findings shall be documented. Where customer data may have been affected, the customer shall be notified as soon as practical (no more than 15 days after close of investigation). These communications shall be documented in the integrity investigation records.

Depending on the findings of that investigation, any violation of the ethics statement may subject the offending employee to disciplinary or corrective action as outlined in this ethics statement or the Employee Manual. Following investigation, if it is determined that a violation has occurred, EMSL, in its sole discretion, may determine appropriate disciplinary or corrective action as outlined in the ethics statement or Employee Handbook, which may include:

- *Verbal warning*
- *Written warning*
- *Termination of employment*

In addition to the above, EMSL reserves all rights to take appropriate legal action when it deems necessary. Employees must also be aware that breaches of personal and legal data integrity may lead to civil liability/criminal prosecution and fines/punishment.

(end of Ethics Statement)

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4.1.5.2.2 Ethics Committee

The Ethics Committee is a group of individuals selected from various departments to review potential ethical violations. Members of the group receive information from employees, customers, assessors, etc., and investigate the instance for validity. A lead person will be assigned, and additional members of the group, along with anyone else deemed necessary for investigation, will gather the information needed to decide whether or not the act in question was done with or without malicious intent. Should the committee decide the situation was unintentional, the matter is documented and filed on the secure QA drive, stating the findings. If an intentional ethical violation is determined, the committee will notify Human Resources, Legal Group and Senior Management of findings, with supporting documentation. The severity of the act will determine the disciplinary action taken, including possible termination. All documentation is filed in the secure QA drive.

4.1.5.2.3 Data Integrity

The data integrity policy is a portion of the ethics policy relating to fabrication of data and misrepresentation of results. EMSL complies with the TNI standard requirements addressing data integrity procedures as described below.

Ethics and Data Integrity Training

One of the objectives of the quality assurance program is to ensure the staff of EMSL is provided training in the aspects of ethics and data integrity as they pertain to corporate policy. The training is provided within three months of hiring, and annually thereafter. The goals of this training program are:

- To understand the responsibility to provide true and accurate information
- The understanding of the consequences of unethical conduct
- Provide direction to employees
- Define right and wrong (as it is job related)
- The understanding of the impact of our actions

Training will be provided in the form of required readings, staff meetings, workshops and/or corporate issued newsletters. Corporate management and the laboratory manager are responsible for ensuring this training is provided to the staff, and that records are maintained documenting the training.

Signed data integrity documentation: The ethics statement is signed by each employee as a condition of employment. In addition, a QMS Manual compliance disclosure form is executed by each employee (see *Compliance Disclosure* at beginning of this document). This compliance disclosure states that, “In executing this Compliance Disclosure, I attest and confirm that I have read and understand the entire contents of this document” (i.e., this manual).

Periodic Monitoring of Compliance - Methods of Monitoring Compliance May Include:

- Review of monthly and or quarterly quality control reports: Reports are submitted to the Quality Assurance Department for review. This review includes a check on integrity such as misrepresentation of data, falsification of

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results, etc. Reports of review are completed and made part of the annual management review report.

- Monitoring of proficiency testing performance: Scores of PT samples are summarized in a report and reviewed by the QA Department, the national director and vice presidents
- Investigations initiated by a customer or internal complaint
- Internal audits
- Periodic submittal of blind samples by management
- Secondary data review

Confidential Reporting

As noted in the ethics agreement, issues that cannot be discussed directly with local lab management may always be directed to the corporate human resources department for review. Issues will be handled confidentially, whenever possible.

Data Integrity Investigations

When data integrity issues are reported, they will be reviewed by the party receiving the report. The issue shall be investigated as appropriate in order to determine its extent and impact, both potential and actual. Where detailed investigation is necessary, the person receiving the integrity complaint shall inform the vice president of quality assurance, or corporate QA manager, or human resources department to assist and review the investigation. Investigations shall be conducted in a confidential manner until they are completed. The investigation shall be documented including details on any notifications made to customers receiving affected data.

4.1.5.2.4 Impartiality

EMSL has reviewed laboratory activities and identified potential situations where impartiality can be affected:

- Financial
- Conflicts of interest
- Bias
- Prejudice
- Intimidation

The management staff and EMSL Quality Assurance personnel ensures impartiality through training, internal and external audits, peer review, ethics and integrity policies, conflict of interest, etc. Certain procedures are performed daily, while others are conducted annually; for example, annual data integrity and ethics training. As new situations present themselves, the management team reviews the potential conflict and brings the occurrence to the Human Resources department and Senior Management.

A more detailed description regarding how EMSL assesses impartiality can be found in QA-FM-10 Risk Assessment.

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4.2 Management System

4.2.1 Program Objectives

The program described in this manual is designed to help plan and institute company policies and quality objectives throughout the laboratory facilities. This program is intended to provide procedures and policies, which provide:

- Development of company quality control programs
- Implementation of good laboratory technique
- Constant oversight of laboratory quality performance
- Establishment of training requirements
- Job descriptions of each employee delineating responsibilities
- Development and maintenance of internal quality audit program
- Use of appropriate analytical technology including review of current literature to capture recent applicable developments
- Proper documentation and quality review of analytical data
- A comfortable work atmosphere away from undue productivity pressures
- Maintenance of accreditation programs
- Assurance that national coherency is maintained through standardization of policies and procedures
- Control and maintenance of round robin programs
- Control of documents
- Respect for customer confidentiality
- Actions to address risks and opportunities

Quality policies and procedures are integrated into our daily work, and are constantly reviewed by national, regional and laboratory management and by the Quality Assurance Department.

The program is managed and maintained by the corporate QA Department.

4.2.2 Management System Review

The efficacy and appropriateness of the Management System is reviewed by the National QA Director and other management staff at least annually, as part of Annual Management Reviews. In addition, frequent periodic reviews are conducted in response to corrective and preventive actions. Per the EMSL document control program, documents which are part of the management system are reviewed at least once every three years, and the QMS Manual itself is reviewed annually. Revisions to the management system are discussed with technical and management personnel with the expertise to discuss the feasibility and acceptability of any requested changes.

4.2.3 Changes to the Quality Management System

The quality management system is designed to ensure the integrity of the system is maintained in the event any changes take place. If any changes to the management system are planned and implemented, the integrity of the management system will be maintained by senior management. Procedures include:

- Contingency plans
- Assignment of the same responsibility by multiple personnel (backups)
- Assignment of deputies or designated second person
- Implementation of procedural change
- Providing training if necessary for change

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4.2.4 Departures from Quality Assurance Policies

Any departure from the procedures and policies as stated in this document must be reviewed by the Quality Assurance Department and corporate management prior to approval and effect. This review will include, at a minimum:

- Reason for deviation from policy and/or procedure
- Applicability of alternative policy and/or procedure
- Availability of resources
- For deviations of analytical procedures, assurance that data is reported with appropriate references and disclaimer on final reports affected by a policy and/or procedure change (if applicable)

A record of the review of the alternative procedure or policy is maintained as part of the project files.

No departures from the policies and procedures, as written in this document, are permitted without acceptance by the QA Director or corporate management.

4.2.5 Roles and Responsibilities of Technical and Quality Management

The roles and responsibilities of the technical and quality management of EMSL are described in the Personnel section of this manual (§ 5.2).

4.2.6 Addressing Risk and Opportunities

4.2.6.1 The policies and procedures in place, QMS Manual, SOPs, QA reports, Annual Management review, internal audits, test method assessments, corrective/ preventative action program, etc., ensure risk is limited during the activities of the laboratory. Each of the policies and procedures implemented are reviewed on a periodic basis by Technical Managers, along with the QA Department, to produce consistently high-quality data and reduce undesired outcomes.

4.2.6.1.1 Should any undesired outcomes arise, each case is evaluated on a case-by-case basis by supervisory personnel, along with the QA Department, through our non-conforming work policy and/or corrective action procedure.

4.2.6.1.2 Instances of questionable judgement are referred to the Ethics Committee. The committee researches the situation, and determines whether the act in question was intentional or accidental. Any intentional instances will result in disciplinary action that may result in termination. Other situations, deemed unintentional, can be addressed through corrective actions, training, or another form of correction.

4.2.6.2 EMSL management holds meetings with personnel on a weekly basis to discuss ongoing business opportunities, risk assessments, and continuous improvements that can be made. Upper Management is provided with information from the EMSL network, and the most appropriate course of action is determined based on the discussions at the meetings.

4.2.6.3 A more detailed description regarding how EMSL assesses risk can be found in QA-FM-10 Risk Assessment.

4.3 Document Control

EMSL document control procedures have been established to meet the requirements of ISO 17025 and the accreditation requirements of AIHA LAP, LLC; A2LA, The NELAC Institute (TNI), NVLAP, CALA and

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state agencies. Procedures and policies apply to all EMSL laboratories. The program is overseen and administered by the Quality Assurance Department, including a designated Document Control Manager, who is the person mainly delegated to posting new and revised corporately approved documents on the E-Link SharePoint site, and sending out notifications when documents are added or revised.

The EMSL document control procedures are documented in the EMSL Controlled Documents SOP (QA-SOP-301), Document Master Lists SOP (QA-SOP-302) and related documents. EMSL controls documents to ensure the laboratories are performing analysis and reporting data following only the most up-to-date corporately approved EMSL policies and procedures. This program also establishes company-wide standardization and preserves company intellectual property. EMSL's document control SOPs referenced above covers the following topics in detail:

4.3.1 Structure of controlled document system
4.3.2 Required elements of a controlled document
4.3.3 Initiation, review, and approval of new or revised documents
4.3.4 Protection of controlled documents
4.3.5 Distribution of controlled documents by laboratory manager
4.3.6 Control of local documents and locally maintained copies
4.3.7 Retirement of obsolete documents
4.3.8 Periodic review of controlled documents
4.3.9 Amendments and revisions
4.3.10 Changes to LIMS final report templates

The list of corporately controlled documents is maintained in QA-FM-304 Corporate Master List of Controlled Documents. Each lab maintains a list of locally controlled documents in QA-FM-303 Local Master List of Controlled Documents. SOPs specific to cGMP are detailed in a locally controlled document, Cinnaminson cGMP Master List of Documents, available on Cinnaminson's local drive.

4.4 Review of Requests, Tenders and Contracts

4.4.1 General

EMSL services are generally offered as line-item tests which reference documented methodologies. Laboratory services are typically requested by the customer as "open order" requests. Samples may be delivered to the laboratory at any given time, without a firm documented arrangement. Analytical services are often performed on verbal contract. In these situations, our general terms and conditions apply. Management review procedures for open orders, verbal contracts and for the cases where a written contract is established are discussed in this section.

4.4.2 Procedures for Review of Contracts, Requests and Tenders

Requests, tenders, and contracts are three parts of the transaction process. Requests for service are made by the customer for a scope of work. The tender is the proposal from the lab to the customer, which could include clarifications of the work desired, proposal of turnaround time, and costs for the service. The contract is the actual agreement between customer and lab on finalized terms.

The customer's request for services may be made directly to the laboratory manager, corporate management, or sales staff. In any case, before the samples are accepted for analysis signifying acceptance of the contract, laboratory or corporate management must review the request. This review must cover:

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- Requirements for analysis - method requested is a standard method (i.e., available on price list) and understood. Special handling procedures (if any) are noted.
- Customer's requirements for Laboratory Accreditation
- Applicability of the method requested - method is available and applicable for the sample type and result(s) will provide the customer with required information
- Technical capabilities- training, experience, and qualifications of the staff
- Understanding of the method(s) requested
- Equipment resources - equipment is available, in working order and calibrated
- Staff resources - number of personnel to perform the work and required QC is suitable
- Subcontracting - identification of outside services needed to support the request or contract (including other EMSL laboratories)

Under general circumstances, the status of the laboratory capabilities is well established. For example, technical ability and equipment resources are monitored with performance of QC analyses, proficiency testing and compliance with the QA policies documented in this manual (e.g., documentation of SOPs, training requirements, analytical specialist's qualifications, and calibration requirements). Applicability of method and staff resources is more subjective. It is the responsibility of the laboratory management to review the requests and ensure the laboratory (or laboratory to which the work will be subcontracted) can perform the services.

4.4.2.1 Documentation of Review

These reviews of customer requests are documented in a manner appropriate to the type of request. The majority of the work being received by EMSL is established as line item, open ended requests according to standard terms and conditions, or to prices which are negotiated with sales representatives ahead of time. Requests are generally made by the customer through the sales representative, corporate management, or laboratory management. Requests are reviewed and checked against the requirements listed above.

When work is received at the laboratory, the customer's COC defines the requested analysis and turnaround time. In addition, any requested deviations from standard terms and conditions or defined contractual requirements will be defined. If any clarification or modification of the request is necessary, the modified tender will be communicated to the customer and documented in writing, along with the customer's approval of these altered terms.

This review, and ultimately the acceptance of the work, is documented with the acceptance of the samples by the laboratory. The acceptance of a sample batch constitutes the review and acceptance of the request (or contract). The initials of the responsible laboratory staff member recorded on the internal chain of custody (in the 'sample accepted' box) documents the contract review.

Where standard terms and conditions are modified (e.g., special reporting requirements, non-standard pricing, modified methods, etc.), this shall be approved by a corporate sales representative. These approved contracts are maintained by the sales department and communicated to the laboratory as appropriate through special notes in SampleMaster. For more formal or complex contracts which involve review by the president or Sr. vice

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president(s), documentation of review is evidenced with the signature of president or Sr. vice president on the contract.

4.4.2.2 Changes in Contracts, Requests and Tenders

If a laboratory is providing services under a written or verbal contract, that contract must be acceptable to both the laboratory and the customer. Any differences identified shall be resolved before the work begins. The customer shall be informed of any deviations to the contract or requests. Documentation of any pertinent discussions with the customer shall be documented.

Documentation of changes (or resolutions) is to be made as appropriate to the type of request. A simple notation on the chain of custody is sufficient for a change in turnaround time requirements, for example. More complex changes must be more formally recorded.

If a written contract needs to be amended after the commencement of the project, both the laboratory management and customer must agree to those amendments. These amendments must be documented.

4.4.3 Beginning New Work

The laboratory manager must not accept any new work without evaluating the current resources. This includes accreditation requirements, the availability of equipment and staffing. For example, a laboratory must not accept an increase in workload, if the laboratory staff is currently at capacity.

Any question regarding the capability of the laboratory to perform such new work must be brought to the attention of corporate management. The corporate management will either:

1) Provide the additional equipment and/or staff
2) Allocate work through the EMSL network
3) Reject the new work

4.4.4 New Technical Service

Prior to the implementation of any new technical service, corporate management performs a review. This review includes market applicability and availability of resources. The Sr. vice president(s) or the president must grant approval. The Sr. vice president or designated management personnel for the area being developed shall be notified of the expansion, and shall ensure standard operating procedures are written and quality control parameters are established for new methods.

4.5 Subcontracting of Tests

4.5.1 General

The EMSL subcontracting procedures are documented in the *EMSL Subcontract SOP (GEN-SOP-10)*. This SOP defines when a laboratory accepts samples to be subcontracted.

The network of EMSL laboratories provides the customer with a valuable resource. As per EMSL standard terms and conditions, EMSL reserves the right to subcontract samples to any EMSL branch lab, as long as the laboratory receiving samples holds equivalent relevant accreditations and scope of testing as the laboratory receiving the samples from the customer, and the customer is notified. By submitting samples for analysis, customers agree to these terms and conditions. In this way, samples may be shipped out for analysis to other EMSL laboratories when a laboratory is at workload capacity, turnaround time cannot be reached, or the laboratory temporarily does not have the analytical

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capability (e.g., instrument is down, personnel are out). This flexibility is an added benefit to the customer, allowing drop-off of samples at any lab with the knowledge their requirements will be met.

When samples are subcontracted to an EMSL laboratory, a Sample Transfer Form or Standing Customer Agreement Form is completed electronically, or hard copy if necessary. These forms ensure the customer has agreed to the subcontract arrangements and is aware of the subcontractor's accreditation credentials, where applicable.

The laboratory receiving samples maintains responsibility for the subcontract lab's work except in those cases when the customer or regulatory authority specify which subcontractor is to be used, or when the receiving EMSL Lab is simply acting as a courier service (i.e., when they do not perform the analysis requested by the customer, or customer agrees beforehand that samples will be transferred).

In the event an outside, non-EMSL lab is required, the laboratory manager will ensure all testing is performed by qualified laboratories. Laboratories must subcontract only to outside laboratories that maintain accreditations appropriate for that analysis.

4.5.2 EMSL Courier Service

EMSL laboratories offer a courier service to customers that wish to drop off samples intended to be transferred to another EMSL laboratory for analysis. When a lab is acting as a courier, they are not seen to be part of the contract review for analytical process, and are not responsible for analytical results provided to the customer.

4.5.3 Selecting a Competent Subcontractor

Regardless of the situation, when subcontracting samples, the samples shall always be placed with a competent subcontractor. Where the customer specifically designates a laboratory to perform the analysis, this will override any other considerations and relieve the receiving laboratory of any responsibility for the selection.

In all other cases, the receiving laboratory shall select a laboratory which holds at least equivalent qualifications for the analysis. Relevant qualifications will depend on the needs of the customer, and should be determined prior to subcontracting. Where a laboratory is accredited for an analysis, the laboratory selected shall hold equivalent accreditations. If not accredited, it should be determined which accreditations are required by the customer and select a laboratory meeting those requirements.

Qualifications of EMSL laboratories are included in the "Laboratory Qualifications" pages on the EMSL website. The website includes copies of all accreditation certificates and scopes of accreditation, licenses, approval letters, etc., from 3rd party accreditors and regulators (e.g., state and federal departments).

If subcontracting to an external laboratory, the laboratory's qualifications shall be reviewed prior to selection. If the subcontract laboratory maintains accreditation for the analysis in question, a copy of their accreditation certificate shall be reviewed and kept on file. Where no accreditations are relevant to the analysis, information on laboratory personnel qualifications, quality system and proficiency testing participation may be requested at the user's discretion.

4.5.4 Customer Knowledge and Approval

As noted above, the EMSL standard terms and conditions reserves EMSL's option to transfer samples between EMSL branch laboratories with equivalent relevant qualifications. By submitting samples, customers agree to these terms, and accept a subcontracting arrangement with notification and

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approval by the customer with the Sample Transfer Form or Standing Agreement Form. Unless otherwise documented on the chain of custody by specifying the lab to do the work, the transfer of samples may occur at the discretion of the laboratory manager as discussed in the EMSL Subcontracting SOP (GEN-SOP-10).

Under ordinary circumstances, the customer will be made aware of the laboratory and qualifications of the laboratory that will be performing the analysis at the time samples are submitted for analysis. In rare instances, a decision to subcontract may be made after the submission as a result of lab capacity, instrument problems, etc. In these cases, the laboratory will contact the customer to inform them the samples will be transferred. This communication will be documented in the customer correspondence logs or via e-mail. A Sample Transfer Form or Standing Agreement form is completed, documenting customer's approval.

In the case of outside subcontracting, the customer will be informed of the subcontract lab and their qualifications prior to sample submission. Unless the customer specifies the laboratory to be used, it is the lab manager and/or department manager's responsibility to select a competent laboratory for the work.

In any case, the test report submitted to the customer will make clear the location and identity of the laboratory which performed the work.

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4.5.5 Responsibility to the Customer

The receiving laboratory (i.e., laboratory initially receiving the samples) is responsible to the customer for the work of any non-EMSL subcontractor, except in the case where the customer specifies which subcontractor is to be used.

In the case of subcontracting between EMSL laboratories, this responsibility is maintained regardless of whether the receiving laboratory is involved in the invoicing or direct reporting to the customer. Due to the corporate structure of EMSL, reporting is completed by the subcontracting lab, and invoicing is completed by the receiving lab, unless samples are relinquished. In this case, the samples are not considered to be subcontracted. Direct reporting from the analyzing laboratory ensures there is no confusion about the location at which the analysis was performed.

In all cases, the receiving laboratory remains the point of contact for the customer and will be involved in resolving disputes, arranging for reanalysis if requested, and generally acting as the responsible party for interacting with the subcontract laboratory.

4.5.6 Subcontract Register

As noted above, only competent laboratories shall be selected for subcontracting. Since EMSL laboratories may transfer samples to other EMSL laboratories with equivalent accreditations, the list of labs and qualifications on the EMSL website will be considered the registry of EMSL subcontract labs. This list is maintained and updated by the EMSL Corporate Quality Assurance Department.

In the case of outside laboratories used for subcontracting, a list of these labs shall be maintained in each branch laboratory that conducts external subcontracting, and these subcontractors shall be added to the EMSL Approved Vendor List and reviewed as per the EMSL vendor review process (see *QA-SOP-500: Evaluation of Suppliers and Service Providers*). In addition to the list, the information reviewed in making the determination of competence will be documented following the policies and procedures in QA-SOP-500.

4.5.7 Retention of Subcontracted Samples and Records

Confidential Business Information/Property of EMSL Analytical, Inc.

When samples are sent to another EMSL laboratory for analysis, the samples will be retained by the laboratory conducting the analysis, unless otherwise documented in project specific instructions. Technical records relating to the analysis (e.g., bench sheets, raw data, QC data) shall be retained by the analyzing lab, unless otherwise specified and documented.

When samples are subcontracted to an outside laboratory, the receiving laboratory shall ensure EMSL retention policies (for both samples and data) are communicated to the subcontracting lab, and samples are retained for the required period of time.

4.6 Purchasing Services and Supplies

4.6.1 General

The EMSL procedures for purchasing and evaluating of supplies and services that are critical to the analysis of samples are documented in two related SOPs:

QA-SOP-500: *Purchasing-Evaluation of Suppliers and Service Providers*
QA-SOP-501: *Purchasing-Receiving Supplies and Services*

These procedures help to ensure purchasing and vendor selection is consistent across all EMSL laboratories.

4.6.2 Purchasing

Prior to placing a purchase order for supplies or services, the laboratory manager shall refer to the EMSL List of Approved Vendors available on e-link. This list contains vendors for the following types of critical supplies and services:

- Laboratory equipment (consumable and permanent equipment)
- Subcontracted analytical work
- Proficiency testing providers
- Onsite services, such as balance calibration and repair
- Outside calibration services
- Reagents and standards

Approved vendors on the list have been evaluated by laboratory managers and the purchasing department on product/service quality, customer service, and delivery (see *QA-SOP-500*). New vendors will be added to the list after the Quality Assurance Department has verified the vendor has the necessary qualifications, and is then evaluated with the next annual evaluation survey. Any complaint regarding a vendor (e.g., defective product, poor customer service) will be communicated to the Purchasing Department, who will then investigate and help resolve the issue. Depending on the significance of the problem, a decision will be made between the national director, vice president, the Purchasing Department, and the Quality Assurance Department to discontinue use of the product, or place the vendor on probation.

Consumable supplies are to be purchased based on laboratory needs as determined by the laboratory manager. SOPs will indicate the specific grades and classes of consumable supply items to be used. Expendable materials intended for single use purposes such as microscope slides, plastic centrifuge tubes, etc., are not to be reused.

Selection of the appropriate grade of reagent(s) is designated in the reagent section of each analytical SOP, and in addition, may be specified by the laboratory manager in unusual circumstances. As a general practice, reagents will be of at least ACS reagent quality.

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Reagents, reference standards and reference materials shall be purchased in accordance with the analytical needs of the laboratory as determined by the laboratory manager. Reference materials are crucial for ensuring traceability of results directly or indirectly tied to the quality and reliability of this material. Therefore, additional care must be taken to ensure qualified reference material providers are selected, and only grades of reference material that are fully accredited and NIST-traceable are purchased from qualified vendors. (See § 5.6.2 on more information on selecting reference material providers). Reference standards shall be NIST-traceable (where applicable) and include a certificate showing traceability. Reference materials and standard reagents shall be obtained from the vendor with a certificate of analysis (certificate must identify the lot number). These certificates shall be maintained in the laboratory files prior to initial use. If no certificate is received, laboratory shall contact the vendor.

For reference materials used in methods within the scope of ISO 17025 accreditations, reference materials shall be from a Reference Material Provider (RMP) accredited to ISO 17034:2016, and the product ordered shall be certified with a certificate bearing the Accredited RMP symbol.

Laboratory managers are to purchase reference materials and reagents in the smallest quantities practical to help reduce inventory. A reduced inventory will be used up more frequently, avoiding the possibility of having the standard stored in the laboratory past the expiration date.

Purchasing documents (e.g., order form submitted to purchasing via intranet, purchase order requests) shall contain technical details about the product or service being ordered. Prior to releasing to the vendor, these documents are reviewed for technical suitability by the laboratory management and/or the Purchasing Department. Most supplies are purchased through the EMSL 'Shopping Cart,' which is available on EMSL's intranet for placing purchase orders.

4.6.3 Approval of Service Providers

Outside services that are contracted and affect analytical testing, such as proficiency testing services, calibrations, repairs to equipment, adjustments to instrumentation, checks on performance, etc., require the vendor be accredited under the ISO 17025 standard, where applicable. Other considerations for the approval of providers (as per *QA-SOP-500*) include:

- Accreditation to appropriate standards (where relevant, e.g., ISO 17025, ISO 9001)
- Reputation in industry
- History of performance with EMSL
- Referrals

Services received must be documented and filed by the laboratory.

Note: When arranging calibrations with an external calibration provider, EMSL requirements for calibration certificates should be discussed with the provider at the time of contracting. See § 5.6.2 for requirements of a traceable calibration certificate.

4.6.4 Reception, Inspection and Acceptance of Reagents and Consumable Supplies

Procedures for the reception, inspection, acceptance, and storage of supplies are covered in QA-SOP-501. Generally, reagents and reference materials shall be verified against the product ordered, then dated and initialed, or a signature applied, with date received and expiration dates. Labels will also be dated and initialed, or a signature applied, when opened and/or when reagent mixtures are prepared. Materials shall be assigned an EMSL ID number and added to the Stock Standard and Reagent Log for the laboratory, along with required information.

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4.6.4.1 Storage and Handling of Reagents, Reference Materials and Reference Standards

Reagents, reference materials and reference standards are to be stored in a manner which will conserve the purity and integrity. Reagents and reference materials are stored following manufacturer requirements (e.g., temperature, humidity). Care must be taken when handling reagents to avoid contamination or evaporation. Lids must be kept secure when not in use. Reference standards shall be stored according to manufacturer requirements.

All reagents shall be stored with bottle caps or stoppers securely sealed. If reagent materials have been spilled on the exterior of storage containers, containers should be wiped clean before being placed in storage. Storage cabinets shall be cleaned periodically to prevent deterioration. If storage cabinets show significant deterioration (e.g., rust) these shall be repaired or replaced to ensure their integrity.

General procedures for storage of reagents require the separation of incompatible materials. Organic solvents (e.g., acetone, THF, reagent alcohols) shall be maintained in a storage cabinet suitable for flammable materials (i.e., metal cabinet). Acids (nitric, hydrochloric, etc.) shall be stored separately from organic solvents in a cabinet away from them. Materials may be stored together when they are of similar classes that will not cause interferences or increase risk of cross contamination (e.g., hydrogen peroxide with acids).

4.6.4.2 Solution Preparation

Solutions prepared from neat materials shall be recorded on the *EMSL Standard Solution Prep Log* available on e-link. The log shall include a description of the solution, date of preparation, concentration and/or purity of solution, identification of parent material (i.e., the ID assigned on the *Stock Standards and Reagents Log*), preparer's initials, and expiration date. Solutions shall be labeled with the ID, ID number from preparation log, and expiration date (usually the expiration date of component materials which is closest to the date of preparation). Using preparation log and standards log, solutions shall be traceable back to parent material and certificates of analysis for that material.

4.6.4.3 Unique Identifier

For TNI labs: All containers of prepared standards, reference materials, and reagents shall bear a unique identifier and expiration date. When more than one container of a standard with the same lot number is received from a vendor, each container shall be labelled with a unique ID; for example, xxxA, xxxB, and xxxC. In the standard receipt log, one line entry for the standard may be made as xxx(A, B, C). This policy for labelling each container applies to standards and reagents prepared in-house as well.

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4.7 Service to the Customer

Clear, continuous, and open communication between the laboratory and the customer is one of the keys to maintaining a successful, quality operation. Communication should be established prior to the start of any work. Information must be clearly understood between laboratory management and the customer. This information should include (but not be limited to):

- Type of analysis requested
- Turnaround times
- Expected deliverables (any requested changes to the standard report format)
- Sampling guidelines (media, recommended sample volume, etc.)
- Type of packaging for sample shipping

- Submission of final report (via fax, hard copy, mail, overnight shipment)

EMSL will cooperate with customer requests to monitor laboratory performance on their projects. Upon request, customers may be granted accompanied access to the laboratory to witness performance of testing or be provided with records (QC data, bench sheets, etc.) so long as doing so does not jeopardize the confidentiality of other customer information. Where a customer requests that we provide information on their project to an outside third party (their customer, for example), we must have written authority to do so. Text or email is acceptable.

Customer requests should be carefully considered and followed, as long as doing so is not detrimental to the business, integrity of the results, misleading, or in violation of any statutory, regulatory or accreditation requirements.

4.7.1 Documenting Customer Correspondence

Correspondence with customers shall be recorded by each EMSL laboratory in a manner fitting to the type of correspondence. Project related information may be recorded on the Chain of Custody forms for the project to ensure the information is available and associated with the project. Other correspondence may be manually recorded utilizing the Customer Correspondence Log template available on E-link, or commercially available bound phone message pads which are dated with initial and end dates, once full. Correspondence may also be recorded using electronic means when available to the laboratory (e.g., Outlook Journal feature, Maximizer, etc.). Regardless of how correspondence is recorded, the date of correspondence and initials of person making the entry is required. These records shall be maintained for 5 years, as per *QA-SOP-350: EMSL Record Control SOP,* or for the life of the project files, whichever is longer.

Customer complaints shall be documented utilizing the EMSL Complaint Resolution procedure (QA-SOP-600) and recorded on the Complaint Record form available from E-link. Where customer correspondence leads to corrective action, these corrective actions will be documented via the EMSL Corrective Action system (QA-SOP-200). When feedback is received via the web-based customer survey (rather than directly by the laboratory manager), the QA Department will forward this information to the laboratory manager for follow-up, as necessary.

4.7.2 Technical Support

EMSL provides quality assurance information and technical support to the customer to assure continued quality service. The support and information provided in relation to the work performed includes:

- Field sampling guides
- Availability of pertinent QC records
- Access to the Quality Assurance Department for technical assistance
- Security of data (confidentiality)
- Reasonable access to the relevant areas of the laboratory for the witnessing of analysis

EMSL also provides a variety of sampling equipment and procedures to support the customer's needs. Equipment is available such as sampling pumps, sampling cassettes and sampling media. Instructions are provided along with the equipment.

4.7.3 Customer Feedback Program

The EMSL customer feedback program includes:

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- Continuous correspondence between customer and the customer service representatives
- Communication tools available on company website
- Direct contact with customer and Laboratory Manager
- Collecting comments offered by customers during seminars and conferences
- Periodic use of active solicitation of feedback such as through the use of customer survey

Summaries of feedback will be shared with laboratories in such a manner that customer confidentiality is maintained while providing the labs with feedback information. Ordinarily, this will be done in the Annual Management Review report.

4.7.4 Notice of Performance

The laboratory manager shall provide the customer with information as it relates to the performance of the analysis and turnaround time. The laboratory must notify the customer if:

- Analysis cannot be performed on time
- Integrity of the sample has been jeopardized (either by the laboratory or the customer)
- A discrepancy in the analysis has been found during QC analysis

4.7.5 Emergency Laboratory Closings

Where a laboratory's operating hours are affected by any emergency condition (e.g., weather events) the lab manager notifies the corporate Sr. vice president(s), the IT Department, and customers, where applicable. An intra-company email is broadcast with the information. Where possible, calls are re-directed to the corporate laboratory or other unaffected laboratory. The corporate customer service group and/or sales and marketing department representatives continue to contact customers as necessary.

4.8 Complaints

Complaints are considered any statement of dissatisfaction with the product or processes of the laboratory for which a reply is expected. Complaints may be received from any party, inside or outside of EMSL. They may be submitted in any form.

It is the policy of EMSL to take reasonable action to resolve complaints as quickly as possible. Whenever a complaint is received, it is investigated to determine whether the complaint is factually sound and whether resolution is within the control EMSL. If a complaint is not factually sound or EMSL is incapable of resolving the complaint (for example, the complaint is not about EMSL, or would require violating regulatory requirements), EMSL will follow-up with the complainant to ensure they are aware of why EMSL cannot resolve their complaint.

If a complaint is sound and capable of being fairly resolved, EMSL will take all reasonable actions to come to a resolution with the complainant that satisfies the complainant's needs, while not damaging or threatening the integrity of the laboratory, its personnel, or its results. EMSL's complaint resolution procedure is documented in QA-SOP-600 Complaint Resolution (QA-SOP-600-1 Complaint Resolution Overview is available for interested persons, upon request).

A complaint about the quality of reported results may be referred to the accrediting authorities who accredit the work being reported, if such complaints cannot be resolved directly with the customer.

4.8.1 Documentation of Customer Requested Re-analysis

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There may be times when a customer will request re-analysis of samples.

4.8.1.1 Results Falling Within Quality Control Acceptance Limits

If the results from the re-analysis fall within the QC acceptance criteria, then the original report remains as the official report. The results should be communicated to the customer, this communication shall be documented, and the supporting data filed with the paperwork from the original analysis.

4.8.1.2 Results Falling Outside of Quality Control Acceptance Limits

If the results from the re-analysis fall outside of the acceptable QC range, and the original results have already been reported, the customer will be notified, and an amended report should be generated and submitted to the customer (See § 5.10.9). The discrepancy will need to be addressed with a corrective action report. All customer communication shall be documented, and the supporting data filed with the paperwork from the original analysis.

4.9 Control of Non-Conforming Testing

The control of non-conforming testing is addressed in detail the *EMSL SOP on Non-conformities and Corrective Actions* (QA-SOP-200). Non-conforming work can be identified by any person working in the laboratory, or brought to the attention of lab staff through an outside party (e.g., a complaint). Upon identification of any non-conforming work, it should immediately be documented using a *Non-Conformity/Corrective Action Record (CAR)* and forwarded to the laboratory or department manager for review. Any employee of EMSL may initiate a temporary work stoppage if it is believed non-conforming work will continue to be produced. The work stoppage shall be reported to the lab manager immediately. If the work stoppage is required for more than an hour, the lab manager must report the stoppage to corporate management.

The review of non-conforming work shall be documented on the CAR form and will include:

- An evaluation of the significance of the non-conforming work
- A determination of acceptability of non-conforming work
- An evaluation of whether the non-conforming work could recur, or whether it is a result of a failure to comply with EMSL policies or procedures

Remedial action will be taken immediately to correct non-conforming work based upon the level of risk evaluated by the lab. If a work stoppage was necessary, the lab or department manager will determine what action is necessary to begin work and document this on the CAR. Only the lab manager or corporate management has the authority to resume work once a stoppage is required.

If the evaluation determines the non-conforming work could recur, or is a result of a failure to comply with EMSL policies or procedures, formal corrective action is required. This shall be recorded on the form available on E-link according to QA-SOP-200 and § 4.11, below.

4.9.1 Notification of Non-Compliance

If a major deviation from policy or procedure is identified which significantly affects customer results, the customer shall be notified within 24 hours of confirmation of the deviation. Major non-conformities may be discovered during an internal audit, external audit, or a regular quality control review. In some cases, the report will require a disclaimer in order to ensure test results can be interpreted properly. Examples of major deviations may include (but are not limited to):

- Quality control reanalysis results outside acceptance limits which call into question test results

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- Calibration measurements are outside acceptance limits and may have a negative impact on the results provided to customer
- Sample contamination is suspected (e.g., as a result of positive blanks)
- Failure to follow procedure as written resulting in possible erroneous results

For DOE associated projects:

- Clients must be notified within 15 business days of any potential deviations from policy or procedure that are identified, which may significantly affect customer results.
- The laboratory must report any instances of inappropriate and prohibited laboratory practices to the accrediting body within 15 business days of discovery. Lab will submit corrective actions to the accrediting body within 30 days of discovery of these occurrences.

4.10 Improvement

EMSL is committed to the continual improvement of the effectiveness of our quality system. As noted previously, the management system is reviewed annually as part of the annual management review, along with the continued efficacy of the quality policy and what progress was made on quality objectives. Management system documents are reviewed periodically and updated, as necessary. In addition, EMSL utilizes the feedback from customers, employees, and assessors in making changes to the management system in order to improve its efficiency. Other systems which are designed to provide feedback on both the design and implementation of the quality system include:

- Corrective and Preventive Action
- Internal Audit Program
- Customer Feedback Survey
- Monthly and Quarterly QC Reports

4.11 Corrective Action

This section briefly summarizes the procedures set forth in QA-SOP-200, which describes the mechanisms used to identify, prevent, and communicate conditions adverse to quality (a non-conformity), determine cause(s), initiate corrective action, document, and report the activities, and verify implementation of the corrective action.

A non-conformity is defined as any failure to meet stated requirements, whether these be technical (e.g., failure to meet internal statistically derived limits, use of wrong testing method), regulatory (e.g., state or federal requirements) or managerial requirements (e.g., corrective action procedures, log-in procedures).

Corrective actions serve as an indicator of the lab's performance. At the end of the year, these are reviewed, and a risk assessment can be conducted based on the type of corrective actions generated. For instance, if a lab has identified repeated training issues in the lab, then QA and management will work on a training program for the facility. This process is evaluated and recorded through the annual management review and the action items created from the document.

See the SOP for detailed procedures on how EMSL laboratories handle corrective actions.

4.11.1 Identification of Non-conformities

Non-conformities can be identified by anyone. Laboratory technical and support staff, internal and external auditors, and customers may all identify non-conformities in the laboratory's operation.

4.11.2 Documenting Non-conformities and Corrective Actions

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Whenever a non-conformity is identified, the person who identified the non-conformity, or another responsible person, shall investigate. Corrective actions shall be taken when necessary, and shall be documented on the form available on E-link when appropriate, or if required by regulatory Standards. This form is used to document the non-conformity, the investigation of the non-conformity, and what actions (if any) were taken to resolve the non-conformity and prevent its recurrence. Its use is discussed in detail in the *Non-Conformities and Corrective Action SOP* (QA-SOP-200).

4.11.3 Evaluation of Non-conformities and Non-conforming Work

In order to evaluate the extent of effect a non-conformity may have on a result, the laboratory management will consider the following:

1) The significance of the nonconforming work
2) The acceptability of the non-conforming work (is it suitable for use?)
3) Whether customer notification is required
4) The most likely root cause(s) of the corrective actions
5) Whether it is necessary to stop work to prevent additional non-conforming work
6) Determine what is required to resume work (if work is stopped)

A stop work order may be given where a breach in the quality system jeopardizes analytical quality, or a failure in procedures presents an eminent safety concern.

4.11.4 Cause Analysis

Non-conformities must be handled in a manner which will provide a way to help ensure they are not repeated. This includes identification of the root cause(s) of the error, determination of corrective actions which will eliminate those root causes, and the initiation of those corrective actions. Identification of root cause(s) is one of the keys to corrective action and prevention. It helps identify the actual reason for the error. The *QA-SOP-200* contains a thorough discussion and guide to root cause analysis.

The investigation of the non-conformity will consist of a review of all steps leading up to the non-conforming condition or event. This may include review of QC data, sample tracking, data transcription, instrument calibration, training documentation, and discussion with personnel. See *QA-SOP-200* for additional details.

4.11.5 Selection and Implementation of Corrective Actions

Corrective actions are those actions which are taken to eliminate the root cause(s) of a non-conformity and prevent its recurrence. This should be contrasted with a remedial action, which is taken to eliminate the effects of a non-conformity (e.g., reissuing a corrected report is a remedial action, while improving the review process which allowed the faulty report may be a corrective action).

Corrective actions taken should be changes which will eliminate the deepest cause(s) possible and which are within the control of EMSL. The corrective action should be proportional to the severity of the non-conformity and the likelihood it will recur, and shall be documented and carried out within a reasonable time frame, so as to not jeopardize the quality of results. The investigation of the non-conformity includes an evaluation of the risk created from the situation, and an opportunity for improvement, to determine the appropriate plan to avoid recurrence.

The laboratory quality representative and/or laboratory's management personnel are responsible for ensuring corrective actions have been addressed in a timely manner. The lab's corrective action records must include proof of compliance with the Corrective Action Report. The laboratory quality

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representative and/or laboratory management staff must indicate when corrective actions are complete.

4.11.6 Monitoring of Corrective Actions

Follow-up to corrective actions shall be scheduled and completed in order to determine whether the actions taken have been effective in preventing its recurrence. Follow-up actions shall be scheduled on a case-by-case basis as soon as practical, but far enough in the future so a recurrence might have had the opportunity to occur.

The follow-up shall indicate the corrective action has been satisfactorily completed, and will include a review of the effectiveness of the corrective action. The scheduled date for follow-up, date follow-up was conducted, and effectiveness of corrective action is documented on the form available on E-link.

The QA Department is responsible for following up on those corrective action reports submitted to the QA Department by the laboratory for further action.

4.11.7 Additional Audits

In some cases, a non-conformity may be cause to initiate an audit of related activities in order to: 1) help identify cause(s) of the error, 2) ensure no other areas are affected by the error, or 3) provide direction for preventative actions. For example, if a customer makes a complaint about a test result, an audit may be conducted involving:

- Review of calibration measurements and QC data associated with the analysis
- Check on analytical specialist qualifications
- Inspection of log-in procedures
- Review of other results that may be affected by the root cause(s) as determined

The audit can be 'free flowing' (no use of checklist), but must be documented.

4.12 Preventive Action

It is EMSL's intention to maintain an active program to prevent occurrences which require corrective actions, or where there is a trend in QC data or activities which may eventually result in an error. A proactive program is an important part of the objectives of this EMSL quality program. All staff members are encouraged to assist in identifying potential sources of non-conformities and to identify opportunities for improvement. EMSL's preventive action program is detailed in QA-SOP-250: *EMSL Preventive Action SOP.*

Preventive actions consist of the policies discussed in this QMS Manual. For example, the quality management system procedures and policies require:

- Analytical specialists satisfy training requirements
- Laboratories perform QC activities at required frequencies
- QC data is reported to the QA Department for review
- Management reports are submitted to corporate management
- Laboratories participate in proficiency testing programs
- Laboratories maintain accreditations from regulatory and other independent agencies

Preventive action measures also include those specific actions taken outside of the normal quality assurance/quality control activities. These actions are those opportunities for improvement associated with a potential non-conformity. This policy requires laboratory staff to attempt to identify potential non-

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conformities, and apply actions which will prevent an occurrence. These actions are documented using the form located on E-link.

4.13 Control of Records

4.13.1 General

The EMSL control of records procedures are documented in the *EMSL Control of Records SOP (QA-SOP-350*). The SOP outlines the requirements of record maintenance, but each laboratory is responsible for the logistics of record control in their laboratory. Each laboratory is responsible for maintaining a *Records Management Log* (*QA-FM-350-1*) which documents where records are located and how they are indexed, accessed, and stored in the laboratory. General policies include:

- All laboratories will retain records of original observations in addition to derived information.
- All handwritten data shall be recorded using permanent ink.
- If a record contains a mistake that must be corrected, the mistake shall be single line crossed out and signed, initialed, and dated using indelible ink, and the correction made alongside.
- Records must never be corrected by erasing, deleting, or otherwise making the mistake illegible (e.g., use of correction fluid, correction tape, scratch-outs).
- Whenever a date is required to be entered by personnel on a document (i.e., COCs, internal COCs, reagent and standard logs, packing slips, etc.), the format used should be month/day/year.
- Records shall be retained in order to ensure sufficient information is maintained to allow for an audit trail. Therefore, records such as employee records, certificates of analysis for standards, calibration certificates, etc., shall be retained for the life of the activity to which they are related (e.g., until 5 years after an employee leaves, until 5 years after the standard is disposed of or completely used, until the next calibration is completed).
- The majority of records shall be retained for a minimum of 5 years or for the period of time established by relevant accrediting authorities or contract requirements (see *QA-SOP-350* for a list of exceptions to the 5-year hold time).
- Where records are removed from storage (e.g., archive boxes, file drawers) for any reason, the laboratory shall insert a Record Out Log card in place of the records, and record on the Log card the name of the person removing the file, the files removed, and the date removed. When replacing the file, the card shall be updated by noting “Replaced” and the date it was replaced in the file.
- Records shall be protected against fire, theft, loss, environmental deterioration, vermin, and, in the case of electronic records, electronic or magnetic sources.
- Records shall be disposed of in a manner that maintains customer confidentiality. Paper records containing customer information shall be shredded or incinerated before disposal. Electronic records shall be managed in such a way that access to backup files remains at least as restrictive as when on the EMSL servers. Specific means of destruction of records may vary from lab to lab and may include services such as a contracted shredding/incineration program by a professional archiving company (e.g., Iron Mountain), locally owned shredders within the lab, or by community shredding events.

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- Electronic records are considered equivalent to paper records, and are to be maintained and controlled in an analogous manner. Backups of electronic records are to be protected according to the procedures in the Control of Records SOP (QA-SOP-350).
- All hardware and software necessary for the historic reconstruction of data must be maintained by the laboratory for the same period of time as the data produced.

4.13.2 Recording Analytical Information

Before beginning analysis of a batch of samples, the analytical specialist is responsible for checking to ensure the labels on the sample containers agree with the data recorded on the chain of custody for that sample. The analytical specialist is also responsible for checking (to the extent possible) the samples have been collected on appropriate sampling media. Any discrepancies are to be noted on the chain of custody and reported to the laboratory manager.

Data generated in the laboratory shall be recorded on preprinted analytical data worksheets or, where available, directly into the computer system via a Direct Data Entry (DDE) system (iL@b). Each analytical procedure has its own specific worksheet or iL@b module. Many of these worksheets, when used, are generated by the LIMS system at the time of log-in.

Observations, data, and hand calculations are recorded at the time they are made and are identifiable to the task. The analytical specialist is to ensure entries on all records are made legibly and using indelible ink. Corrections are made using a single line strikeout with the correct entry written in. Corrections are to be initialed and dated. Obliterating data using ink or correction fluid is prohibited.

Where iL@b DDE is available, data is recorded directly into the lab database. Any additional information recorded manually in hard copy shall be maintained along with the COC and ICOC in project records.

4.13.3 LIMS (SMXP/Element) Data and Security

SMXP/Element data is retained in a "live" redundant replicated instance of SQL Server 2014 Enterprise in a Master database for a minimum of 16 (SMXP) and 24 (Element) months. Data older than 16 or 24 months is migrated to an archive instance of SMXP/Element LIMS data. This production database contains analytical data for all local and remote company labs.

Although our computer equipment has proven to be reliable, unexpected problems do occasionally occur. Regarding EMSL Analytical, Inc. Computer Systems as one of the components of our Business Continuity and Disaster Recovery Plan, should EMSL experience an individual system and/or large-scale system outage, critical systems and data will fail-over to our disaster recovery systems. Critical systems include LIMS platforms; network and server infrastructure; phone systems; accounting; customer portal systems; e-mail; and customer service systems.

The process of restoring company systems to normal operations follows a tiered process prioritized to best support operational tasks. During the outage, recovery, and return to normal operations, department teams would continue to contact outside parties and perform manual processes, if needed.

All SMXP/Element data is replicated to a central SQL Server 2014 Enterprise database, which functions as the primary backup for the LIMS data. LIMS data is also copied (backed up) onto a backup disc subsystem nightly, and transferred to high density tapes which are relocated to secure, temperature controlled, fireproof vaults within Iron Mountain to prevent permanent data loss in the case of systems failure, accidents, or disasters. In most cases, duplicate equipment has been provided, so if

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one computer experiences unexpected problems, a duplicate computer can be utilized while the other is being repaired.

More information on the backup and archiving of SMXP/Element data can be found in the *EMSL Control of Records SOP* (QA-SOP-350).

The security of the software is controlled by the corporate IT staff and the laboratory manager. Each computer user is assigned password protected rights and privileges specific to the tasks the user is allowed to perform. Access to all LIMS analytical related software is password protected on a user-by-user basis to ensure security. The IT staff is responsible for ensuring access to SMXP/Element is controlled, and assignments are held secure, using laboratory management approval.

The corporate IT staff is responsible for ensuring all computer systems, both hardware and software, are documented, inventoried, and adequate for use. All systems are operated in safe environments and maintained to ensure proper operation. The computer systems responsible for handling of analytical data have been set up to process data in a way that ensures data integrity with password specific approval assignments. Data integrity is also maintained by performance of daily tape backups as discussed in the *Control of Records SOP* (QA-SOP-350).

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4.13.4 Electronic Record Retention Policies

Record retention policies for electronic records are analogous to policies for retention of non-electronic records maintained by EMSL laboratories. These policies are discussed fully in the *EMSL Control of Records SOP* (QA-SOP-350), including retention times and disposal.

All digital analytical records are permanently archived. The data is transferred to a disk-to-disk back-up system nightly, and once a week is transferred to high density tapes and transferred to Iron Mountain for storage. Access to these records is restricted and controlled by EMSL record policies and procedures. The record keeping system allows for the reconstruction of all activities required to produce an analytical result.

4.13.5 Signature and Initials Log

A log of the signatures and initials of laboratory staff is maintained with the Compliance and Commitment Agreement form found in this Manual. The information recorded includes

- Printed name
- Signature
- Initials (unique to laboratory; for duplicate initials, also use middle initial)
- Date of entry

This form helps identify the initials and/or signatures entered on laboratory documentation such as chain of custodies, analytical worksheets, final reports, etc.

4.13.6 Use of Electronic Signatures

Signatures are provided to the IT Department using *GEN-FM-901 Final Report Approval and Signature Sample*. Signatures are scanned, stored as an image, and forwarded back to the signatory via e-mail. The signatory maintains responsibility for the use of their signature. They may provide approval for its use through an e-mail or verbally. Documents are printed to PDF to secure signatures from alteration.

4.14 Internal Audits

An audit is an on-site, qualitative review of the various aspects of the total laboratory system. It represents an objective evaluation using an interactive program with respect to strengths, deficiencies, and potential areas of concern. Audits may also be performed remotely.

EMSL performs annual internal audits in laboratory facilities to verify work activities are being performed in full compliance with stated policies, established standard operating procedures, this quality assurance program, ISO 17025, TNI standards, and additional requirements as set forth by relevant accrediting authorities (e.g., AIHA LAP, LLC; NVLAP, A2LA, CALA). Audits will be conducted by laboratory management or by 3rd party personnel approved by the QA Department. Auditors and assistant auditors must complete the *QA-TC-700 Internal Auditor* training checklist.

The internal audit is scheduled by the Quality Assurance Department and covers aspects of the management system, including testing activities. Audit findings are recorded on an audit report, or on the *EMSL Internal Audit Checklist (QA-FM-700)* which is based on ISO 17025 requirements, with additions made for additional requirements of accrediting agencies. Non-conformities identified during the internal audit will be corrected and followed up according to EMSL corrective action process.

EMSL's internal audit procedures are located in the *EMSL Internal Audit Procedures SOP (QA-SOP-700).*

4.14.1 Test Method Assessments

As an added measure to evaluate methods and analysts, EMSL performs TMAs to ensure the laboratory is following the correct procedures, as set forth in EMSL SOPs. Test method assessments may be completed independently, or along with annual quality system audit.

In order to evaluate the performance of an analyst's compliance with method procedures, method specific assessments are performed every 3 years. PALA accredited labs are required to perform TMAs every 2 years. An assessor observes the analyst and evaluates every step of the method, from sample preparation to the reporting of results (QA-SOP-700).

4.15 Management Reviews

Management reviews are designed to provide the top management of EMSL with an overview of the performance of the management system and laboratory operations. They address the quality topics documented in the ISO 17025 and the TNI standard for each laboratory location, and include:

- The suitability of policies and procedures
- Reports from managerial and supervisory personnel
- The outcome of recent internal audits
- Corrective and preventive actions
- Assessments by external bodies
- Results of inter-laboratory comparisons or proficiency tests
- Changes in the volume and type of work
- Customer feedback
- Complaints
- Recommendations for improvement
- Review of quality policy objectives
- Status of previous management review action items and fulfillment of objectives
- Risk identification
- Effectiveness of improvements
- Changes to internal and external issues in laboratory
- Other relevant factors, such as quality control activities, resources, and staff training

During the first quarter of each year, the Quality Assurance Department, national directors, and vice presidents review labs for the previous calendar year.

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The report shall be based on the recorded information and non-recorded observations made by the QA Department, national directors, vice presidents, outside accrediting agencies and customer feedback. It is a tool to ensure the laboratory activities comply with the procedures and policies of the quality assurance program, ensure the program's continued effectiveness, and to introduce any necessary changes or improvement.

Action items are created from the management review to address internal and external issues brought to management's attention. These items will include detailed objectives to be completed during the upcoming year, and a review of the past year's items identified to ensure completion. Improvements made as a result of the review are evaluated from year to year to verify effectiveness.

Follow-up on action items for improvement of laboratory activities identified in the management review is performed by corporate management, the QA Department, and EMSL branch laboratories. Those action items must be completed according to a reasonable schedule. Management Review procedures can be found in the *EMSL Annual Management Review SOP (QA-SOP-750).*

Section 5.0: Technical Requirements

5.1 General

This section discusses the general technical requirements of the EMSL management system which are applicable to lab operations. Specific and additional requirements for certain areas will be found in the program specific modules.

5.1.1 Selection of personnel is recorded in job requisition forms filed with the Human Resources Department.

5.2 Personnel

5.2.1 Laboratory Job Roles and Responsibilities

5.2.1.1 Scope

This section describes general laboratory job roles and responsibilities of the technical personnel in a basic laboratory operation of EMSL. It does not include specialized assignments or positions that may have been instituted for specific projects or special laboratory needs. It is possible that more than one of these job responsibilities is shared among one person. For example, an analytical specialist may also be assigned administrative support duties.

Minimum education and experience requirements are listed generally for each job role. Specific requirements for education, training and skills for specific positions are listed in each of the individual program modules where these are defined by outside agencies. Specific job titles/descriptions and responsibilities are maintained in personnel folders.

Roles discussed in this section include the responsibility to ensure compliance with the policies documented in this manual and the requirements of the quality standards including, but not limited to, ISO/IEC 17025, TNI, A2LA, AIHA LAP, LLC-specific requirements, NVLAP, CALA and state accreditation agencies where applicable.

5.2.1.2 Administrative Specialists

Job titles include: Administration, Administration Coordinators, Data Entry, Office Administrator, Administrative Assistant, Login

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Administrative specialists report to the laboratory manager.

The minimum education and experience requirement is on the job training.

These are support positions for the laboratory including the analytical specialists. Responsibilities may include, but are not limited to, those listed below:

5.2.1.2.1 Sample Receipt Responsibilities

- Reviews paperwork for all incoming samples to ensure completeness and correctness
- Inspects samples to ensure sample integrity is retained and that packaging is not compromised, and informs the lab or department manager if there are any concerns noted regarding sample integrity
- Ensures laboratory has ability, capability, and capacity to analyze samples prior to log-in (with laboratory or department managers)
- Logs in all samples in a timely manner based on turnaround time
- Delivers incoming samples to the laboratory
- Ensures all samples are placed in the proper storage area to await analysis
- Informs the laboratory manager or analytical specialist of any special priorities regarding the samples

Administrative specialists with sample receipt responsibilities shall be aware of sample origin as it impacts regulatory requirements. The administrative specialist follows sample tracking protocols in handling samples, in particular, completing and verifying chain-of-custody forms as per EMSL *Sample Receiving and Chain of Custody SOP* (GEN-SOP-702).

Administrative specialists with receiving responsibilities are also responsible for ensuring proper sample numbering and labeling is performed, and sample information is transcribed correctly into the Laboratory Information Management System (LIMS) and onto applicable forms. The administrative specialist also ensures compliance with all relevant quality standards as related to job responsibilities.

5.2.1.2.2 Data Entry Responsibilities

- Generates analytical reports
- Enters data produced by the analytical specialists into the computer system for production of the final, customer-ready report
- Generates reports in the priority in which laboratory management staff assigns them
- Ensures the final report is prepared within the required time frames, and results are reported to the customer in a timely manner
- Reviews the information in the report and checks the data for any obvious errors
- Checks both technical and non-technical information, such as sample location, volume, and sample I.D. numbers for possible transcription

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errors

- Reports any observations of erroneous or unusual data or apparent errors to the laboratory management
- Ensures compliance with all relevant quality standards as related to job responsibilities

The administrative specialist contributes to the achievement of EMSL quality objectives by ensuring they act as a professional interface between technical personnel and laboratory customers. Administrative specialists ensure samples are received with the appropriate paperwork, and data is transcribed accurately and in a manner which prevents questions about the integrity of laboratory data. They also ensure they record non-conformities as per the Corrective Action system, opportunities for improvement as per the Preventive Action system, and customer complaints as per the Complaint Resolution system, and reports these to the personnel authorized to handle these situations.

5.2.1.3 Technicians

Job titles include: Lab Technician, Prep Technician, Lab Prep Technician, Sorter

All technicians report directly to laboratory management.

Minimum education and experience requirements:

- In-house training documented by the EMSL qualifications checklist or SOP acknowledgement documentation

  Participation in ongoing training programs (in-house workshops, laboratory meetings, etc.)

Minimum requirements will vary depending on specific job title and responsibilities, and may include particular experience and/or education requirements as specified on job description posted.

A technician is responsible for non-administrative, non-analytical work performed in the laboratory. Assigned responsibilities may include preparation of samples, preparation of media or reagents, cleaning of glassware or equipment, transport of samples between administration and lab and ensuring proper storage, and performing calibrations or verifications of equipment. They are usually not involved in the analysis of customer samples, although they may act as analytical specialists in some areas, while remaining technicians in others.

The technician is responsible for maintaining any associated paperwork (e.g., logbooks, forms, notebooks) for the work performed in accordance with established laboratory procedures. He/she must ensure familiarity and compliance with all relevant quality standards as related to job responsibilities by reading and following EMSL policies and procedures which adopt these standards.

Technicians contribute to the EMSL quality objectives by ensuring they have read and understood all EMSL policies and procedures relevant to their job tasks, and follow SOPs in order to ensure integrity of samples and workflow are maintained. Technicians also ensure they record non-conformities as per the non-conformity/ Corrective Action system, possible

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opportunities for improvement as per the Preventive Action system, and customer complaints as per the Complaint Resolution system, and report these to the attention to those personnel authorized to handle these situations.

Additionally, technicians contribute to the overall quality of EMSL final results by ensuring they avoid any actions which may call into question the integrity of their work.

5.2.1.4 Analytical Specialists

Job titles include: Analysts (including specialties, e.g., microscopist) and Scientists (including specialties, e.g., microbiologist, mycologist)

All analytical specialists report directly to laboratory management.

Minimum education and experience requirements:

- In-house training documented by the EMSL qualifications checklist
- Participation in ongoing training programs (in-house workshops, laboratory meetings, etc.)

Minimum requirements will vary depending on specific job title and responsibilities, and may include particular experience and/or education requirements as specified on job description posted.

The analytical specialist is responsible for performing calibrations of equipment, assigned analysis, and recording and maintaining analytical data according to established procedures including the Control of Records system. The analytical specialist must use good analytical technique and he/she must provide analytical results suitable for inclusion in a customer report.

The analytical specialist manages all work assigned and completes all paperwork in accordance with established laboratory procedures. The specialist reviews all paperwork for correctness and completeness and ensures that work progresses in a timely and productive manner.

The analytical specialist is responsible for performing required analysis on QC samples as directed by the laboratory management or designated quality representative, and for notifying the laboratory management or quality representative of any occurrence that could potentially affect the validity of an analytical result.

He/she must ensure familiarity and compliance with all relevant quality standards as related to job responsibilities by reading and following EMSL policies and procedures which adopt these standards.

The analytical specialist contributes to the EMSL quality objectives by ensuring they have read and understood all EMSL policies and procedures relevant to their job tasks, and follow all SOPs in order to ensure consistent and accurate analyses. The analytical specialist ensures all required QC functions of their job are performed in a timely manner, including calibration of equipment and analysis of QC samples at the required frequency. Analytical specialists also ensure they record non-conformities as per the Corrective Action system, possible opportunities for improvement as per the Preventive Action system, and customer complaints as per the Complaint Resolution system, and report these to the attention to those personnel authorized to handle these situations. Additionally, analytical specialists contribute to the

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overall quality of EMSL final results by ensuring they avoid any actions which may call into question the integrity of their work.

For PALA accredited labs, only a PALA approved microbiologist can approve and send final reports.

5.2.1.5 Laboratory Quality Representatives

Job titles include: Quality Assurance Coordinator, Quality Coordinator, Quality Manager, Quality Officer, and Quality Associate (however named).

The laboratory quality representative works with the laboratory management (or regional manager if the laboratory quality representative is the laboratory manager) with direct reporting for quality responsibilities to a higher-level lab quality representative (e.g., a department quality coordinator reporting to the lab quality manager) or Vice President of Quality Assurance.

Minimum education and experience requirements:

- Basic understanding of EMSL QA/QC program (including statistical analysis)
- Participation in ongoing training programs (in-house workshops, laboratory meetings, etc.)

Minimum requirements will vary depending on specific job title and responsibilities, and may include particular experience and/or education requirements as specified on job description posted.

Laboratory quality responsibilities may be assigned to a single quality representative or to a group of quality representatives. In large labs, for instance, there may be a single quality manager who oversees quality representatives assigned to individual departments. Ultimate reporting responsibility is to the Corporate QA Department, specifically, the vice president of quality assurance.

The laboratory quality representative is responsible for ensuring all QA/QC procedures for which they are assigned responsibility are performed at the required frequencies for the laboratory or departments under their supervision. He/she collects and maintains all QC data for reporting to the laboratory manager.

He/she oversees the QA/QC program as assigned and is responsible for the laboratory's compliance with all standard policies as guided by the corporate quality assurance Director. An analytical specialist or laboratory manager may also function as the laboratory quality representative for a particular location.

The laboratory quality representative ensures the laboratory maintains compliance with the policies and procedures documented in this manual, and the requirements documented in all relevant quality standards listed in Section 2.0. The laboratory quality representative is responsible for reporting any non-compliance issues to the laboratory manager or, if necessary, directly to the Corporate QA Department.

The laboratory quality representative contributes to the EMSL quality objectives by ensuring quality management system requirements are being followed at all times and/or according to designated frequencies. The laboratory quality representative oversees the implementation of the system in their laboratory, and ensures it is consistently followed in such a manner that the

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laboratory remains a coherent part of EMSL, and is not operating on its own set of policies and procedures. Quality representatives will oversee the quality reports being submitted to the Corporate QA Department to ensure they are generated on time, and that any problems reported have been handled and resolved in a manner which maintains the accuracy and integrity of laboratory data. They are responsible for designating qualified personnel (deputies) to assume temporary quality related responsibilities normally assigned in the event of absence.

5.2.1.6 Laboratory Management

Job titles include: Lab Director, Lab Manager, Technical Manager, Department Manager, Supervisor, Group Leader, Assistant Lab Manager, and Assistant Department Manager

Hierarchies of job positions make up the management team for a laboratory. In most branch laboratories, there is an individual who is designated a lab manager and is the technical head of that laboratory. Due to the diverse nature of services offered by EMSL, often a laboratory manager will be supported by other lab management positions, such as assistant managers, department managers, supervisors, group leaders, etc. In some cases, usually in larger laboratories, there may be multiple lab managers in charge of different aspects of the laboratory services.

Laboratory management personnel usually directly report to regional manager(s).

Minimum education and experience requirement for the lab management position is one (1) year of related analytical experience. Managers must also meet requirements specified in applicable regulatory standards.

The laboratory management position may be assigned various responsibilities depending on the role they serve within the laboratory. Lab and department managers will usually be responsible for technical decisions for the laboratory such as:

- Assuring requirements for laboratory equipment and supplies are met
- Resolution of analytical problems
- Development and implementation of training programs for analytical specialists
- Providing sufficient oversight of laboratory operations
- Review and approval of analytical results for release
- Development of new methodology and analysis
- For PALA accredited labs, only a PALA approved microbiologist can approve and send final reports. If the approved signatory is absent from the lab, final reports will not be approved or distributed.

Supervisors, group leaders, and assistant managers will be delegated some set of responsibilities over which they are responsible. Such duties may include supervising the workflow of the lab or a particular portion of the laboratory, overseeing a group of analysts and/or technicians, etc.

As a whole, laboratory management personnel are responsible for overall administration of laboratory operations. They ensure company policies are understood by all personnel, adequate supervision is provided to staff, work scheduling procedures adequately address customer needs, and are responsible for ensuring all customer complaints are resolved. They shall also approve all employee reviews and promotions, and provide regional or corporate

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management with information regarding laboratory budgeting issues (e.g., purchase of equipment and supplies, expenses for out-of-house training, staffing requirements). The laboratory management staff shall ensure adequate supervision is provided for the laboratory technical personnel.

They are responsible for designating qualified personnel (deputies) to assume specific, temporary management responsibilities normally assigned to the laboratory management staff in the event of absence. The deputy is identified on the laboratory organization chart. For those single person laboratories, in the event the laboratory manager/analytical specialist/quality representative is absent, no analysis will be performed, and therefore the assignment of a deputy manager/quality representative is not applicable.

Laboratory management is also responsible for ensuring a comfortable working atmosphere, free from excessive pressures (including unreasonable productivity rates), for their laboratory employees. Laboratory management must ensure the policies and procedures of this quality management system are communicated to the laboratory staff.

Ultimately, laboratory management personnel are responsible for the data reported by the laboratory. He/she or approved designees review and approve the final customer reports for release to the customer. This responsibility includes the verification of the sample results which, include:

- Verification of sample number
- Correctness of sample result
- Check for typographical errors
- Completeness of chain of custody

Management personnel shall ensure any designees are fully capable of performing these reviews on their behalf. Management assigns designated personnel to perform the task of final review and approval following the *EMSL SOP for Final Report Approval and Electronic Signature* (GEN-SOP-901).

Management personnel or a designee shall ensure QA standards are established, understood, and administered. He/she is ultimately responsible for ensuring the QA program is conscientiously implemented. He/she reviews the QA program with the regional manager or national director to ensure completeness and effectiveness, and supports the local quality representatives, regional manager and/or the National Quality Assurance Department in carrying out the program by use of authority. Laboratory management is ultimately responsible for ensuring QC reports are submitted to the National QA Department in accordance with these QA program requirements.

Laboratory management personnel contribute to the EMSL quality objectives by ensuring the laboratory maintains compliance with the policies and procedures documented in this manual, and the requirements documented in relevant quality standards listed in Section 2.0. They oversee employee qualifications, ensuring they are properly qualified and trained prior to conducting analysis.

The management staff is ultimately responsible for the data reported from the laboratory. Management staff ensures non-conformities and complaints are resolved in a timely manner, leading to continual improvement at the laboratory.

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In accredited labs, should the person identified with the accrediting body as the lab manager, technical director, technical manager, quality manager or quality assurance officer be absent for a period of time exceeding fifteen (15) consecutive calendar days, the laboratory shall designate another full-time staff member meeting the qualifications of said manager to temporarily perform this function. The Interim Manager shall also meet all the education and experience standards required of said manager, in order to function as Interim Manager.

If this absence exceeds twenty (20) consecutive business days, the appropriate accreditation body(ies) shall be notified in writing regarding how requirements will be met in the interim.

5.2.1.7 Regional Manager

The regional manager reports directly to the Vice President.

Minimum education and experience requirements:

- 2 years related analytical experience
- 1 year management experience

The regional manager assumes responsibility for the overall performance of two or more laboratory locations. He/she controls the analytical programs, reporting processes, general management and is accountable for the overall operational of the laboratories under authority.

The regional manager reports directly to the vice president and coordinates with the national director on technical issues, and initiates and controls operational policies in the areas of administrative and technical matters. The regional manager may also function as a laboratory manager.

The regional manager works closely with the National QA Department in developing and maintaining the QA program. He/she consults directly with the National QA Department regarding the effectiveness and applicability of the program, recommends needed changes, if any, and reports any problems with the program. The regional manager is responsible for ensuring annual technical QA/QC audits are performed at each of their laboratories.

The regional manager ensures the laboratory maintains compliance with the policies and procedures documented in this manual and the requirements documented in relevant quality standards.

The regional manager contributes to EMSL quality objectives by assisting laboratories in their implementation of the quality system, improving consistency across their laboratories. The input they provide to the National QA Department assists in the continual improvement of the quality system.

5.2.1.8 National Director/Vice President

The national director/vice president reports to the EMSL Sr. Vice Presidents.

Minimum educational/experience requirements:

- Associate of Science degree in related science
- 3 years related analytical experience
- 2 years management experience

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The national director/vice president is responsible for the overall quality performance of the business service line they are responsible for, including the initiation, development, and maintenance of the quality management system. The national director/vice president advises the president and Sr. vice presidents on quality management system issues, and has the primary authority to ensure the integrity of the management system is maintained at all times, and initiates actions to prevent or minimize departures from the quality management system.

The national director/vice president ensures appropriate communication processes are established for implementation and effectiveness of the quality management system. He/she participates in the management review process and commits to continually improve the effectiveness of this system.

The national director/vice president provides input on decisions related to the status of laboratory certifications and accreditations.

The national director/vice president contributes to the quality objectives of the laboratory by ensuring the company maintains compliance with the policies and procedures documented in this manual, and the requirements documented in relevant quality standards.

As part of top laboratory management, the national director/vice president assists in setting the quality objectives of EMSL. In addition, the national director/vice president ensures these quality objectives are adequately communicated and understood by laboratory staff, and ensures they remain aware of the effectiveness of the EMSL quality system. The national director/vice president also contributes to the program by ensuring they are committed to the development, implementation, and continual improvement to the program. As part of top management, the national director/vice president shall ensure the integrity of the management system is maintained at all times when changes are made to laboratory operations.

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5.2.1.9 National Quality Program Support Representatives

Titles include: Vice President of Quality Assurance, Quality Assurance Manager, Quality Assurance Specialist, Quality Assurance Coordinator, National [service area, i.e., asbestos] Manager.

The national quality program support representatives report to the vice president of quality assurance.

A minimum educational /experience requirement is 2 years related analytical experience.

The national quality program support representatives work under the direction of the vice president of quality assurance. They are responsible for providing support to the Quality Assurance Department, which includes:

- Participation in the development, implementation and maintenance of QA/QC policies and procedures
- Guidance to the laboratory operations on quality issues
- The monitoring and assurance of compliance with the QA plan
- Establishing and maintaining standardization throughout EMSL locations
- Processing accreditation applications and administration of documentation related to accreditation requirements

The national quality program support representatives provide reports of performance (frequency of report submittals and review of quality of reports) to the vice president of quality assurance, regional managers, national directors, and vice presidents.

The national quality program support representatives ensure the laboratory maintains compliance with the policies and procedures documented in this manual, and the requirements documented in relevant quality standards.

The national quality program support representatives contribute to the quality objectives by tracking whether quality control programs are being implemented at branch laboratories through the review of monthly and quarterly reports. This review of quality reports ensure QC is being properly documented and reviewed, thus improving the quality of data from all laboratories, and allowing corporate management to act when areas of concern are identified. The national quality program support representatives' participation in the annual management reviews includes feedback on individual lab performance and advice on areas for improvement.

5.2.1.10 Vice President of Quality Assurance (previously National Director of QA)

The vice president of quality assurance reports directly to the EMSL Sr. Vice Presidents. The vice president of quality assurance also has direct access to the EMSL President.

Minimum educational/experience requirements:

- 2 years related analytical experience
- 1 year management experience
- Course work on quality programs

The vice president of quality assurance has the authority to:

- Develop and implement quality assurance and quality control policies
- Implement change to ensure the effectiveness of the quality management program
- Participate in business decisions related to the development of additional service areas, accreditations, etc.
- Report non-conformities and breaches in ethics policies to senior corporate management
- Direct other departments in order to achieve the goals of the quality program
- Write and/or issue Standard Operating Procedures

The vice president of quality assurance director is responsible for establishing, implementing, and maintaining the entire QA program as described in this manual. He/she develops statistical protocols for data reduction and acceptance criteria. He/she defines requirements for submitting QC samples, controls results reporting policies, sets standards for analytical performance, and issues protocols for yearly on-site audits for the branch laboratories.

The vice president of quality assurance is also responsible for maintaining the QMS manual and all standard operating procedures (SOPs). He/she is responsible for conducting and/or establishing policies for QA audits, and setting the standards for laboratory practices. The vice president of quality assurance confers with the national directors, regional managers and/or the laboratory managers on QA policies, and supports the laboratory management and

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laboratory quality representatives in the daily maintenance of the QC program. The vice president of quality assurance oversees laboratory accreditations including initial applications, maintenance of proficiency testing programs and responses to non-conformities identified during on site audits.

The vice president of quality assurance participates in the annual management review. The vice president of quality assurance also ensures the laboratory maintains compliance with all relevant quality standards.

The vice president of quality assurance assists top management in defining the EMSL quality objectives. As head of the quality unit, the vice president of quality assurance ultimately has oversight of the entire quality program of EMSL, and ensures the management systems meet the quality objectives.

The vice president of quality assurance is granted the authority by EMSL senior management to perform these tasks and ensures the EMSL quality management system is being implemented and followed at all times.

5.2.1.11 Senior Vice President - Technical Divisions

Titles include: Senior Vice President, laboratory services

The senior vice president (Sr. VP) is responsible for the overall quality performance of the entire company, including the initiation, development, and maintenance of the quality management system. The Sr. VP advises the president on quality program management issues, and has the ultimate authority to ensure the integrity of the management system is maintained at all times (including when changes are made) and initiates actions to prevent or minimize departures from the quality management system.

The Sr. VP ensures appropriate communication processes are established for implementation and effectiveness of the quality management system. He/she participates in the management review process and commits to continually improve the effectiveness of this system.

The Sr. VP makes all decisions related to the status of laboratory certifications and accreditations.

The Sr. VP contributes to the quality objectives of the laboratory by ensuring the company maintains compliance with the policies and procedures documented in this manual and the requirements documented in relevant quality standards.

As part of top laboratory management, the Sr. VP assists in setting the quality objectives of EMSL. In addition, the Sr. VP ensures these quality objectives are adequately communicated and understood by laboratory staff, and ensures they remain aware of the effectiveness of the EMSL quality system. The Sr. VP also contributes by ensuring they are committed to the development, implementation, and continual improvement of the laboratory quality system. As part of top management, the Sr. VP shall ensure the integrity of the management system is maintained at all times.

5.2.1.12 President

The president focuses and directs the path of the company and assumes complete responsibility for the success of the quality management system.

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He provides the authority and approves the resources necessary to maintain compliance with the quality assurance program policies documented in this manual and applicable accreditation standards.

The president, as part of top laboratory management, assists in setting the quality objectives of EMSL, and issues the Quality Policy under which the company operates. The president contributes to the quality objectives by ensuring adequate resources to establish, maintain and improve the quality system of the laboratory, and by clearly communicating the company's commitment to its Quality Policy and quality system policies and procedures.

5.2.2 Training

5.2.2.1 Scope

This section describes the corporate procedures and policies of the EMSL training program. Additional requirements for training for each analytical methodology, if any, are discussed in the program modules. Details on documenting training for analytical specialists are available in the *Training on Analytical Methods SOP* (GEN-SOP-100) available on E-Link.

Analytical specialists must complete the EMSL training program in order to perform analysis independently and receive a completed Demonstration of Capability, authorizing the analyst to perform the methods listed on the certificate. All employees (full-time or part-time, permanent or temporary, including interns) must read the QMS manual and SOPs which are related to the work with which they will be responsible, ensure these are understood, and acknowledge the document, stating their commitment to follow the procedures and policies outlined therein.

Because the amount of training needed will vary based on the education, past experience and skills of the trainee, the requirements described in this section and the program-specific modules are considered minimums. Laboratory managers are responsible for ensuring appropriate training is provided to every analytical specialist, and they are completely competent, qualified, and signed off to perform analysis.

5.2.2.2 Identification of Training Needs and Goals of Training

The need and goals for training are determined by the laboratory manager or corporate management. Needs are identified considering:

- Cross training to increase laboratory productivity
- Decreasing trend in quality
- Change in type of work
- Change in requirements or procedure
- Addition of analytical services

The goals of training will differ based on the area of training. In general, training is intended to familiarize personnel with the policies and procedures of the laboratory, ensure personnel are aware of changes to policies and procedures, are knowledgeable and skilled in proper analytical and/or preparatory technique, and understand the theory underlying the work.

5.2.2.3 Types of Training

There are a variety of training programs offered. Documentation of these programs (certificates, training records, records of participation in training sessions, etc.) is considered the property of EMSL and not the trainees.

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5.2.2.3.1 "In-House" Course

These are organized EMSL courses designed for a classroom setting (they can be scheduled in workshop type modules) with syllabus and course materials. These courses contain recommended contact hours. A certificate is issued which documents attendance.

Formal in-house courses are developed and implemented under the direction of corporate management. The trainer must follow the requirements of the EMSL training program and ensure all topics are covered according to the workshop outline or qualifications training checklist. The assignment of a trainer can be performed by laboratory management staff, regional manager, national director, QA manager, vice president or president. Capability will be determined based on knowledge, experience and demonstrated technical competence. The trainer must have a thorough and comprehensive understanding of the topics involved.

5.2.2.3.2 "On the Job" Technical Skills Training

This is training provided at the hands-on level. The amount of training time needed will vary for each method and for each trainee. If the training involves analytical procedures, the trainer must be a qualified analytical specialist with at least one (1) year of experience. Non-analytical procedures may be trained by any experienced EMSL employee with a thorough and comprehensive understanding of the topics involved.

5.2.2.3.3 "Out of House" Formal Training Courses

Under some circumstances, EMSL will provide staff members with formal, outside training. The certificate of training is maintained in the employee folder along with course outline. Courses will be selected based on applicability to job responsibilities. The qualifications of the course provider and instructor shall be reviewed prior to course approval. Contact hours vary based on the course.

5.2.2.4 Initial Training and Authorization of Analytical specialists

5.2.2.4.1 Training Checklist

Analytical specialists must satisfy theoretical and practical knowledge requirements in order to be authorized to independently analyze samples. Each EMSL program area utilizes a set of training checklist to document these requirements and track an analytical specialist's training. The EMSL training checklists are available on the E-link site and are referenced in the program specific modules.

The training checklist documents the aspects of the analytical specialist's training, from their understanding of the theory behind applicable concepts, to their ability to capably perform analysis of each method on which they are being trained. Specific requirements for each analysis are detailed in the QMS Manual Modules and the training checklists.

As training of an analytical specialist proceeds, the trainer and trainee sign and initial each item on the checklist as they are completed. There are a number of ways a new analytical specialist can satisfy the requirements presented in the training checklist.

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The date the checklist is signed is the date on which the new analytical specialist demonstrated understanding or ability satisfying the requirement. This demonstration may be completed in a number of ways.

- The analytical specialist may receive training on the topic from a qualified trainer (an analytical specialist that has at least one year of experience and a completed DOC for the method being trained), and subsequent to the training, demonstrates their understanding and/or ability. Once the trainer is satisfied the analytical specialist has met the requirement, the trainer shall initial and date the training checklist for that requirement.
- Based on previous experience and training, a qualified trainer (as defined above) or the laboratory manager, may verify that knowledge or skills are already present through interviews and observed technique, and once satisfied the analytical specialist has met the requirement of the checklist, may initial and date the training checklist for that requirement without further training.

Note: Previous EMSL training policies allowed for a "qualifications statement" from the national director in lieu of a training checklist. This option was eliminated beginning with Revision 10 of this document. Analytical specialists must have each checklist item verified by laboratory manager or trainer and initialed on the checklist. "Qualification statements" issued prior to the removal of this option (Dec. 2008) will still be considered valid, and should remain a part of the analytical specialist's training records. Likewise, previous revisions of the training checklist are acceptable as it represents the state of training documentation at that time. Analytical specialist performance will have been demonstrated through acceptable QC analysis. However, if no training documentation exists, the current checklist should be used to document the current competency of the analytical specialist. Each item should be reviewed, and acceptable performance/knowledge documented by the analytical specialist and the department manager, or national director in the case of department managers.

Once all requirements of the training checklist have been completed and marked on the checklist by the analytical specialist and trainer, the laboratory manager signs off on the training checklist, stating the training of the analytical specialist has been completed.

Where no training checklist exists for a particular method, or if the checklist does not detail a method for initial demonstration of capability, an initial demonstration of capability shall be performed as per the method, or where the method does not specify, the method outlined in TNI Standard (2016) Sect. 1.6.2.2, or an equivalent method.

Frequency of Initial DOC

An initial DOC for each analyst shall be completed prior to a new method being introduced, or when there is a change in method or instrumentation. TNI also requires an initial DOC whenever an analytical specialist or the lab has not performed a method within the past twelve (12) months [six (6) months for AIHA LAP, LLC accredited laboratories]. This requirement shall be taken into account when considering accepting samples for a method that has not been performed in the past year.

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Analytical specialists shall perform analysis with each method on QC samples at least once a year to maintain their capability with infrequently used methods.

5.2.2.4.2 Demonstration of Capability (DOC) Certificate

Following completion of the training checklist, the signed checklist is reviewed by the lab manager and regional manager, as needed.

EMSL utilizes a DOC certificate which is based on the sample provided in Appendix C of Section 5 of the 2016 TNI Standard. The form allows for the recording of all analyses for which demonstration has been completed for a particular analytical specialist.

The certificate is prepared by the lab manager, with assistance from the regional manager and/or QA Department, as needed, and signed by the department or lab manager, against the information provided by the laboratory manager on the training checklist, and supporting documentation for each matrix and method for which the analytical specialist is authorized to perform analysis. Each analyses type is listed, along with the date upon which Demonstration of Capability was completed. The date of the signature indicates the date upon which the information contained on the form was updated and confirmed, and the form issued by the lab manager or QA Department.

Once the DOC certificate is signed, the analytical specialist is authorized to perform work for those methods listed on the DOC certificate. (Note: When the analytical specialist being authorized is the laboratory manager, the DOC certificate shall be signed by either the regional manager or national director.)

The DOC certificate shall be revised whenever an analytical specialist completes a new demonstration of capability, or when their capability to perform the analysis changes. In such cases, the supporting material shall be sent to the laboratory designee, or the QA Department along with the most recent version of the DOC certificate. Once updated, the laboratory designee or QA Department will re-sign for re-affirmation of the information contained on the form. Thus, the dates of the signature always correspond to the date the certificate is issued, and the information contained therein is confirmed, not necessarily the date upon which specific demonstrations were completed.

5.2.2.4.3 Exception to Certification Form:

Where a method has been used in the laboratory since July 1999, and there have been no significant changes in instrumentation type, personnel or method, evidence of ongoing performance (see below) will be acceptable. The laboratory manager must have a record on file to demonstrate an initial DOC is not required.

5.2.2.4.4 Authorization to Perform Analysis

Analytical specialists must receive formal authorization to perform analysis. This is performed with the signature of the laboratory manager, regional manager, or national director and/or vice president of quality assurance on the qualifications/training checklists. These checklists are then followed up with the Demonstration of Capability certificate.

5.2.2.5 Ongoing Training and Continued Demonstration of Capability

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5.2.2.5.1 Ongoing Training

Ongoing training of our staff is a very important piece of analytical quality. It provides an opportunity to sharpen skills and keep all employees up to date with the current procedures, techniques, regulations, etc.

Laboratory managers are to ensure ongoing training is provided to all employees on a consistent basis. The opportunity for ongoing training occurs in many different forms. The following list suggests a number of different types of ongoing training:

- Laboratory staff meetings – scheduled as needed, these can cover a variety of technical topics. There is no organized agenda and interaction between all attendees is encouraged (much like an open forum). Examples of topics could include technical subjects/analytical method updates, customer service issues, health and safety, etc. This training must be documented.
- Laboratory audits – the staff can consult with the auditor (of both internal and external audits) and ask questions to be advised on many topics.
- Workshops provided by professional organizations, regulatory agencies, or instrument/equipment vendors. If a certificate is not provided by the outside trainer, such as in a workshop, an open use training form is completed for each described topic covered during the training. A copy of this training record is maintained in the laboratory files.

5.2.2.5.2 Ongoing Demonstration of Capability

Continuous demonstration of capability by each analytical specialist is achieved through the QC reanalysis of samples by the same analytical specialist (intra-analyst), different analytical specialist (inter-analyst), inter-laboratory analysis, the analysis of standard reference samples/LCSs, and performance in proficiency testing programs. This is performed at a minimum of every 12 months, and is documented with:

- Copies of reports of individual analytical specialist's performance in proficiency testing programs (stored in employee training files)
- Copies of reports of individual analytical specialist's performance in round robin programs (stored in employee training files)
- Analytical quality control reports (QC results, standards analysis, etc.) generated during the course of analysis
- All target analytes shall be included in the DOC Study.

  ***Note**: This data is normally stored with the laboratory quality control data vs. in the individual analytical specialist's files.*

Whenever possible, inter-analyst QC should be performed by analytical specialists that have completed their training, and for whom certifications of demonstration have been completed.

When PT studies are used for ongoing demonstration of capabilities, only analytes that met PT acceptance criteria shall be used.

5.2.2.5.3 Recertification Statements

Every 12 months (or 6 months for lead methods within the scope of AIHA LAP, LLC ELLAP accreditation), the laboratory or department manager shall sign a Recertification Statement for each analytical specialist to document continued authorization to

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perform analysis. If the laboratory/department manager is also authorized to perform analysis, the regional manager, national director, lab quality manager (if different), or designee shall review and sign the *Continuing Certification Statement* for the laboratory manager. The recertification statement will be attached to the original DOC certificate in the analytical specialist's folder.

5.2.2.6 New Manager Training

EMSL has created several video trainings describing the responsibilities a new manager must handle. Upon accepting a managerial position in an EMSL laboratory, the manager has approximately one to three months to view the training videos. After completion, a meeting will be conducted between the manager, QA, the Regional Manager, and or National Director/ Vice President, to discuss any questions the manager has related to their new responsibilities. GEN-TC-120 New Manager Training Checklist will then be approved and signed by the Regional Manager or other appropriate Corporate representative.

Supervisors and QA Representatives will view the applicable videos associated with their duties, and will follow the same process as above. These supervisory position employees have approximately six months to view the videos.

The QA Department will take note of new managers, and track their viewing of the video training sessions. Each month, the QA Department will contact the managers or supervisory personnel to address any questions they may have; this will also serve as a reminder to view their associated training videos to ensure completion.

5.2.2.7 Measurement of the Effectiveness of the Training Program

The effectiveness of our training program is evaluated using a number of identifiers. These include:

- Analytical specialist's performance in the quality control program (inter/intra analyst, analysis of standards, blanks)
- Performance in proficiency testing programs
- Evaluation of data generated in round robin programs
- Analysis of blind QC samples
- Performance at internal and external onsite site audits

The evaluation of any of these items may identify the need for additional training or modifications to the training program. Some examples of findings that may indicate training needs include:

- Poor performance in the quality control program
- Outliers reported in proficiency testing programs or round robin programs
- Findings noted during internal and external audits
- Feedback from laboratory staff self-identifying training needs
- Trends in non-conformities reported in the laboratory

5.2.2.8 Authorizations Log

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Laboratory managers are responsible for authorizing lab personnel to perform critical tasks. This may be accomplished by utilizing a log which contains both technical tasks (preparation and analysis of samples), as well as any non-technical tasks which are critical to the operations of the laboratory (e.g., ordering supplies, discussing reports with customers, logging in samples). Alternatively, authorizations can be documented through Demonstration of Capabilities (DOCs), training records, job descriptions, and organizational charts.

The *Authorizations Log* spreadsheet and its "Instructions" tab is available on E-link.

5.2.2.9 Training and Personnel Files

Personnel and training files shall be maintained for all technical employees. Personnel files shall contain all general documentation associated with the employee. Training files shall include all files associated with the initial and ongoing training of the employee.

A completed personnel file must contain at a minimum:

- Resume/CV
- Signed Ethics Acknowledgment
- Diplomas for degreed employees (complete transcripts may also be used if showing graduation)
- Copies of any registrations/certifications held by analytical specialist

A completed training file must contain at a minimum:

- Training checklists for all analyses for which the analytical specialist is qualified
- Demonstration of Capability certificate (DOC) which lists all the methods the analytical specialist is authorized to perform
- Raw data supporting initial DOC for all analyses*
- Summaries of data reviewed to demonstrate ongoing capability*
- Misc. training records (certificates from classes taken and in-house training sheets)
- For Asbestos: NIOSH 582 training certificates
- For Lead: 4 independent runs for each matrix
- Results of performance on proficiency testing samples/round robin samples

*** Note:** Copies of raw data supporting the initial and ongoing demonstration of capability for the analytical specialist may be referenced in the personnel folder, instead of being included. Copies of the original raw data shall be maintained for the length of employment and for five (5) years after the end of employment. For ongoing demonstration of capability, summaries of data reviewed with references to the original data are sufficient in the training folders.

Files are to be maintained and updated by the laboratory manager.

5.2.3 Reporting of Significant Changes

Any changes in laboratory ownership, location (except for mobile and field operations laboratories), management, laboratory key personnel, or any other change that significantly affects the laboratory's capability, scope of accreditation, or ability to meet the policy

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requirements, shall be reported in writing to the appropriate accrediting body within their required time frame. Any absence of personnel for an accredited body's required period, that impacts the laboratory's ability to perform its scope of testing, shall be reported to the appropriate accrediting body within their required time frame.

5.3 Accommodation and Environmental Conditions

5.3.1 General

EMSL is committed to ensuring laboratory facilities are appropriate for ensuring the correct performance of tests. For example, attention will be paid to energy sources, lighting and environmental conditions, and separation between neighboring areas in which there are incompatible tests.

Any specific technical requirements for a specific method are documented in the program specific modules of the QMS Manual, or in the specific technical SOPs. Examples of specific environmental conditions that may affect tests and will be documented in the modules or SOPs include sterility of work area, electromagnetic disturbances, temperature, and/or humidity, radiation, and vibration levels.

Where it is determined controlled environmental conditions are crucial for the performance of a test or the interpretation of results, the lab will monitor, control, and record these conditions as necessary (i.e., through the use of temperature logs, humidity logs, readings included on bench sheets, etc.).

Should a laboratory or department manager determine the facility must be modified to meet requirements, these requests will be sent to the President or Senior Vice President of Laboratory Services for approval.

Access to the laboratory beyond the receiving area is restricted to laboratory employees or contracted employees. If non-laboratory personnel wish to enter these areas, they shall be accompanied by authorized lab personnel. Applicable employees are provided keys or electronic fob keys by Management or Human Resources Department when hired, and must return keys when their employment ends.

The laboratory manager is responsible for ensuring good housekeeping practices are in place in the laboratory. This includes periodic wipes of areas prone to contamination, proper cleaning of lab glassware, disposal of disposable consumables following use, and general cleanliness of the laboratory facility, including non-analytical areas. Where specific procedures must be followed, these will be documented in the QMS Manual program specific modules or in analytical SOPs.

5.3.2 Contamination Management

This section describes reagent control and contamination management. Proper observance of these procedures is necessary to guarantee accuracy of results and the safety of laboratory staff members.

Contamination of samples, the laboratory environment and reagents used in analysis must be avoided to provide the highest quality, legally defensible data to our customers. In order to achieve this goal, laboratory staff must adhere to various preventative measures and use the testing procedures for contamination detection.

Contamination control is focused both on sources and on targets of contamination. Sources of contamination include samples and laboratory debris. Targets include things such as, samples, equipment (e.g., tools), supplies (e.g., microscope slides and reagents) and work areas.

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Contamination control consists of 3 parts:

- Avoidance
- Detection
- Resolution

5.3.3 Contamination Avoidance

To avoid contamination, the following procedures must be followed:

- Maintain good housekeeping
- Clean all tools before and after preparing each sample
- Clean tool sets at the end of the workday
- Dispose of wipers after use; do not let them pile up during the workday
- Wipe all work surfaces before and after sample preparation. Surfaces include bench tops, slide trays, stereo microscope stage, and slide preparation surface.
- Control work areas
- Work only on clean surfaces

Only one active sample should be processed at each time. The sample containers are kept closed when not being processed. Inactive samples are stored in a suitable, out-of-the-way area. Target items (samples, reagents, and containers) are opened one at a time, as practical.

5.3.4 Detection of Contamination

Contamination control is verified by the evaluation of blank sample analysis and results of air/surface sampling.

5.3.4.1 Blank Analysis

The number of blank samples analyzed is specified in the quality control section in the appropriate SOP. This data is generated and tracked for the purposes of monitoring any possible contamination only, and is not to be used for statistical quality control.

5.3.4.2 Ambient Air Monitoring/Wipe Sampling

On a quarterly basis, or if there is a reason to suspect contamination, the laboratory is to perform ambient air monitoring and/or wipe sampling throughout the facility. This procedure not only helps to monitor possible sample contamination, but also provides data to evaluate any possible personnel exposure.

For air samples, a sampling pump is set up in a location that represents areas of most activity. The pump's rotameter must be calibrated against a primary standard, annually. Sampling is conducted according to the appropriate NIOSH, OSHA, or other published method as available. Flow rates, sampling times, media and all other parameters will be in accordance with appropriate methods and good scientific practice.

Specific sample volume, method of analysis, and acceptance criteria for the targeted compounds are listed in the individual modules.

Results of these samples are filed in the laboratory. If any result is above the contamination/exposure limit, the laboratory manager must immediately notify the Quality Assurance Department and/or the corporate health and safety officer. An investigation into

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the source of contamination/exposure is performed, and a corrective action implemented. All actions are documented.

See the program specific modules for specific details on what quarterly contamination monitoring is required.

5.3.5 Resolution

If contamination is detected in any situation, the source of contamination must be traced, and the problem resolved to prevent reoccurrence. A Corrective Action Record (CAR) should be completed to document the analysis of the source of the contamination, as well as actions taken to resolve a contamination circumstance.

After corrective actions have been completed, and the contaminated areas have been cleaned, re-sampling and analysis shall be performed in order to ensure the contamination has been eliminated. A subsequent contamination check prior to the scheduled quarterly check may be warranted depending on source and/or type of contamination in order to ensure effectiveness of corrective actions.

5.4 Test Methods and Method Validation

5.4.1 General

Instructions or procedures for the activities affecting the quality of our analytical services shall be developed by management. This quality assurance program shall be used as a guideline for their development, use, and revision.

Technical standard operating procedures are documented in the SOP Manuals, located at each laboratory facility. These SOPs include step by step procedures for the preparation, analysis, and reporting of data.

Note: Not all methods written in our SOPs are applicable to all EMSL laboratories.

General and Administrative SOPs include, but may not be limited to:

- **EMSL Complaint Resolution SOP (QA-SOP-600)** – *Standard Operating Procedures for Complaint Handling and Resolution*
- **EMSL Corrective Action SOP (QA-SOP-200)** – *Standard Operating Procedures for Non-Conformities and Corrective Actions*
- **EMSL Preventive Action SOP** (**QA-SOP-250)** – *Standard Operating Procedure for Preventive Actions*
- **EMSL Final Report Approval and Electronic Signature SOP (GEN-SOP-901)** - *Procedures and Policy for Final Report Approval Using Electronic Signature*
- **EMSL Controlled Document SOP (QA-SOP-301)** – *Standard Operating Procedures for Document Control Program*
- **EMSL Document Master List SOP (QA-SOP-302)** – *Standard Operating Procedures for Maintaining Master Lists of Documents*
- **EMSL Control of Records SOP (QA-SOP-350)** – *Standard Operating Procedure for Control of Laboratory Records*
- **EMSL Internal Audit SOP (QA-SOP-700)** – *Standard Operating Procedure for Internal Quality Assurance Audits*

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- **EMSL Annual Management Review SOP (QA-SOP-750)** – *Standard Operating Procedure for Annual Management Review Reporting*
- **Purchasing: Evaluation of Suppliers and Services SOP** (**QA-SOP-500**) – *Standard Operating Procedure addresses the evaluation and selection of suppliers and services critical to the analysis of samples*
- **Purchasing: Receiving Supplies and Services (QA-SOP-501)** – *Standard Operating Procedure addresses procedures for receiving and approving supplies and services for use upon receipt*
- **Prep and QC of Materials SOP-Micro (GEN-SOP-810)** – *Standard Operating Procedure for the receipt, preparation, handling, storage, quality control and disposal of consumables, kits, media, reagents, solutions, and standards used in Microbiology*
- **Safe Sample Handling Log-In Personnel (GEN-SOP-701)** – *Standard Operating Procedure covering the practices personnel shall use to prevent potential exposure to hazardous customer samples*
- **Sample Receiving and Chain of Custody SOP (GEN-SOP-702)** – *Standard Operating Procedure to track the custody of samples using the Chain of Custody form*
- **EMSL Method Validation SOP (GEN-SOP-310)** – *Standard Operating Procedure for Validation of Methods and Method Modifications*
- **EMSL Training on Analytical Methods SOP (GEN-SOP-100)** – *Standard Operating Procedure for Documentation of Training on Analytical Procedure*
- **EMSL Sample Transfer and Subcontracting SOP (GEN-SOP-10)** – *Standard Operating Procedure for the distribution of samples to other laboratories for analysis, including transfer of samples to other EMSL laboratories*
- **Amending Final Reports SOP (GEN-SOP-902)** – *Standard Operating Procedure to ensure all EMSL amended reports are appropriately and consistently identified as an amended report*
- **Analytical SOPs** – *Relevant analytical SOPs for each analytical method are found in the appropriate modules. These SOPs cover methodology for analytical procedures, calibrations, contamination checks, reporting procedures and quality control frequency.*

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A list of the SOPs for each test method the laboratory is accredited for can be found on form 'List of Accredited Methods Validated by Use,' on EMSL's intranet. The link to each laboratory's list (located in individual laboratory folders) is https://elink.emsl.com/labs/default.aspx

The laboratory manager is responsible for ensuring the SOPs reflect the actual laboratory procedures. Managers are to submit suggestions for revisions to the vice president of quality assurance for review. The vice president of national quality assurance is responsible for controlling revisions and distribution of the SOPs. (See *Document Control and Control of Records* section of this manual.)

If analysis is performed using modifications to the EMSL SOP or the standard published methods, the final report will describe the modification in the report title or in the form of a disclaimer. See method SOPs for specific detail.

5.4.2 Selection of Method

EMSL always uses test methods which meet the requirements of its customers. Whenever published and widely accepted methods are available, these standard methods shall be reviewed and adopted when deemed appropriate. Where EMSL specific adjustments or modifications are necessary, these

shall be documented in the SOP for that method. Continued use of laboratory developed methods (vs. ASTM, for example) can be consistent with our policy of using standard methods when possible.

Methods shall be labeled as "Modified" if they are non-performance-based methods, and the changes to the methods are such that they alter the chemistry of the method, or change the determinative step of the SOP as compared to the approved method. Adjustments to the method which do not change the determinative step or chemistry shall be clearly stated in the SOP, or an addendum to the SOP which is referenced from the SOP itself. Reasons for the change, as well as any supporting data showing adjustments do not adversely affect the performance of the method, shall also be documented.

Most tests offered by EMSL are included on the standard chain of custody forms and selected by the customer by use of this form, or by documenting the test number selected on their own chain of custody. If a method is not selected by the customer, the laboratory shall communicate with the customer to determine which methods are most appropriate. If a customer selects an inappropriate method, they will be contacted immediately to determine the most appropriate method for their needs.

Where no standard methods are available, laboratory developed or modified standard methods may be used once they are appropriately validated, and once the laboratory confirms it can operate the procedure. The customer will always be made aware of the procedure to be used prior to testing.

5.4.3 Laboratory-Developed Methods

As noted above, where published standard methods are not available, EMSL will develop its own methods for an analysis, or modify existing methods to ensure they are appropriate for the test requested. Validation of these methods is discussed below. Development of new methods is a planned activity and assigned to personnel with appropriate expertise. The SOP will be reviewed and approved by the national director for that area of analysis.

5.4.4 Non-Standard Methods

5.4.4.1 Use of Non-Standard Methods

Before any non-standard method, including modified methods, is implemented, the customer (or other recipient) must be consulted on the new procedures. The customer should provide approval prior to beginning the work.

Non-standard analytical procedures must be written and validated. The method validation process should prove that the alternate method:

- Meets acceptable criteria for precision and accuracy (see validation section below)
- Meets or exceeds analytical sensitivities required by the customer
- Does not introduce uncontrolled or unknown biases, including matrix interferences

5.4.4.2 Departures from Standard Operating Procedures

Major departures from the EMSL standard operating procedures, whether technically adjustments or modifications, must go through a review by the national directors, regional managers, or quality assurance manager prior to use. Major departures include, but are not limited to:

- Different sample preparation procedures

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- Use of alternative analytical instrumentation
- Use of additional or different reagents

Departures from standard operating procedures may be a result of a customer request. Review and documentation of major departures include:

- Reason for deviation from method
- Validation of procedure
- Applicability of alternative method
- Availability of needed resources (if applicable)
- Assurance data is reported with appropriate references and disclaimers (if applicable)
- Record of alternative procedure or policy is maintained as part of the corporate files

Where departures from standard operating procedures are not a result of a customer request, the laboratory must gain the customer's approval.

Validation of Non-Standard Methods or Departures from SOPs

A validation study must be performed before analysis is performed on customer samples for any non-standard method or departure from method. A validation study involves:

- Comparison against established methods (if available)
- Effects of deviation
- The assurance results are equal to or better than the original method (if original method exists)

The procedure used to validate a method also involves an ongoing process with continuous review of the QC data, including analysis of standards, inter/intra analyst reanalysis of samples, participation in round robin programs and proficiency testing programs.

Standard quality control acceptance criteria are applied to monitor performance of the method unless other QC criteria are established. If other criteria are used, they should follow general Good Laboratory Practice (GLP) guidelines.

5.4.5 Validation and Verification of Methods

The majority of the procedures utilized by EMSL laboratories are based on published methods issued through governmental regulatory agencies and independent standards organizations. These methods must be validated following the *EMSL Method Validation SOP* (GEN-SOP-310) to verify acceptable method performance. Validation must occur before performing analysis on customer samples.

TNI requires an initial DOC be conducted for each method and analytical specialist prior to using any method, and at any time there is a change in instrument type, personnel or method, or any time that a method has not been performed by the laboratory or analytical specialist in a twelve (12) month period.

In cases where a lab analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for TNI accreditation, and there have been no significant changes in

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instrument type, personnel or method, the ongoing DOC shall be acceptable as an initial DOC. The laboratory shall have records on file to demonstrate an initial DOC is not required.

Methods used by EMSL are also continually validated through the review of QC analysis including analysis of known standards, inter/intra analyst reanalysis of samples, and participation in round robin programs and proficiency testing programs. When new services/methods are implemented in a laboratory location with newly trained analysts, a data review period will be set up by corporate QA and the National Director/Vice President of the related division. This process is created to ensure the data originating from the laboratory has the proper oversight to confirm its accuracy, and to provide any guidance necessary. During this time period, QA and the head of the related department will inform laboratory personnel of any issues/concerns discovered during the review. Once both the QA department and head of the related department are comfortable with the data, and a sufficient period of time for review has elapsed, the review period can end. The review period will be flexible, and the amount of data to review will be determined by QA and the head of the related department. A minimum data review period is one month, but is recommended to extend up to three months. The volume of data/reports reviewed is also based on the number of samples received, and can be adjusted as time progresses. For example, 50% of the data will be reviewed for the first month, 25% for the second month, and 10% for the third month, as long as no issues or concerns are detected.

5.4.5.1 **Verification of Methods**

When a new published method is implemented in a laboratory, a verification package shall be compiled. This package would include initial calibration of the instrument; proficiency tests (if available); a new demonstration of capability, if required; any quality control associated with the method; and other specific requirements written into the method, if applicable. Once the package is compiled, it is sent to the QA department for recording. When new method versions are released, the QA department or related head of the department will notify the laboratory if a method validation package is required.

5.4.6 Estimation of Uncertainty of Measurement

The QMS Manual program-specific modules and SOPs address the estimation of analytical uncertainty for each program area. EMSL's policy is to have a procedure for the reasonable estimation of analytical uncertainty for its quantitative tests.

EMSL's uncertainty procedures address only analytical uncertainty and do not account for contributors to uncertainty resulting from sampling procedures. Contributors are listed in the workbooks and/or the SOPs. Unless stated otherwise in the analytical procedure or QMS Manual Modules, EMSL uses measurands from repeated analysis of prepared standards over time as a basis for determining uncertainty for a test method (Type A approach). In general, replicate and/or duplicate quality control measurands are used to generate mean recoveries and standard deviations for the method over time. Using this mean recovery, each method will be evaluated upon request to determine the uncertainty and probable bias of the method. Expanded uncertainty will then be derived by multiplying the standard uncertainty by a k factor (i.e., the student t value at 95% confidence interval which is related to the degrees of freedom (v) of the data set used in the calculation (v=n-1)).

Uncertainty is determined using QC template Excel workbooks which have been designed to calculate sample results, chart control chart data for precision and accuracy of each run, and which calculate uncertainty data for each measurand. Instructions on the use of these workbooks can be found in the workbooks themselves. References to the proper workbooks can be found in the program specific QMS Manual Modules.

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Each method (either in the SOP or in a separate document, such as an uncertainty worksheet) contains an evaluation of the sources of uncertainty, as well as the procedure for estimating uncertainty. Uncertainty will be reported if requested by the customer, when required by the analytical method, when necessary for interpretation of results, or when uncertainty affects compliance with a known specification limit. Even if not requested, all necessary data for evaluating uncertainty will be retained in the laboratory. When uncertainty is reported, it shall be reported in the same units as the measurand, and shall include the coverage factor and confidence interval used in the estimations. Bias will be reported separately where it exists and is uncorrected.

Uncertainty shall be re-estimated when changes to operations occur that could affect it, such as changes in instrumentation, modifications to methodology or technique, etc.

5.4.7 Control of Data

5.4.7.1 Continuous Data Validation

Data validation is a continuing process that takes place every time samples arrive at the laboratory and is carried through during log-in, analysis and final reporting. If any of the errors found during this proofing process are not traced back to transcription or analytical error, then the computer system is suspect and will be investigated. The processes that undergo this continuous validation include:

5.4.7.1.1 Sample Receiving

At completion of the log-in phase, the internal chain of custody and bench sheets appropriate to the analysis requested are produced by LIMS (SMXP or Element). Also at this time, an internal chain of custody is produced. This document summarizes the sample set with customer and sample information (including IDs), and generates a chain of custody log that is initialed and dated by everyone that handles the samples in the laboratory. The laboratory manager checks the accuracy of this information generated in LIMS.

Only labs and methods approved by corporate management for remote log-in may follow this process.

5.4.7.1.2 Sample Preparation

After log-in, the samples and all its corresponding paperwork are sent to the lab for preparation prior to analysis. Upon receipt, the prep person and/or analytical specialist initials the customer chain of custody confirming the requested analysis is being performed. At this stage too, any problems with the samples or paperwork are noted and brought to the attention of the laboratory manager.

5.4.7.1.3 Sample Analysis

After sample prep, the samples and all corresponding paperwork are sent to the analytical specialist. The analytical specialist initials the requested analytical method on the original chain of custody. At this stage, any problems with the paperwork (or samples) are documented on the sample paperwork and also brought to the attention of the laboratory manager. Upon completion of analysis, the analytical specialist dates and initials the internal chain of custody in the appropriate section.

The analytical process is obviously one of the most important stages in assuring data validity. The procedures taken to ensure the validity of the sample result include

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calibration of equipment, formulation of method detection limits, instrument detection limits, determination of analytical specialist qualifications, instrument, and method precision and bias, etc., are very specific to the particular analysis being performed. Details of these procedures can be found in the SOPs for the various analyses.

5.4.7.1.4 Analytical Results Entry

iL@b is a custom module developed for the EMSL LIMS. It allows analytical specialists to input data directly into the lab database rather than relying on the added step of transcribing from paper bench sheets to the database, and does not utilize predefined default optical properties. iL@b is being rolled out gradually to all departments. Once approved by the analytical specialist, the data is available in the database for future review as discussed below, both as raw data and in the final report format.

For analyses not covered by iL@b, once sample analysis has been completed, all paperwork including field data sheets, field chain of custodies, internal chain of custodies, sample bench sheets, and any other paperwork generated to this point is sent to the data entry personnel. At this stage, results are transcribed from the bench sheets and instrument printouts into the LIMS (or Excel) reporting spreadsheet. Analytical results are entered either by personnel approved for data entry, or by the analytical specialists themselves. The software stores the analytical data, performs calculations, and generates the final report. The person performing the data entry would be aware of any error or unusual performance of the LIMS and would bring this to the attention of the laboratory manager.

This final report is reviewed by the laboratory manager (or designee) and approved before being forwarded to the customer. Chains of custody are copied and placed in the laboratory master files along with the analytical worksheets and raw data.

5.4.7.1.5 Proofing of Reports

After data entry, reports are sent to the laboratory manager or designee for review. The reports are reviewed for completeness and accuracy. A check on the quality control analysis performed in association with the results is also performed. This is also another point where transcription errors are caught and corrected. In addition, if the analytical data looks questionable for any reason, hand calculations are performed to verify results.

If errors are found, the report is returned to data entry for transcription error corrections or back to the lab if there are problems with the data. Where errors are determined to be a result of non-conformities in lab process, a corrective action will be initiated. Random errors, such as typographical errors, do not need to initiate corrective action unless they occur frequently, indicating a systematic problem which needs correction.

5.4.7.2 Computer Software

5.4.7.2.1 General

EMSL utilizes an automated Laboratory Information Management System (LIMS) to record, document, and assimilate pertinent field, laboratory, and administrative data. The LIMS system is referred to as SampleMaster XP (SMXP) or Promium Element.

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The validation of the SMXP software, including final report templates, are performed by the corporate IT Department and the Quality Assurance Department and the SampleMaster Beta testing team, which consists of several EMSL Subject Matter experts.

The IT Department is responsible for maintaining updates and revisions and for tracking distribution. Release notes for each release of SMXP are prepared and distributed by the IT Department. A complete release history and historical release notes can be obtained from the IT Department at any time.

Validation of Element was conducted by Promium, and is maintained by Promium through routine service. New versions are tested at Promium, and implemented at EMSL, when available.

5.4.7.2.2 Validation of Computer Software and Data

Analytical data storage, processing, and reporting are facilitated through use of SMXP. SMXP software is run on Windows-based, PC computers. EMSL-developed Excel spreadsheets are used to track QC data, equipment calibrations, and environmental conditions. These spreadsheets are validated before being made available on E-link. The corporate IT staff are responsible for ensuring all computer systems, hardware, and software, are documented, inventoried and adequate for use. All systems are operated in safe environments and maintained to ensure proper operation. The computer systems responsible for handling of analytical data have been set up to process data in a way that ensures integrity.

Additional information on the EMSL Software Development Life Cycle, which includes the validation of LIMS software, can be found in the *General Guidelines for EMSL Information Technology* document found on E-link.

All computerized systems, especially the software used for data reporting, must be initially validated prior to use, and then subsequently periodically re-checked during the ongoing validation process.

All calculations and reporting performed by the software is implemented by the laboratory management, the corporate IT staff, or the QA manager. This coordination between the QA Department, laboratory management, and the IT Department allows the software to be reviewed and altered as necessary to comply with regulatory agencies and/or accrediting organizations requirements.

EMSL employs a system to periodically test and verify the software used for sample log-in and report generation is performing properly. To do this, a “dummy” set of samples has been created for each type of analysis the lab performs. Each set has a sufficient number of samples to be able to test as many variables as possible. Examples are:

- No volume
- Low volume / low sample weight
- High volume
- Low concentration
- High concentration
- None detected
- Overloaded sample

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The "dummy" sample reports are proofread for accuracy of all text fields, and all results have been verified by hand calculation. The results of each periodic software validation are documented along with the date performed. If there is any discrepancy from the master that cannot be attributed to data entry error, the QA Department is notified, and corrective actions implemented.

5.5 Equipment

5.5.1 Local Equipment Inventory and Logbook

Each laboratory is required to maintain an inventory of all critical equipment in use at the laboratory. Since each laboratory's inventory varies according to size and scope of work performed at the laboratory, it is the responsibility of the lab manager to ensure this equipment inventory reflects actual equipment at that laboratory and includes wherever available, the manufacturer, model, serial number, date put into service and date taken out of service. This equipment inventory is maintained in the "Equipment Inventory" tab of *GEN-FM-450 Equipment Inventory and Maintenance Log*. The column indicating 'Date Taken Out of Service' on the "Equipment Inventory" tab refers to the date when non-functioning equipment was moved to storage in a lab, returned to EMSL's corporate office, or otherwise disposed of. For non-functioning equipment removed from the lab, the lab will add a copy of the "Equipment Inventory" tab, rename it "Out of Service Equip. Inventory," and list only equipment no longer present in the lab. On that tab, the lab will enter 'Returned to EMSL Corporate office' or 'Disposed of' in the 'Equipment Location' column.

In addition, a logbook shall be maintained for each piece of critical equipment in use at the laboratory. All maintenance, repairs, calibrations performed on the instrument shall be recorded, along with the identity of the equipment and software, mfg. name, type ID and serial number, and current location (if appropriate). For most labs, this is done within *GEN-FM-450 Equipment Inventory and Maintenance Log*. However, in some circumstances this will be maintained in a separate Equipment Log notebook. Labs are strongly encouraged to use the spreadsheet whenever possible. Each instrument service entry shall contain the following information:

- Date and time
- Initials of servicing individual (include if in-house or outside agency)
- Description of problem, evaluation of equipment and any data that may have been affected; notify client if necessary
- Maintenance element examined (note if any repairs or replacement of component were made); or, make the Certificate of Analysis available, detailing the equipment's service or repairs
- Description of equipment's acceptability to return to service and name of personnel approving; or, make the Certificate of Analysis available, detailing the equipment's acceptability, i.e., passing calibration, criteria, etc.
- Pertinent comment(s)

NOTE: All information from the items listed above may be entered into the Description of Problems and Action Taken sections of *GEN-FM-450 Equipment and Maintenance Log*.

5.5.2 Subcontracted or Leased Equipment

Any laboratory equipment which is to be used during analysis, other than EMSL equipment, (e.g., equipment borrowed/eased from an outside organization such as an academic institution), must undergo complete calibration, applicable start-up procedures and QC checks, as described in the laboratory SOP for the utilized instrument. These procedures must be performed prior to the start of

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any sample analysis. All maintenance records, manuals, and performance records must be made available for review and approval by EMSL staff.

Records are to be maintained which include:

- Type of instrument subcontracted
- Date and purpose
- All raw QC data generated including calibration information

5.5.3 Instrument Calibration

Analytical instruments including GC, GC/MS, ICP/MS are calibrated following applicable SOPs, as per associated analytical method requirements, and also meeting regulatory Standards.

Accrediting authorities and standard published methods have specified the frequency and manner in which a laboratory must calibrate their support equipment (including thermometers, balances, weights, pipettes, etc.). For laboratories maintaining ISO 17025 accreditations (e.g., AIHA LAP, LLC; NVLAP, A2LA, TNI), calibrations of equipment used in accredited tests must be performed internally by trained personnel using approved accreditation procedures, or by an outside calibration firm accredited to the ISO/IEC 17025 standard. The calibration must be performed following the ISO standard.

Before being placed into service, or returned to service after repairs or modifications, the equipment and its software is calibrated and checked to establish it meets EMSL and method specifications. Thereafter, calibration schedules established in this QMS Manual and related program specific modules, as well as related SOPs shall be followed. Intermediate calibrations may be required, as necessary. All calibrations should be documented in *GEN-FM-450 Equipment Inventory and Maintenance Log.*

Labels shall be placed on all calibrated equipment and reference standards, where space permits, which include date of last calibration and date calibration is next due, along with any correction factor, where applicable. Where space does not permit the use of a label, a label shall be placed near the instrument or standard and shall be associated with the instrument by serial number or equipment ID.

Whenever calibration leads to a set of correction factor, these correction factors shall be referenced on the accreditation label or otherwise affixed to the equipment, and shall be included in any calculations for which the correction factor is relevant.

Specific analytical instrument calibration requirements are found in the appropriate program module or related SOPs. Requirements for the calibration of common support equipment are included below. Also see § 5.6 of this manual for requirements for calibration/verification of common Reference Standards.

Note: References to ***calibrations*** refer to EMSL internal procedures or those performed for EMSL by outside calibration providers. EMSL does not provide external calibration services to customers.

5.5.3.1 Balances

Balances shall be calibrated upon installation, then annually thereafter, by an outside 17025-accredited calibration provider.

Balances are verified in the laboratory to stated tolerances each day of use against working calibration weights traceable to NIST as per *GEN-SOP-410 Balance and Weights Calibration Verification.* Acceptance criteria are established in the SOP and included in *GEN-FM-410 Balance Calibration Verification Workbook,* which is used to record verification data.

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Where verifications do not meet set acceptance criteria, the instrument shall be cleaned and re-checked. If verification still does not pass, instrument shall be taken out of service until it can be repaired.

5.5.3.2 Pipettes

Pipettes used for quantitative measurement shall be calibrated upon initial use, and verified quarterly thereafter, at a minimum. Pipettes may also be verified daily as described in *GEN-SOP-411 Pipette and Dispenser Verification and Calibration.* Measurements of dispensed weight are taken as per *GEN-SOP-411*, and results calculated using *GEN-FM-411 Pipette and Dispenser Verification.*

Acceptance criteria are established in *GEN-SOP-411 Pipette and Dispenser Verification and Calibration.* Where verification results are outside acceptance limits, the instrument shall be removed from service and adjusted or replaced, as appropriate. For adjustable pipettes, a failure at any check point requires the entire calibration to be repeated after adjustment.

Additional pipette, bottle top dispenser, and syringe verification or calibration forms are available for specific uses, including GEN-FM-411-1, GEN-FM-411-2, GEN-FM-412 and GEN-FM-413.

5.5.3.3 Working Thermometers/Thermocouples

All working thermometers shall be verified against a NIST-traceable reference thermometer (See § 5.6 below) following *GEN-SOP-401 Thermometer Calibration Verification.* Data shall be recorded on *GEN-FM-401 Thermometer Verification Calibration*. If deviations between the working and reference thermometers are within acceptable criteria range as defined by the SOP, the thermometer shall be labeled with the Correction Factor (CF) and use continued by applying the CF. If acceptance criterion is not met, the thermometer shall be immediately removed from use and repaired or replaced as appropriate.

NOTE: When recording results from Thermometers/Thermocouples for which a CF is necessary, the log where temperature is recorded shall make clear whether the CF has been applied. One approach is to record as Temp + CF (example: Instead of recording “31.8°C,” record as “32.0 - 0.2°C CF”).

5.5.3.4 Anemometer:

Thermal anemometer used for measuring laboratory hood flow shall be calibrated annually by an external service provider. The unit must have a valid NIST traceable ISO 17025 compliant calibration certificate.

5.5.4 Requirements for Calibration Certificates from External Calibration Services

When obtaining calibration services from an outside calibration service, it is crucial the calibration certificates received meet accreditation requirements. The following information must be present on the certificate, or if provided supplemental to the certificate, it shall be explicitly related to the certificate (e.g., by use of a calibration certificate number):

5.5.4.1 Evidence the measurements are traceable to NIST or an equivalent National Metrology Institute

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5.5.4.2 The report or certificate shall be endorsed by the recognized AB's symbol (or otherwise make reference to accredited status by a specific, recognized AB) with an indication of the type of entity that is accredited.

5.5.4.3 An estimate of uncertainty for the measurements made

5.5.4.4 Date of calibration, reference standard ID, and due date for next calibration

Note: While many reports contain a "best" uncertainty capability for calibrations performed under ideal conditions in the lab [a Calibration and Measurement Capability (CMC)], this does not meet the requirement of uncertainty of measurement for the specific measurements being reported.

5.5.5 Equipment Maintenance

The laboratory manager, in cooperation with the corporate QA Department, shall determine whether an instrument is maintained and repaired in-house or by an outside service firm. Servicing will also be performed when a need has been identified by calibration or other QC checks. When special service is needed, the laboratory manager should notify the national director and corporate QA manager of the need and reasons for service.

Where regular maintenance schedules are necessary (spectrophotometric instrumentation, for example), the schedules are documented in the analytical SOP. The laboratory manager is responsible for ensuring maintenance schedules are met.

As noted above, all maintenance shall be recorded in *GEN-FM-450 Equipment Inventory and Maintenance Log,* or in a laboratory-assigned notebook. This record includes all minor and major equipment maintenance. Thorough maintenance records provide valuable information regarding the equipment, and can serve as a tool to aid in future repairs. Once the maintenance/repair is completed, the laboratory is responsible for entering a description detailing what maintenance or repair was performed, in order to close the entry. In addition, laboratory management must ensure all areas of the maintenance log are completed, including but not limited to software and firmware versions, date in and out of service, model and serial numbers, EMSL asset ID (if applicable), etc.

5.5.6 Equipment Handling, Transport and Storage

The management of major laboratory instrumentation is performed at the corporate level by the Department of Instrumentation and Planning. This department purchases, tracks and ships primary analytical instrumentation and a variety of support equipment.

5.5.6.1 Shipping

Equipment is assigned a serial number and inventoried. Packaging and shipping are handled internally for equipment which is relatively easy to handle such as optical microscopes, hot plates, etc. When microscopes are shipped, each microscope is placed into a Pelican case for safe handling. Each item of the microscope must be placed into its specific area in the case, to ensure no damage to the microscope, and to maintain the microscope's proper functionality.

A professional hauling service vendor may be used for large equipment (generally > 100 lbs.) such as TEMs, spectrophotometers and fume hoods, or where equipment is fragile.

Once equipment has been received by the laboratory, the instrumentation must undergo performance checks including:

- Calibrations

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- IDL and MDL study (where applicable)
- Quality control checks

These performance checks may be completed by the laboratory manager and/or the Department of Instrumentation and Planning depending on the type of instrument and the ability of the laboratory manager. All checks must be documented electronically or in the laboratory equipment maintenance log.

Note: See also the analytical SOP for that test applicable to the specific instrumentation.

5.5.6.2 Storage

Laboratories are to adhere to the manufactures' requirements for the storage of instrumentation.

5.5.7 Equipment Serviced or Calibrated by an Outside Vendor

In the event any major equipment is sent out of house for repair, the laboratory manager will maintain a file documenting:

- Date of shipment
- Vendor information
- Service needed
- Date of return

This information is to be recorded on *GEN-FM-450 Equipment Inventory and Maintenance Log*.

The laboratory is responsible for ensuring all equipment is calibrated prior to placing back into service. Calibrations must meet the acceptance criteria established for that equipment.

For laboratories maintaining ISO 17025 accreditation, outside calibrations must be performed to ISO 17025 standards by a calibration laboratory accredited to ISO 17025. The certificate of calibration must indicate the calibration has been performed following the ISO standards.

5.5.8 Authorization to Operate Equipment

The laboratory manager is responsible for ensuring only authorized personnel operate the major laboratory instrumentation. Authorization is granted based on training and experience as detailed in each of the method sections. Authorization may be given to personnel through the completion of the qualifications checklist or verbally, depending upon type of instrumentation. For example, approval for operation of the transmission electron microscope or spectrophotometer is recorded on the training checklist for the test method, while the approval for an acetone vaporizer or water bath may be done verbally.

5.5.9 Instrument Manuals

The laboratory manager is responsible for maintaining and reviewing all instrument manuals pertaining to use, calibration and maintenance. Instrument manuals are to be made available to the analytical specialists. The laboratory manager is responsible to be informed of, and keep current with, all new releases of information on all equipment.

5.5.10 Defective Equipment

Analytical and support equipment found to be defective or performing poorly (out of calibration) is removed from operations until it can be repaired. The defective equipment is to be clearly labeled as "out of service." In PALA accredited labs, defective equipment must be subject to control of non-

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compliant work. The laboratory manager is to investigate whether the defect has affected any reported analytical results.

5.5.11 Changes to Equipment Inventory

In the event equipment is replaced, this information is recorded on the equipment maintenance log.

5.6 Measurement Traceability

5.6.1 General

According to the International Vocabulary of Basic and General Terms in Metrology (VIM), traceability is the "property of the results of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparison, all having stated uncertainties." Any material used for calibration purposes in the laboratory must have its value traceable to NIST, if possible. Procedures have been developed following AIHA LAP, LLC's *Guidelines for Traceability*.

EMSL is committed to ensuring the traceability of data to national standards. This is accomplished by setting specific requirements, including:

- Use of Standard Reference Materials (SRMs) as certified and traceable to the National Institute of Standards and Technology (NIST). SRMs are used for QC analysis and training for achieving measurements of analytical specialists and overall laboratory accuracy. Certificates of analysis for SRMs must be on file in the laboratory before using the material.
- Calibration of instrumentation against NIST-traceable standards. Wherever possible, reference materials used in the calibration and verification of instruments shall be obtained from a recognized National Metrology Institute (NMI) (e.g., NIST), or a producer accredited to ISO 17034:2016 in combination with ISO 17025 calibration. For labs accredited to ISO 17025 by A2LA or AIHA LAP, LLC, the 17025-accrediting body of the producer shall also be an APLAC signatory (e.g., A2LA, ACLASS, and NVLAP).
- Analysis of consensus standards or proficiency testing samples where a qualified NIST-traceable reference material is not available
- Ensuring results are traceable to lots of consumables used in the prep and analysis of samples

5.6.2 Reference Standards and Reference Materials

EMSL strives for reference materials used by the laboratory to be traceable to certified reference materials or other well-categorized reference materials, where applicable. Reference materials shall be obtained from a vendor with a certificate of analysis which identifies the lot number. When selecting sources for reference material, sources should be from a national metrology institute or an accredited reference material provider (RMP) that conforms with ISO 17034:2016 in combination with ISO/IEC 17025, or *ILAC Guidelines for the Competence of Reference Material Producers, ILAC G12*. For laboratories accredited by AIHA LAP, LLC or A2LA, reference material providers must be selected which hold accreditations by accrediting bodies recognized directly or indirectly by ILAC. The two major North American accreditors of RMPs are A2LA and ACLASS. Accredited RMP lists can be found on their websites. Care must be taken when ordering standards to ensure the material ordered is under the RMP Accreditation. Accredited RMPs often have several classes of reference materials, with only one or two classes being compliant with ISO G34 guidelines. Certificates shall be endorsed with the ISO 17034:2016 RMP accreditation, when available. ISO 17025 accreditation symbols are insufficient for

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reference materials under new ILAC guidelines, but are good intermediate quality signifiers when no ISO 17034:2016 compliant material is available.

Reference standards shall be NIST-traceable where applicable, and include a 17025 calibration certificate showing traceability and uncertainty of measurement in compliance with the requirements in § 5.5.4 above. The reference standards shall be with ±10% of the requested concentration, unless the method or other requirement is more stringent. Standards received within this tolerance are considered acceptable, and may be used without applying a correction factor. Should the standard be received outside the ±10% tolerance, a correction factor will be applied, or a new standard will be purchased. Recording the standard/reagent in the logbook is verification of review for the acceptance criteria. Certified reference materials received that are produced under ISO 17034 and/or NIST, do not require review, as they undergo strict testing and tolerance to meet method specifications. Reference standards of measurement (e.g., NIST traceable thermometer, calibrated weights) maintained by the laboratory should only be used for verification of calibrations, when possible.

Having multiple laboratory operations can facilitate the cost savings associated with the variety of standard materials required to check the performance of both instrument and analytical specialists. EMSL Analytical allocates and distributes these standard reference materials, where possible from 3 sources:

- The corporate laboratory facility
- The Quality Assurance Department
- The regional managers or national directors

In order to track the transfer of standards and reference materials between the original sources and the laboratory(ies), a chain of custody type form must be completed (see *EMSL Standard and Reference Material Traceability Form*). This form ensures traceability of measurements to a national standard and verification of measurements to reference samples. Reference materials are to be clearly labeled and stored as to maintain integrity.

As with equipment, specific procedures for which reference standards and reference materials are required are detailed in the QMS Manual program-specific modules and analytical procedures.

Reference materials shall be stored according to manufacturer recommendations. If no expiration date is included on the material, then a date shall be assigned that is appropriate for the material.

Common measurement standards and general policy requirements for verification/recertification are listed below:

5.6.2.1 Laboratory Working Weights:

Laboratory working weights used to verify balances and other equipment must be checked annually in-house using reference weights.

5.6.2.2 Reference Thermometer/Thermocouple:

The laboratory shall send at least one thermometer to an outside ISO 17025-accredited calibration service for calibration annually. Additional details regarding thermometer calibration frequency can be found in department-specific modules. This thermometer shall have readability (e.g., the smallest division which can be distinguished) at least as precise as the most precise temperature measuring instrument in the laboratory. Each temperature measuring instrument shall be verified to this Reference Thermometer at least every twelve

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(12) months. See *GEN-SOP-401 Thermometer Calibration Verification* for additional requirements.

5.6.2.3 Stage Micrometers

Stage micrometers used in the verification of microscope performance as per the program specific QMS Manual modules and technical SOPs shall be calibrated prior to first use, and if damaged, by an ISO 17025-accredited calibration service. The calibration certificate shall meet the requirements of § 5.5.4 above. If a laboratory does not own its own calibrated Stage Micrometer, one can be loaned from the corporate QA Department upon request.

5.7 Sampling

With the exception of certain customers for whom EMSL performs wastewater sampling (see *GL-SOP-026*), EMSL does not conduct sampling for its customers. Sampling guides are available from the EMSL website for tests conducted by EMSL. Customers are instructed to ship samples in clearly labeled, non-breakable airtight containers, and to package such samples so as to minimize damage or change in condition of the samples. Samples shipped by air must be placed in containers that minimize jostling and damage. Samples should be packaged in non-static packaging, as applicable.

As EMSL is not present at the time of sampling, (except as noted above), we take no responsibility for the quality of the sampling performed or information provided (e.g., sampling method, identity of sampler, locations, times, or volumes). EMSL procedures cover only the analysis of the samples submitted. Any specific comments about sampling that the customer wishes to add to the report should be communicated on the chain of custody form, or in written correspondence to the lab.

Compliance samples may be rejected if it is determined they have been inappropriately sampled (e.g., improper volumes, containers, preservation, holding times). The customer is notified immediately if it is clear sampling has been performed incorrectly in such a manner as it may affect the analysis. Reports may contain disclaimers if the sampling may affect the analysis.

5.8 Handling of Test and Calibration Items

Rigorous sample tracking is fundamental to a QA program. The most thorough and complete analysis is useless if performed on the wrong sample.

The EMSL sample-tracking system is designed, to the extent that it is possible, to meet all litigation requirements. It is also designed to have redundancy safeguards wherever possible.

The procedures summarized below are described in greater detail in the *EMSL Sample Chain of Custody SOP* (GEN-SOP-702).

5.8.1 Chain of Custody

In order to ensure the integrity of any sample, records of its custody must be maintained throughout the sample collection in the field, acknowledgement of receipt, acceptance by the laboratory and analysis. The custody of the sample will be tracked via the completion of a chain of custody form.

With the exception of the sampling of wastewater for a select group of customers, EMSL Analytical, Inc. does not collect samples. Therefore, the chain of custody begins with the customer in the field, with the exception of TO-15 equipment, where the chain of custody begins with the preparation of the canisters and flow controllers. EMSL maintains chain of custody documents that customers are encouraged to use where they do not have their own form. Customers delivering samples without a chain of custody form will be required to complete a chain of custody prior to samples being logged-in

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at the laboratory. EMSL takes possession of samples by signing the "Received" section of the chain of custody form. The chain of custody then accompanies the samples through the laboratory until analysis and final reporting is complete. Original chain of custody forms are returned to the customer with the final test report.

In those instances referenced above where EMSL collects wastewater samples for a customer, an EMSL chain of custody will be initiated by the collector in the field as per *SOP GL-026,* and submitted for testing with the samples.

In most instances, information provided by the customer related to samples is received through the chain of custody. Disclaimers are included in the report when the information received can affect the validity of the data. Typical disclaimers state EMSL does not accept responsibility for sample collection or analytical method limitations, and the results only relate to the materials received.

5.8.2 Sample Receipt

Upon receipt of samples, the administrative specialist will check for obvious signs the sample integrity has not been compromised. Any problems with the samples will be reported to the customer immediately. The customer chain of custody will be signed indicating samples have been received by the laboratory.

5.8.3 Sample Acceptance

Samples are not accepted for analysis until they have been received and reviewed by the analytical specialist or preparatory personnel. This review includes verification of receipt of all samples against the customer chain or custody. If samples are found to be unacceptable for analysis (see SOP for examples of reasons for unacceptability) this will be communicated to the customer immediately, and this communication and any resulting instructions recorded. Refer to GEN-SOP-702 Sample Receiving and Chain of Custody for more information.

5.8.4 Log-in and Internal Chain of Custody

Log-in of samples is accomplished by authorized personnel using the Laboratory Information Management System (SampleMaster XP (SMXP) or Element). It is at this point that unique order ID numbers and Sample ID numbers are assigned. This order number is physically attached to the sample batch and serves to identify the sample set throughout the analysis. This, in combination with the customer ID number, uniquely identifies each sample. An internal chain of custody is also generated at log-in which documents the handling of samples throughout the laboratory. See the EMSL *Sample Receiving and Chain of Custody SOP* (GEN-SOP-702) for additional details on log-in and internal chain of custody procedures.

5.8.5 Archival and Disposal of Samples

Once the analysis is complete and the analytical worksheet is signed, the analytical specialist stores any remaining portion of the sample in an appropriate storage area. All storage boxes are to be stored in a safe manner for the period indicated for that category of waste, in accordance with regulatory requirements. When a storage box is full, the month in which the samples were analyzed (or similar reference numbering system as appropriate for the operations, i.e., billing number), is marked on it. A new storage box replaces the old one, which is then stored until time of disposal. All samples will be stored so as to provide protection from any possible contamination or loss of integrity.

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Any specific storage requirements are documented in the analytical SOPs or in the QMS Manual program-specific modules. Default retention times for samples are established in the program-specific Modules in this manual.

Upon request, samples will be returned to the customer.

5.9 Assuring the Quality of Test and Calibration Results

Laboratory performance will be determined by use of results from the following sources:

- Results from intra-lab and inter-lab testing
- Performance in on-site assessments from accrediting agencies
- Performance in proficiency testing programs
- Completion of internal quality audits
- Continued analysis of standard and reference materials traceable to third party programs
- Quality control reanalysis
- Calibration measurements

Quality control is performed continuously throughout the course of laboratory operations regardless of laboratory productivity, and is made part of the normal course of laboratory sample analysis. Frequency and volume of QC analysis is based on regulatory requirements and good laboratory practice. The frequency of QC analysis must be consistent and reflect the sample volume at any given time.

Performance criteria will be maintained for both individual analytical specialists and for the entire laboratory. The standards for acceptance criteria, frequency and volume are documented in the program modules.

5.9.1 Quality Control Program and Review

The overall quality control program is established and overseen by the Vice President of QA and national directors in order to ensure each EMSL laboratory produces quality data. Each branch laboratory's QA program is implemented and managed by the laboratory quality representative for that location. This process ensures fulfillment of our commitment to our customers, that our data is legally defensible, and that all personnel perform their responsibilities properly.

In addition to the review of quality control data for final report approval, the overall QC performance of the laboratory shall be reviewed on a regular basis in accordance with regulatory agency requirements. Specific quality control procedures are detailed in the program modules.

In general, QC analysis represents at least 10% of all analysis performed. QC analysis will entail inter-analyst reanalysis, intra-analyst reanalysis, intra-laboratory reanalysis, analysis of reference standards and blanks at the frequencies required by the analytical method and/or program specific QMS Manual Modules.

Where a specific percentage of QC is required, the lab manager or lab quality representative must ensure this is considered the minimum percentage of QC performed. If QC is to be performed with each run, even if the run is smaller than the maximum allowed run-size, QC shall be performed with the run. If the maximum allowed run size is exceeded, the required QC shall be increased accordingly to maintain the required percentage. Where a specific number of samples between QC is not specified, the lab shall strive to conduct QC in as real-time as possible, and should be completed prior to the reporting of analytical results for samples used for QC. The intent of percentage requirements is to suggest an approximate frequency at which QC should be performed. Likewise, QC results should be reviewed in real-time and prior to reporting of results, in order to identify potential problems without calling into question associated samples.

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The laboratory manager or designee reviews the quality assurance data on a monthly basis (minimum). If the quality control analyses are within control limits, the results will be cleared for reporting. As long as those statistics are deemed acceptable, customer reports will continue to be processed.

If the difference between duplicate analyses exceeds statistically derived control limits, the laboratory manager and the analytical specialist will review the sample data and resolve the differences. A detailed corrective action report recording all activity is submitted to the QA manager. (See "Control of non-conforming work" and "Corrective action" sections of this manual.)

The quality review also includes a check on verification checks of the instruments and/or analysts (standards). Measurements are checked against the acceptance criteria. If any measurement is out of compliance, the laboratory manager is responsible for investigating the cause(s) and initiating a corrective action.

In cases where analytical specialists are transferred temporarily to another laboratory, QC data produced by that analytical specialist will be associated with the laboratory at which the data was produced for purposes of determining percentages of QC analysis performed. Likewise, inter-analyst data produced by that analytical specialist will be associated with the lab at which it was produced. The analytical specialist's CV from their original lab shall be utilized when applicable.

However, a transfer analytical specialist's QC data will also be associated with the analytical specialist for purposes of determining on-going capability. A copy of the data may be held by the analytical specialist and placed in their ongoing training records at their home lab. This may include intra-analyst samples as well as analysis of known samples or PT/RR results.

5.9.2 Quarterly Report

The person responsible for overseeing the QA in the lab (i.e., laboratory quality representative or laboratory manager) completes a report every quarter for the laboratory manager. In the cases where the laboratory manager is the laboratory quality representative, the report is written for the national director or corporate QA manager. These reports are designed to express concerns, address needs, and report any major changes to management. They are ultimately submitted to the corporate QA Department for review.

Format shall include the following topics:

- Summary of quality control data (e.g., QC reanalysis that may have been out of control limits and the corrective action)
- Uncertainty measurements – Sr for Micro; CV for PCM asbestos
- Summary of the number of corrective actions initiated and closed along with detail on any major issues (CAR/PAR workbook attached to report)
- Summary of preventative actions (CAR/PAR workbook attached to report)
- Calibration/Instrument maintenance; dates of any quarterly, semi-annual, or annual equipment calibrations and any non-routine maintenance performed
- Equipment issues; summary of any outstanding equipment issues
- Summary of quarterly contamination monitoring
- Customer problems
- Safety issues and results of safety audits
- Report of findings from any internal audits or external audits conducted during quarter
- Results of proficiency testing and/or round robin analysis
- Summary of staffing issues or changes
- Risk identification, improvements, and internal/external issues

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- Miscellaneous
- Review of corporate website to ensure lab accreditations, open hours, etc. are accurate

5.9.3 Proficiency Testing Programs

Laboratories participating in proficiency testing (PT) programs will ensure the analysis is performed using the same sample tracking procedures and analytical methodology, and is analyzed by the same analytical specialist(s) as under normal, customer sample conditions. At no time is there inter-laboratory exchange of proficiency samples.

- Asbestos
    - NVLAP – for PLM bulk and TEM airborne asbestos analysis
    - AIHA LAP, LLC-IHPAT
    - New York State ELAP – for asbestos in air, bulk, and water
- Env. Micro
    - AIHA LAP, LLC-EMPAT – for environmental microbiology
    - NYS ELAP – water microbiology
    - ERA – microbiology
    - CDC Elite for Legionella
    - Wisconsin State Laboratory of Hygiene for Cryptosporidium and Giardia
    - Sigma Aldrich for Legionella
- Env. Lead
    - ERA – Environmental lead
    - NYS ELAP – Lead (wipes, paint, soil, air)
    - AIHA LAP, LLC-ELPAT Lead (wipes, paint, soil, air)
- IH/Chem
    - IHPAT, organics, metals, silica
    - NYS ELAP – non-potable water chemistry
    - ERA – TO-15, organics, inorganics
    - WASP – for formaldehyde
- Food
    - API for Food Micro and Food Chemistry
- Radiochemistry/Radon
    - Bowser-Morner – for radon
    - ERA – for radiochemistry
- Materials Science
    - ASTM for Carbon and Alloy Steel (Materials Science)

Samples with instructions and accompanying report sheets are distributed to the appropriate laboratory staff or designee. The samples are incorporated into the normal sample load and analyzed as a normal customer sample, on a rotating basis, between qualified analysts. Results are calculated and reported on the supplied forms. The result forms are double-checked against the raw data for data entry transcription or omission errors.

Records of proficiency testing analysis are to be completed and maintained in a separate laboratory PT file. This data may also be maintained for each participating analytical specialist in his or her personal training file.

PT samples are scheduled, analyzed, reviewed, and reported similar to customer samples.

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Note, for Asbestos only: For laboratories with multiple analysts, only one analyst analyzes the PT sample. Once the results are reported and the scored results are received from the PT provider, all qualified analytical specialists shall analyze the proficiency samples. Results from all analytical specialists are reviewed by the laboratory manager and compared to the official results.

The data is reported using the appropriate format and method. Data may be reported by mail, fax or by the internet, depending on the requirements. If email results are required, the instructions given by the submitting agency are followed. Copies of confirmation of "data sent and received" are placed in the file with the data. The laboratory manager is responsible for submitting the scored results from each PT round to the Quality Assurance Department, where they are tracked for trends and evaluated against acceptance limits.

Whenever a laboratory reports an outlier on a proficiency testing round, a Corrective Action shall be initiated to review the root cause(s) of the outlier. As this is equivalent to reporting incorrect results to a customer, a PT outlier should be treated accordingly. This process shall be completed within thirty (30) days of receipt of results.

The laboratory must maintain Proficiency status, "P," for all parameters tested and reported. If the laboratory becomes non-proficient, this will be indicated in the report to the laboratory containing the results of a given study. The lab manager, lab quality representative or designee shall investigate the reasons for the poor performance. A corrective action plan will be developed by the QA manager and the lab manager. The plan will be written by the laboratory manager, who will submit the plan to QA manager for review. The plan will include all actions that will be taken (along with a timetable) to bring the quality of data to an acceptable level. Once the plan is acceptable, this should be forwarded to the corporate quality assurance manager for review and approval.

All records for proficiency samples are kept in files for each analytical specialist, along with the scored results.

Several accreditation bodies (ABs) require that, as a condition of accreditation, results from proficiency testing (PT) programs used as a demonstration of competency for methods for which the laboratory is accredited be reported to the AB on a regular basis. EMSL authorizes the release of proficiency testing results from the proficiency testing provider to its various accrediting authorities whenever such disclosures are required. When possible, standing authorizations are granted. The QA Department is responsible for ensuring the distribution of proficiency testing results to outside agencies when requested or required. See *GEN-SOP-851 3rd Party PT Reporting* for current requirements. A list of ABs that require PT results be forwarded on receipt is included in the SOP, along with details on how results should be reported.

In addition, for food accreditations, A2LA requires form F237 be submitted with the application specifying the four-year testing plan for accredited food tests.

Where commercial proficiency testing programs are not available, proficiency is obtained by:

- Participation in a round robin program, and/or
- A minimum of 20 QC data points are obtained initially to determine upper and lower control limits at three standard deviations. Program shall offer at least 2 rounds per year, separated by a six-month time period. Each set of samples must include 4 blind spikes.

5.9.4 EMSL Round Robin Programs

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Periodically, the Quality Assurance Department, national directors and/or technical division VPs, will provide a company-wide round robin program. Samples are to be analyzed by all active analytical specialists. The laboratory manager is to submit results of all analytical specialists who participated in the round to the Quality Assurance Department, where all results will be scored and graphed using standard deviation statistics.

The laboratory manager is responsible for ensuring any results falling outside of the control limits be investigated, and a corrective action report completed.

5.9.5 Infrequent Analysis

In cases where a laboratory may receive few or infrequent samples for which they hold accreditation programs, they must maintain analysts' skills and proficiency, and continue to follow the procedures for proficiency testing and participation in RR programs.

5.9.6 Trend Analysis

QC data is charted over time in order to evaluate analyst and laboratory performance. This data shall be reviewed by the laboratory and/or the Quality Assurance Department. Statistically relevant trends should trigger an evaluation.

Items being monitored:

- Failures exceeding the Control Limits (3s)
- Two consecutive points above or below the Warning Limits (2s)
- Seven (7) consecutive data points on either side of the mean
- Seven consecutive points moving in the same direction

Trend analysis shall be documented along with conclusions. If any actions are taken as a result, these may be documented as preventive actions unless a failure has occurred. Failures should be documented as a corrective action. Trend evaluations shall be included in quality reports submitted to the laboratory manager and corporate Quality Assurance Department, where appropriate.

5.10 Reporting the Results

The customer report is, ultimately, our "final product." This report reflects on our standard of quality. This section describes EMSL corporate policy on the procedures, policies, and formats for reporting analytical data. Additional, test specific requirements are listed in the program modules.

5.10.1 Test reports

Each final report will have at a minimum the following information:

- Laboratory identification and address
- Name and address of customer
- Date of receipt by laboratory (or original chain of custody attached)
- Unique sample IDs
- Description of sample (or original chain of custody attached)
- Identification and description of test procedures performed
- Results of testing and analysis
- Sample preparation date (where applicable)
- Analysis date, and time (if holding time is <72 hours)
- Any deviations or additions to test specifications
- Name and signature of responsible person (laboratory manager or designee)
- Any applicable disclaimers and statements (See specific SOPs)

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- Notification of any deviations from the test method
- An estimation of uncertainty when requested by customer, required in the analytical SOP, or when necessary for the interpretation of data
- For reports issued under NVLAP, a statement that the report must not be used by the customer to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the federal government
- For PALA accredited labs, including the following: Title; unique ID number on report; page numeration, including end point; units of measure; disclaimer stating report relates only to samples tested and not reproduced; and date of sampling
- Information on any analyses that had been subcontracted (attach subcontract lab's report)

The signature of the analytical specialist is not made a part of the final report unless requested by the customer. Analytical specialists accept responsibility for the data generated by entering the data electronically, or signing the worksheets where applicable.

Any modifications to the methods cited on the report will include all applicable comments and disclaimers as issued by the QA manager.

When by written agreement any of these items are excluded from the final report, a copy of the written agreement shall be maintained in the laboratory, and all information not reported shall be readily available upon request. Where requests to remove required disclaimers are received, the laboratory should consult with the QA Department or national directors prior to proceeding, since these are in many cases designed to protect EMSL by qualifying results.

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5.10.1.1 Use of Significant Figures

Where stated, results are to be reported to the amount of significant figures prescribed by the analytical method or accrediting agency. In the absence of a method requirement for significant figures, the value reported can be based on either significant figures, or decimal places, in order to report values that show significant detail to comply with various regulatory requirements and accommodate sensitivity requests/requirements.

5.10.1.2 Reference to Accreditation

Each accreditation agency sets its own requirements for use of its symbol on customer reports. Likewise, additional requirements may be set for references made to accreditation. EMSL adheres to policies of the accrediting authorities. NVLAP Policies are found in Handbook 150:2020 (August 2020), specifically Annex A, NVLAP accreditation, and Annex E, Accredited Laboratory Combined ILAC MRA Mark. PALA accredited laboratories reference accreditation is based on PALA requirements in document DR-12-SCA-01. EMSL's general policies can be found in § 5.11, below.

5.10.1.3 Listing of Accreditation/Required Statements (See also § 5.11, below)

Laboratory accreditation is presented on the report with a reference to the agency, followed by the Lab ID code (such as: NVLAP Lab Code 000000-0) or via the use of approved accredited laboratory symbol.

The citation of the accreditation will not be used in a manner which misrepresents a laboratory's accreditation status. Citation of accreditation will be provided for the type of analytical test applicable to that accreditation only. If a particular analysis is performed which is not covered by an accreditation program, the report contains no reference to that

accreditation agency or contains the statement, "This report contains data that are (is) not covered by the XXXX accreditation." If a final report contains a combination of data for both accredited and non-accredited analysis, the non-accredited tests will be marked as such.

Reference to an accreditation by an applicant laboratory that has not yet achieved accreditation shall include a statement accurately reflecting the laboratory's status. Certificates of accreditation (applicable to the analysis) may be made part of the report if requested by the customer.

The title of the approval signatory shall appear on the final report that displays the accreditation.

In the rare cases where the analysis (or part of the analysis) has been subcontracted, the report will clearly state the data had been subcontracted. The report will include the statement "This report contains data that were produced under subcontract by Laboratory X." If the subcontract laboratory is accredited, the report will cite the accreditation agency and the Lab's ID code.

5.10.1.4 Proficiency Testing

Ambiguous reference to a Proficiency Testing Program (PAT) must be avoided. For example, listing of a PAT Identification number must be clearly identified with a statement such as *"EMSL XXXX (location) Participates in the AIHA LAP, LLC Proficiency Analytical Testing (PAT) Program for Asbestos: ID #123546"* to avoid inappropriate representation of full accreditation.

5.10.1.5 Statement on Quality Control Results – ELLAP AIHA LAP, LLC Requirement

For those laboratories which maintain the ELLAP AIHA LAP, LLC certification, final reports will state: "The QC data associated with the sample results included in this report meet the recovery and precision requirements established by AIHA LAP, LLC unless specifically indicated otherwise."

5.10.1.6 Suspension of Accreditation

In the unlikely event a laboratory's accreditation is revoked or suspended, reference (symbol and lab code number) to the accreditation and the scope of accreditation will be removed from all applicable documentation until accreditation is reinstated. Documentation includes:

- Final reports
- Marketing materials such as brochures, mailers, etc.
- EMSL website

In addition, at the discretion of the laboratory manager, national director and QA Department, samples may be subcontracted to a laboratory with equivalent accreditations.

In the case of AIHA LAP, LLC ELLAP matrix suspensions, the laboratory shall inform AIHA LAP, LLC in writing within ten (10) business days, of procedures for any samples that are received by the laboratory for analysis in the suspended FoT(s) until accreditation is restored.

5.10.1.7 Reporting to Governing Agencies (Notification of Compliance Reports)

At the request of the customer, EMSL can report analytical results directly to a compliance agency (state water authority, state environmental department, etc.). Results can be submitted on the agency's specialized forms, if requested. In these cases, the original EMSL report must also be submitted.

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5.10.2 Final Report Approval

Final customer reports are released only after the data has been reviewed by an approved reviewer. In almost all cases, the review is independent and performed by a qualified individual other than the analytical specialist (some exceptions are listed below). This review is documented with the initials of the reviewer on the "Screened" line on the Internal Chain of Custody form. This review includes:

Quality Control Review

Quality control analysis performed for that specific batch of customer sample is compared against acceptance criteria.

Note: Our quality control program is designed to comply with the requirement of state, federal and independent accrediting authorities' policy for reanalysis. Specific batch QC requirements are specified in the Program Specific QMS Manual Modules and/or Method SOPs. For percentage-based QC requirements, the quality control samples may or may not include samples associated with the set of results being approved for reporting.

In addition to QC review, analytical data is reported with confidence based on compliance with this QA program. The quality of the data reported is ensured through the procedures and policies as documented in this manual, including:

- Delineation of responsibility
- Compliance with analytical standard operating procedures
- Following calibration protocols
- Fulfillment of the required amount of quality control analysis
- Satisfaction of training requirements

Review of Data

- Raw data (e.g., from bench sheets, prep logs, printouts from instrumentation) and the information on the chain of custody are reviewed for correctness and compared against the typed information on the final report to check for any transcription errors.
- Date derived from calculations will be reviewed to ensure they appear correct based on the recorded data (this may be a brief overview).
- Where appropriate, correlations between data will be reviewed to ensure the sensibility of the data.

Appropriate Methodology

The review also verifies the correct methodology was performed on the samples. This is done by checking on the customer's request as documented on the chain of custody, as well as any supplemental conversations with customer as recorded in laboratory records (if any).

5.10.2.1 Approved Signatories

An approved signatory is responsible for the technical content of the report, and is the person to be contacted by the accrediting authorities or customers in case of questions or problems with the report. Signatories shall be persons with responsibility, authority and technical capability for the results provided. Technical capability is defined as having the aptitude for understanding the analysis and ability to recognize an error. It does not mean the approval signatory must be an approved analytical specialist. For PALA accredited labs, a PALA approved microbiologist is an approved signatory.

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The Quality Assurance Department, regional manager or national director can qualify the laboratory manager as an approved EMSL signatory. (See *GEN-FM-901 Final Report Approval and Signature Sample.*)

The laboratory manager may assign designated personnel to perform the task of final review and approval. This designation must be clearly documented (See *GEN-FM-901 Final Report Approval and Signature Sample.*)

Exceptions to Peer Review Requirement

5.10.2.1.1 All AIHA LAP, LLC and/or NLLAP* accredited analysis must be independently reviewed before it is released to the customer. No exceptions can be applied to work done under the AIHA LAP, LLC and/or NLLAP* accreditation. If work must be released prior to independent review, it must be marked "Preliminary" as per § 5.10.7 below.

***NOTE:** National Lead Laboratory Accreditation Program (NLLAP) is an EPA program which provides a list of accredited environmental lead laboratories. AIHA LAP, LLC and A2LA are both recognized NLLAP accrediting bodies. In addition, as of the time of this publication, Perry Johnson Lab Accreditation, Inc. (PJLA), ANSI-ASQ National Accreditation Board/ACLASS, and Laboratory Accreditation Bureau (L-A-B) are also recognized as NLLAP accreditation bodies. The most recent list of accrediting bodies can be found on the NLLAP website:

http://www2.epa.gov/lead/national-lead-laboratory-accreditation-program-nllap

5.10.2.1.2 For analysis not covered by AIHA LAP, LLC/NLLAP accreditations, an independent review shall always be performed, except under the specific circumstances identified below. In all other cases, work being reported prior to customers prior to independent review must be marked as "Preliminary" as per § 5.10.7, below.

5.10.2.1.3 Only in the following circumstances can a report be issued as Final without a second independent review being performed. In these circumstances, the report shall be reviewed by the original analytical specialist prior to release. Whenever an exception is being applied, the number of the exception which appears below shall be documented next to the "Screened" line of the Internal Chain of Custody to document the circumstances.

(1) Non-AIHA LAP, LLC analysis performed outside of a laboratory's regular business hours (i.e., 8-5 M-F) when a reviewer is not available to review work before the TAT.
(2) Non-AIHA LAP, LLC analysis performed during a laboratory's regular business hours when a reviewer is not available to review work before the TAT due to extended leave.

5.10.3 Opinions and Interpretations

EMSL generally discourages statements of opinions and interpretations on reports; however, a specialized report which contains results and interpretations as to whether the results are in or outside criteria is available. Any statement included in the test report shall be reviewed by the manager, QA,

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or upper management team prior to release. The source of the decision rule or interpretation will be cited, when applicable.

Specialized statements included on test reports are communicated to the customer either by phone or email prior to the report being sent. These types of statements are related to samples that have non-typical components to the analysis, and prompt the lab to communicate the situation with the customer before the report is sent. The communication with the customer is documented through email or a phone call, and noted on the internal COC.

5.10.4 Testing Obtained from Subcontractors

When a test report contains results obtained from a subcontractor, these will be clearly identified. This can be done either by scanning in the subcontracted report stating which laboratory performed the work, or by entering the data into Sample Master, commenting who completed the analysis. See the *EMSL Subcontract SOP* (GEN-SOP-010) for detailed procedures.

5.10.5 Confidential Transmission of Results

All EMSL employees have signed confidentiality agreement on file. Customer confidentiality is maintained when results are reported.

There are a number of forms of result transmission used by EMSL. These include:

1) Fax through Sample Master – A fax cover sheet is automatically included with the transmission. The fax cover sheet includes the standard confidentiality statement, *"This information may contain privileged and confidential information and is solely for the use of the sender's intended recipient(s). If you receive this information in error, please notify the sender and delete all copies."*

2) Email through SampleMaster – The confidentiality statement is (automatically) included in the body of the e-mail, *"This email may contain privileged and confidential information and is solely for the use of the sender's intended recipient(s). If you received this email in error, please notify the sender by reply email and delete all copies and attachments. Thank you."*

3) Manual fax – The cover page and report are printed through SampleMaster and manually faxed to the customer. The cover page includes the confidentiality statement, *"This information may contain privileged and confidential information and is solely for the use of the sender's intended recipient(s). If you receive this information in error, please notify the sender and delete all copies."* Note: Evidence of transmittal (fax receipt or email record) is to be retained and will serve as a formal record of receipt.

4) Use of LabConnect – The user must agree to the terms before using this service. The agreement includes the statement: *"The results available on this site are provided as a matter of service and convenience for customers of EMSL. They are intended for use only by authorized parties and are confidential in nature. It is the responsibility of our customers to maintain and update their user accounts to ensure that no unauthorized access is allowed by its employees. If you are not an authorized user, do not attempt to enter. While the results have been verified for accuracy against our analytical reports, they are not intended as a substitute for a hard copy or approved electronic report. Please contact your Account Representative if you have any questions regarding the available information.*" The user is prompted to check *"I accept the legal conditions above" or "I do not accept the legal conditions above."*

5) Mail (US Postal Service) – The front of the mailing envelope includes a statement, *"The information contained in this correspondence may contain privileged and confidential information and is solely for*

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the use of the sender's intended recipient. If you received this correspondence in error, please notify EMSL Analytical and return to sender."

5.10.6 Verbal Results

Where it is necessary to provide verbal results, it is EMSL policy to discuss analytical methodology and results only. Results are provided 'verbatim' by giving sample number and concentration only. Under no circumstances are results given as fail, pass, meeting acceptance criteria, etc. Interpretation of results is the responsibility of the customer. A note to the file must be made each time verbal results are given (note on the chain of custody and/or the customer communication log).

5.10.7 Preliminary Reports

Corporate policy discourages the issue of draft or preliminary data (for example, results that have not yet gone through a quality control review). However, there are circumstances where this may be unavoidable as a result of turnaround time issues, staffing situations, etc. If the laboratory manager chooses to provide preliminary data, the report is not signed and will clearly state "preliminary results."

A report is defined as 'preliminary' when it has not been reviewed following the procedures in § 5.10.2.1.2, above.

A final, signed report must eventually be provided to the customer. If any changes are made between the preliminary and final reports, the customer is notified with a statement on the final report, or by verbal contact. Verbal notifications must be recorded in writing on the internal chain of custody and/or in the customer correspondence log.

5.10.8 Exported Data

Exported data is provided in a variety of formats, (generally PDF format) depending on the specific needs of our customers. Export formats for data deliverables are implemented and controlled by the corporate IT staff, which has the flexibility to implement new export formats as required. Final, signed customer reports are to be submitted in addition to delivery by email or CD. Electronically delivered data is not intended to replace hard copy results unless otherwise requested by a customer. In this way, exported data can be verified. Electronically transmitted results meet the requirements of the QA policies as documented in this manual.

5.10.9 Amendments to Test Reports

In the event of any change to the final report after issue, the amended report must indicate the report is revised, the date of the revision and the reason for the amendment. The revisions must include the original reference number. A statement indicating the report is amended, the date and time of amended and original reports, and an amendment reason code, is included in the report footer for all amended reports. Customers must be informed immediately of the changes.

The laboratory sample set is not re-logged into the LIMS program. Tracking is done with the laboratory files, which include a printout of the original and amended report. When amendments to the final report result from a non-conformity, a corrective action form will be completed and filed by appropriate personnel following the EMSL Non-Conformities and Corrective Action SOP (QA-SOP-200).

Changes requiring an amended report include, but are not limited to:

- Errors in sample results
- A typographical error (sample location, sample volume, sample ID, etc.) that impacts the final results

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- Reports issued to incorrect customer
- Changes requested by customer

5.11 Use of Accreditation Symbols and/or References to Accreditation in Advertising and Customer Reports

EMSL has defined the requirements for referencing accreditation in reports, advertising, and promotional materials in the *EMSL Referencing Accreditation – Advertising Policy SOP* (QA-SOP-310). This procedure has been developed based on the requirements *of ISO/IEC 17025:2017, A2LA – P101*, *NVLAP* Handbook 150:2020 (August 2020**),** *AIHA LAP, LLC Policy Module,* among others.

Section 6.0: Revision History

Rev. 20	12/15/2017
Rev. 20.1	10/02/2018
Rev. 21	12/17/2018
Rev. 22	12/13/2019
Rev. 23	12/16/2020
Rev. 24	12/17/2021
Rev. 25	12/21/2022

Rev. #	Rev. Date	Changes in this Revision
26	12/15/2023	Added Appendix C to cross reference the QMS Manual to ISO 17025:2017 sections Removed reference to MDDELCC in Section 1.1 Updated national director of quality assurance to vice president of quality assurance throughout Noted EMSL does not place information related to our customers in the public domain in Section 4.1.5.1 Added cGMP Cinnaminson local SOP master list information in Section 4.3 Added 'however named' to clarify quality representative job titles in Section 5.2.1.5 Added language emphasizing the DOC lists all methods analyst is authorized to perform in Sections 5.2.2.1, and 5.2.2.9 Revised title for Section 5.4.5 to include 'and verification' and added requirement for QA and head of department data review when new services/methods are implemented in lab with newly trained analysts Added Section 5.4.5.1 to require verification package when new published methods are implemented in lab Added requirements to update GEN-FM-450 when differentiating between out of service equipment present or removed from the lab in Section 5.5.1 Revised to all checks must be documented electronically or in the log in Section 5.5.6.1 Added CAR/PAR workbook to be attached to report; corporate website reviewed for lab accuracy to quarterly report requirements in Section 5.9.2

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APPENDIX A: Glossary

ACS – American Chemical Society

Accuracy – The closeness of a measured result to a known, theoretical or target value. This should be distinguished from "Precision" below.

AHERA – Asbestos Hazard Emergency Response Act

AIHA LAP, LLC – American Industrial Hygiene Association Laboratory Accreditation Program

Alternative Method (procedure) – A major modification to standard methods and EMSL Standard Operating Procedures

Amended Report (see also revised report) – A report which reflects a change or correction to an original report

Analyte – A substance, organism, physical parameter, property, or chemical constituent(s) for which an environmental sample is being analyzed

Analytical Sensitivity – The lowest concentration that can be detected by the method, based upon the amount or portion of sample analyzed (e.g., for methods involving a count = 1 raw count per amount or portion of sample analyzed, calculated, and expressed in the final reporting units)

Analytical Worksheet (Bench Sheet) – The form used by the analytical specialist to collect the raw analytical data during analysis

Bench Sheet – (see "**Analytical Worksheet**")

Branch Laboratory – All EMSL laboratories excluding those located at 200 Route 130 North, Cinnaminson, NJ 08077

CALA – Canadian Association for Laboratory Accreditation

Chain of Custody (COC) – An unbroken trail of accountability that ensures the physical security of samples, data, and records

Chemical Hygiene Plan – A program which defines the work practices and procedures to ensure that employees of EMSL Analytical are protected from health hazards associated with hazardous chemicals with which they may work or be exposed. EMSL's chemical hygiene plan also includes its Biosafety Guide.

Coefficient of Variation (CV) – Standard deviation divided by the mean. Note: The Relative Standard Deviation (RSD) is the absolute value of the coefficient of variation.

Consensus Standards – Samples with values assigned based on a statistically significant number of repetitive analyses

Corporate Management – Staff members which include the Company President, Vice Presidents, QA Manager, National Directors, MIS Manager, Controller, Collection Manager and Equipment Manager

Culturable – Capable of, or fit for, being cultivated (antonym: non-culturable)

> **Note:** Prior to Revision 10 of this document the terms Viable/Non-viable were used in place of Culturable/Non-culturable. This terminology may still occur in some documents published prior to the date of publication of Revision 10.

Customer – Any person or entity that receives products or services from EMSL

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Demonstration of Capability – A procedure to establish the ability of the analyst to perform analyses with acceptable accuracy and precision

Detection Limit – The minimum result, which can be reliably discriminated from a blank with a predetermined confidence level; also used as Method Detection Limit

Document (*noun*) – A written policy, procedure, instruction, form, template, etc., which is revision sensitive. If an outdated revision is used it could cause the wrong process to be followed (e.g., not all required information is included on a previous revision of a form template). Contrast with "Record" below.

EMSL Environmental Laboratories – Laboratory facilities/locations performing the analysis for the analytical programs including asbestos, environmental lead, environmental microbiology, various IH parameters (organics, metals, etc.) and environmental chemistry parameters (metals, organics, inorganics, wet chemistry)

Integrity – Sound, honest, true

Inter-analyst/lab – Re-analysis of the same sample by a different analyst/lab

Intra-analyst/lab – Re-analysis of the same sample by the same analyst/lab

Limits of Quantitation (LOC) – The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence; also used as Reporting Level

Lot – A definite amount of material produced during a single manufacturing cycle, and intended to have uniform character and quality

Measurand – The quantity intended to be measured. This varies depending on the test, and takes into account the type of substance carrying the quantity.

Measurement Uncertainty – The uncertainty (or range of dispersion) of a measurement resulting from random and systematic errors in each step of the measurement process. Where a systematic bias exists and is not corrected for, it should be reported separately.

Method Detection Limit (MDL)/Detection Limit (DL) – The minimum measured concentration of a substance that can be reported with 99% confidence the measured concentration is distinguishable from method blank results

Method Validation – See *Validation, Methods*

NIST – National Institute of Standards and Technology

NLLAP — National Lead Laboratory Accreditation Program

NMI – National Metrology/Measurement Institute (e.g., NIST)

Non-conformity – A deficiency, error, or a lack of compliance with the procedures or policies documented in this manual

Non-Standard Method – An analytical procedure, which is developed in-house, or a significant modification to a published procedure which requires validation prior to being introduced into the laboratory. See also *Standard Method*.

NVLAP – National Voluntary Laboratory Accreditation Program

NYS ELAP – New York State Environmental Laboratory Approval Program

Precision – Closeness of repeated measurements to one another. This should be distinguished from "Accuracy" above.

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Proficiency Testing (PT) – As systematic program in which one or more standardized samples is analyzed by one or more laboratories to determine the capability of each participant

Program Module – Sections of this QMS Manual which address analytical method specific requirements (e.g., asbestos, lead, microbiology, IH organics and IH inorganics)

Quality Assurance (QA) – The total integrated program for assuring reliably of the measurement and monitoring of data

Quality Assurance Department – The QA Department is headed by the Quality Assurance Director. The Department minimally consists of the QA Manager and Document Control Manager, but may also include other EMSL staff members or outside consultants assigned to special projects or teams as assigned.

QAM – Quality Assurance Manager

Quality Control (QC) – The routine application of procedures for obtaining prescribed standards of performance in the monitoring and measurement process

Quality Management System – A set of policies, processes and procedures required for planning and execution

Quality Management System (QMS) Manual – This manual and related program modules; previously named "Quality Assurance Manual" or "QAM" prior to Revision 16. Older references in other management system documents to the "Quality Assurance Manual" or "QAM" refer to this document.

Reagents – A substance reacting with another substance. Lab reagents are compounds such as hydrochloric acid used in the analysis.

Reanalysis – A second analysis of the same sample (see also inter or intra)

Record (noun) – A written record of events which are not revision sensitive. Data records related to analytical activities should form an unbroken trail between sample receipt and reporting, including records of custody, prep and analytical steps, customer correspondence, equipment used, calibration records of that instrument, etc. Records are controlled as per the *EMSL Control of Records SOP* (QA-SOP-350). Contrast with a "Document" defined above. A form template is a document (revision sensitive); once information is entered on form, the completed form is considered a record (cannot be revised, only corrected, as per SOP).

Reference Materials – General term used to describe samples which have a known value. These could include standards, proficiency testing samples and consensus standards.

Reference Material Provider (RMP) – EMSL requires that for tests accredited by AIHA LAP, LLC or A2LA, all reference materials purchased after January 1, 2013 be purchased from ISO 17034:2016 accredited RMPs. A2LA and ACLASS both accredit to the ISO 17034:2016 guideline.

Reference Method (to be used to determine the extent of method validation in Modules 3-7) – A reference method is a published method issued by an organization generally recognized as competent to do so. (When the ISO language refers to a 'standard method,' that term is equivalent to 'reference method.') When a laboratory is required to analyze by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another reference method of the same matrix and technology.

Relative Standard Deviation (Sr, **S_r**, or **RSD)** – See "Coefficient of Variation" above

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Reference Weights – Set of weights which are used only to calibrate working weights in the laboratory. They may also be used for periodic calibrations of other equipment, but not on a routine basis (e.g., for daily balance verifications). Reference weights shall be calibrated at least every five (5) years. Extra care shall be taken to maintain the integrity of the standard.

Reporting Limit/LOQ– The lowest concentration of analyte in a sample that can be reported with a defined, reproducible level of certainty. This value is based on the low standard used for instrument calibration. For environmental lead analyses, the reporting limit must be at least twice the MDL/DL.

Revised Report (see also amended report) – A report which reflects a change or correction to an original report

Round Robin – An exchange of samples with other laboratories; may be 2 or more

RPD – Relative Percent Difference; calculated as $RPD = \frac{|R1 - R2|}{R} \times 100$

Where: R1-R2 = difference in two values
R = average of the two values

SRM – Standard Reference Material

Standards – Samples (materials) of known concentrations

Standard Methods – Methods published by regulatory agencies such as EPA, NIOSH, OSHA, State agencies. Also includes methods developed by recognized scientific agencies and/or individual groups, such as ASTM and Chatfield. If a method is significantly modified (e.g., changes to the method which may affect the principle of analysis), it shall no longer be considered Standard and shall be validated as a non-standard method.

Standard Operating Procedure – A written document that details the method of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed, and which is accepted as the method for performing certain routine or repetitive tasks

Sub-facility – Term used in association with the NVLAP program. A sub-facility is considered an extension of the Main Facility (Cinnaminson, NJ). It receives technical direction and quality management from the Main Facility.

Traceability – A process whereby the result from a measuring instrument (or a material measure) can be compared, in one or more stages, with a national or international standard for the measurand in question

Validation, Method – Planned process which must be completed prior to adoption of a new method by which the method's performance criteria are determined and documented. Performance criteria may include accuracy, precision, linearity, LOQ, LOD, and/or ruggedness.

Verification, Equipment – Process whereby equipment is checked against acceptance criteria to ensure that it is operating properly. Generally, a routine scheduled check performed by the laboratory.

Verification, Methods – A process whereby a laboratory verifies that it can perform a standard method or previously validated method within acceptable criteria at the location, and with analytical specialists and equipment at the location at which verification is performed

Working Weights – A set of weights which are used during routine measurements and verifications in the laboratory. Working weights shall be calibrated annually in-house using a set of reference weights as defined above, or by an outside vendor if lab does not have a set of in-house reference weights.

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APPENDIX B: Personal Conflict of Interest Statement

It is the policy of EMSL Analytical, Inc. (hereafter, "EMSL") that all employees avoid any conflict between their personal interests and those of EMSL. A conflict of interest is defined as any relationship between an Employee and another entity that may impair the objectivity of the Employee in performing their work. In order to avoid such situations, it is crucial that any *potential** conflict of interest is reported to EMSL Human Resources. A report of any potential conflict of interest, even where none actually exists, protects the employees and EMSL by ensuring transparency.

The participation of the Employee or a member of the Employee's immediate family in the following activities may be considered to be a conflict of interest:

- Holding a controlling interest in, or accepting free or discounted goods from any organization that does, or is seeking to do business with EMSL, by any employee who is in a position to directly or indirectly influence either EMSL's decision to do business, or the terms upon which business would be done with such organization. A "Controlling Interest" means that through ownership (i.e., stockholder, partner, sole owner) or position (i.e., director, officer, trustee) the individual has the capacity to control the actions of the organization in question.
- Holding an interest in an organization that competes with EMSL. There is no conflict of interest if one owns diversified mutual funds, money market funds and/or other diversified investments where the individual does not control the choice of specific investments.
- Being employed by (including as a consultant) or serving on the board of any organization which does, or is seeking to do, business with EMSL or which competes with EMSL. There is no conflict if Employee family members are employed by, but cannot influence the relationship between an organization and EMSL.
- Profiting personally from any organization seeking to do business with EMSL (except as noted above).
- Performing services for another employee similar to the services provided by the Employee to EMSL, on or off EMSL property, without the express prior permission of Dr. Frasca, President of EMSL, which may or may not be granted.
- Employees may not accept gifts from vendors or customers of a value greater than $50.00.

It is the Employee's responsibility to report any actual, potential, or apparent conflict of interest that may exist between the Employee or their immediate family and EMSL. In the absence of a report, violations of the principles and standards contained in this policy statement may subject the Employee to discipline, up to and including termination of employment. This report can be made in writing and appended to this form.

Employees who become aware of an actual or potential conflict of interest as defined above are responsible for and authorized to confidentially report the conflict to the Human Resources Department immediately, not to exceed 3 business days from recognizing the conflict.

Conflict of interest situations will be reviewed by Human Resources and/or Senior Management. Dr. Frasca, in his capacity as President of EMSL, retains sole discretion to determine appropriate actions to alleviate an actual conflict.

My signature below is evidence that I have read and understand the policy stated above, and declare that no unreported potential conflict of interest exists between me, my immediate family, and EMSL.

_____	_____
Printed Name	Signature
	_____
	Date

**Reports of potential or apparent conflicts do not automatically trigger any actions other than review. Each case will be considered case-by-case based on facts. In most cases, no action is necessary other than ensuring the relevant details are on record in order to defend both Employee and EMSL from future potential accusations of improper practices.*

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APPENDIX C: Cross Reference EMSL QMS Manual to ISO 17025:2017

EMSL QMS Manual and Related Modules	ISO/IEC 17025:2017
Section 1.0	**1.0 Scope**
Section 2.0	**2.0 Normative references**
Appendix A - Glossary	**3.0 Terms and definitions**
Section 4.0 Management requirements	**4.0 General requirements**
Section 4.1.5.2.4	4.1 Impartiality
Section 4.1.5	4.2 Confidentiality
Section 4.1	**5.0 Structural requirements**
	6.0 Resource requirements
Section 5.1	6.1 General
Section 5.2	6.2 Personnel
Section 5.3	6.3 Facilities and environmental conditions
Section 5.5	6.4 Equipment
Section 5.6	6.5 Metrological traceability
Section 4.6	6.6 Externally provided products and services
	7.0 Process requirements
Section 4.4	7.1 Review of requests, tenders and contracts
	7.2 Selection, verification and validation of methods
Section 5.4.2	7.2.1 Selection and verification of methods
Section 5.4.5	7.2.2 Validation of methods
Section 5.7	7.3 Sampling
Section 5.9	7.4 Handling of test or calibration items
Section 4.13	7.5 Technical records
Section 5.4.6	7.6 Evaluation of measurement uncertainty
Section 5.9	7.7 Ensuring the validating of results
Section 5.10	7.8 Reporting of results
Section 5.10	7.8.1 General
Section 5.10.1	7.8.2 Common requirements for reports
Section 5.10.1	7.8.3 Specific requirements for test reports
Section 5.8	7.8.4 Specific requirements for calibration certificates
Section 5.7	7.8.5 Reporting sampling-specific requirements
Section 5.10.3	7.8.6 Reporting statements of conformity
Section 5.10.3	7.8.7 Reporting opinions and interpretations
Section 5.10.9	7.8.8 Amendments to reports
Section 4.8	7.9 Complaints
Section 4.9	7.10 Non-conforming work
Section 5.4.7	7.11 Control of data and information management
	8.0 Management system requirements
	8.1 Options (8.1.1 General; 8.1.2 Opt. A; 8.1.3 Opt. B-N/A to EMSL)
Section 4.2	8.2 Management system documentation
Section 4.3	8.3 Control of management system documents
Section 4.13	8.4 Control of records
Section 4.2.6	8.5 Actions to address risks and opportunities
Section 4.10	8.6 Improvement
Section 4.11	8.7 Corrective actions
Section 4.14	8.8 Internal audits
Section 4.15	8.9 Management reviews

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STATE OF LOUISIANA
DEPARTMENT OF ENVIRONMENTAL QUALITY

Is hereby granting a Louisiana Environmental Laboratory Accreditation to

SGS North America Inc - Scott
500 Ambassador Caffery Pkwy
Scott, Louisiana 70583-8544

Agency Interest No. 24751
Activity No. ACC20260002

According to the Louisiana Administrative Code, Title 33, Part I, Subpart 3, LABORATORY ACCREDITATION, the State of Louisiana formally recognizes that this laboratory is technically competent to perform the environmental analyses listed on the scope of accreditation detailed in the attachment.

The laboratory agrees to perform all analyses listed on this scope of accreditation according to the Part I, Subpart 3 requirements and acknowledges that continued accreditation is dependent on successful ongoing compliance with the applicable requirements of Part I and the 2016 TNI Standard by which the laboratory was assessed. Please contact the Department of Environmental Quality, Louisiana Environmental Laboratory Accreditation Program (LELAP) to verify the laboratory's scope of accreditation and accreditation status.

Accreditation by the State of Louisiana is not an endorsement or a guarantee of validity of the data generated by the laboratory. Accreditation of the environmental laboratory does not imply that a product, process, system, or person is approved by LELAP. To be accredited initially and maintain accreditation, the laboratory agrees to participate in two single-blind, single-concentration PT studies, where available, per year for each field of testing for which it seeks accreditation or maintains accreditation as required in LAC 33:I.4711.

Tonya Landry
Administrator
Public Participation and Permit Support Division

Issued Date: 6/24/2026

Effective Date: July 1, 2026
Expiration Date: June 30, 2027
Certificate Number: 02048

STATE OF LOUISIANA
DEPARTMENT OF ENVIRONMENTAL QUALITY

Is hereby granting a Louisiana Environmental Laboratory Accreditation to

Waypoint Analytical Mississippi Inc
235 Highpoint Dr
Ridgeland, Mississippi 39157-6018

Agency Interest No. 88081
Activity No. ACC20250002

According to the Louisiana Administrative Code, Title 33, Part I, Subpart 3, LABORATORY ACCREDITATION, the State of Louisiana formally recognizes that this laboratory is technically competent to perform the environmental analyses listed on the scope of accreditation detailed in the attachment.

The laboratory agrees to perform all analyses listed on this scope of accreditation according to the Part I, Subpart 3 requirements and acknowledges that continued accreditation is dependent on successful ongoing compliance with the applicable requirements of Part I and the 2016 TNI Standard by which the laboratory was assessed. Please contact the Department of Environmental Quality, Louisiana Environmental Laboratory Accreditation Program (LELAP) to verify the laboratory's scope of accreditation and accreditation status.

Accreditation by the State of Louisiana is not an endorsement or a guarantee of validity of the data generated by the laboratory. Accreditation of the environmental laboratory does not imply that a product, process, system, or person is approved by LELAP. To be accredited initially and maintain accreditation, the laboratory agrees to participate in two single-blind, single-concentration PT studies, where available, per year for each field of testing for which it seeks accreditation or maintains accreditation as required in LAC 33:I.4711.

Tonya Landry
Administrator
Public Participation and Permit Support Division

Issued Date: 6/24/2026

Effective Date: July 1, 2026
Expiration Date: June 30, 2027
Certificate Number: 04023

STATE OF LOUISIANA
DEPARTMENT OF ENVIRONMENTAL QUALITY

Is hereby granting a Louisiana Environmental Laboratory Accreditation to

Waypoint Analytical LLC
2790 Whitten Rd
Memphis, Tennessee 38133

Agency Interest No. 86553
Activity No. ACC20250001

According to the Louisiana Administrative Code, Title 33, Part I, Subpart 3, LABORATORY ACCREDITATION, the State of Louisiana formally recognizes that this laboratory is technically competent to perform the environmental analyses listed on the scope of accreditation detailed in the attachment.

The laboratory agrees to perform all analyses listed on this scope of accreditation according to the Part I, Subpart 3 requirements and acknowledges that continued accreditation is dependent on successful ongoing compliance with the applicable requirements of Part I and the 2016 TNI Standard by which the laboratory was assessed. Please contact the Department of Environmental Quality, Louisiana Environmental Laboratory Accreditation Program (LELAP) to verify the laboratory's scope of accreditation and accreditation status.

Accreditation by the State of Louisiana is not an endorsement or a guarantee of validity of the data generated by the laboratory. Accreditation of the environmental laboratory does not imply that a product, process, system, or person is approved by LELAP. To be accredited initially and maintain accreditation, the laboratory agrees to participate in two single-blind, single-concentration PT studies, where available, per year for each field of testing for which it seeks accreditation or maintains accreditation as required in LAC 33:I.4711.

Tonya Landry
Administrator
Public Participation and Permit Support Division

Issued Date: 6/24/2026

Effective Date: July 1, 2026
Expiration Date: June 30, 2027
Certificate Number: 04015

STATE OF LOUISIANA
DEPARTMENT OF ENVIRONMENTAL QUALITY

Is hereby granting a Louisiana Environmental Laboratory Accreditation to

EMSL Analytical Inc - Cinnaminson NJ
200 Rt 130 N
Cinnaminson, New Jersey 08077

Agency Interest No. 131900
Activity No. ACC20260001

According to the Louisiana Administrative Code, Title 33, Part I, Subpart 3, LABORATORY ACCREDITATION, the State of Louisiana formally recognizes that this laboratory is technically competent to perform the environmental analyses listed on the scope of accreditation detailed in the attachment.

The laboratory agrees to perform all analyses listed on this scope of accreditation according to the Part I, Subpart 3 requirements and acknowledges that continued accreditation is dependent on successful ongoing compliance with the applicable requirements of Part I. Please contact the Department of Environmental Quality, Louisiana Environmental Laboratory Accreditation Program (LELAP) to verify the laboratory's scope of accreditation and accreditation status.

Accreditation by the State of Louisiana is not an endorsement or a guarantee of validity of the data generated by the laboratory. Accreditation of the environmental laboratory does not imply that a product, process, system, or person is approved by LELAP. To be accredited initially and maintain accreditation, the laboratory agrees to participate in two single-blind, single-concentration PT studies, where available, per year for each field of testing for which it seeks accreditation or maintains accreditation as required in LAC 33:I.4711.

Tonya Landry
Administrator
Public Participation and Permit Support Division

Issued Date: 6/23/2026
Effective Date: July 1, 2026
Expiration Date: June 30, 2027
Certificate Number: 04127

United States Department of Commerce
National Institute of Standards and Technology

Certificate of Accreditation to ISO/IEC 17025:2017

NVLAP LAB CODE: 101048-0

EMSL Analytical, Inc.

Cinnaminson, NJ

is accredited by the National Voluntary Laboratory Accreditation Program for specific services, listed on the Scope of Accreditation, for:

Asbestos Fiber Analysis

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communique on ISO/IEC 17025).

2026-07-01 through 2027-06-30

Effective Dates

For the National Voluntary Laboratory Accreditation Program

National Voluntary Laboratory Accreditation Program

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

EMSL Analytical, Inc.
200 Route 130 North
Cinnaminson, NJ 08077
Ms. Samantha Rundstrom
Phone: 856-303-2577
Email: srundstrom@emsl.com
http://www.emsl.com

ASBESTOS FIBER ANALYSIS **NVLAP LAB CODE 101048-0**

Bulk Asbestos Analysis

Code	*Description*
18/A01	EPA -- 40 CFR Appendix E to Subpart E of Part 763, Interim Method of the Determination of Asbestos in Bulk Insulation Samples
18/A03	EPA 600/R-93/116: Method for the Determination of Asbestos in Bulk Building Materials

Airborne Asbestos Analysis

Code	*Description*
18/A02	U.S. EPA's "Interim Transmission Electron Microscopy Analytical Methods-Mandatory and Nonmandatory-and Mandatory Section to Determine Completion of Response Actions" as found in 40 CFR, Part 763, Subpart E, Appendix A.

For the National Voluntary Laboratory Accreditation Program

APPENDIX D

Example Field Forms

Daily Field Report

Project No: _____ Project: _____ Date: _____ Report No: _____

Client: _____ Rep: _____

Contractor: _____ Rep: _____

Subcontractors: _____ Rep: _____

Terracon Reps: _____

Area Working (Station Numbers): _____

_____

Weather Conditions: AM Clear Pt Cldy Rainy Windy Calm PM Clear Pt Cldy Rainy Windy Calm

Temp Range: _____ ° F Rainfall: _____ When: _____

Summary of Daily Activities

Departed Office: _____ hrs Arrived Site: _____ hrs Departed Site: _____ hrs Arrived Office: _____ hrs

Planned Activities: _____

Attached Forms: ☐ Daily Record _____

Samples Collected: _____

Input: _____ By: _____

Terracon

Log of Soil Boring No. _____

Sheet 1 of _____

Project: _____ **Location:** _____ **Project No.:** _____

Logged By: _____ **Driller:** _____ **Drill Rig:** **Date:** _____

Client: _____ **Weather:** _____ **GPS: Latitude:** _____ N **Longitude:** _____ W

Depth (feet)	Well Set Data	Sample		Field Data	Visual Classification (Show Strata Breaks)	Stratigraphy and Lithology	Analytical samples submitted
		Container: bag, jar ...	Recovery	PID/OVA/Pent.			
4							
8							
12							
16							
20							
24							

Well Purge/Development & Sampling

Purge method: _____

Gallons Purged: _____

Sample Time: _____

Boring Abandonment

Cuttings: ☐

Grout: ☐

Bentonite Crumbles: ☐

Well ID: _____

Screen: _____

Sand Pack: _____

Pellets: _____

Groundwater Information

First Encountered: _____ feet

Rise: _____ after _____

Static: _____ after _____

Comments / General Notes

Topsoil Depth / Surface Conditions: _____

Groundwater Conditions: _____

Terracon

Log of Soil Boring No. _____

Sheet 2 of _____

Project: _____ **Location:** _____ **Project No.:** _____

Logged By: _____ **Driller:** _____ **Drill Rig:** **Date:** _____

Client: _____ **Weather:** _____ **GPS: Latitude:** _____ N **Longitude:** _____ W

Depth (feet)	Well Set Data	Sample		Field Data	Visual Classification (Show Strata Breaks)	Stratigraphy and Lithology	Analytical samples submitted
		Container: bag, jar ...	Recovery	PID/OVA/Pent.			
28							
32							
36							
40							
44							
48							

Well Purge/Development & Sampling

Purge method: _____

Gallons Purged: _____

Sample Time: _____

Boring Abandonment

Cuttings: ☐

Grout: ☐

Bentonite Crumbles: ☐

Well ID: _____

Screen: _____

Sand Pack: _____

Pellets: _____

Groundwater Information

First Encountered: _____ feet

Rise: _____ after _____

Static: _____ after _____

Comments / General Notes

Topsoil Depth / Surface Conditions: _____

Groundwater Conditions: _____

Groundwater Sampling Information

Project:	Project No.:	Date:

Well Information

Well ID:		Location:	
Well Diameter:	in.	Well Construction:	
Casing height above grade:		ft.	
Well depth from TOC:	ft. measured by: interface probe		ft. from Records

Weather

General:	Ambient Temperature:	Precipitation:

Well Observations

Static water level below TOC:	Time:	Method of measure:	interface probe
LNAPL observation:	Time:	Method of measure:	interface probe

Volume of Water in Well

K = 3/4" - 0.0227gl/ft 1" - 0.0405 gl/ft
2" - 0.163 gl/ft 3" - 0.365 gal/ft
4" - 0.648 gl/ft 6" - 1.459 gl/ft

Height (Ht) of water in well (Well depth from TOC - Static level from TOC):

Volume of water in well (Ht. x K):

Well Purging

Purging method: Start Time: Completion Time:

pH	Temp. ©	Conductivity	Time	Volume (gal)

Purged to Dryness:

Sample Information

Method of sampling:

Decon. procedures:

Sample ID	Container	Preservative	Required Analysis

Sample Transport and Preservation:

Sample Destination: Via: Date/Time Shipped:

Chain of Custody completed:

Terracon Technician(s)

Asbestos Air Sample Log & Chain of Custody

Lab Use Only:

Select a Laboratory:

Lab Location:

New Orleans: 524 Elmwood Park Blvd., Ste. 170, New Orleans, LA 70123 (504) 818 3638

Project Name:		Project Number:		Project Manager:	
Project Address:		City/State / Zip:		Email Results To:	

Site/Building:	

Sample ID	Sample Location	Sample Volume (Liters)	Sample Date and Time

Sampling Date:	Collected by (print):	Signature:	
Relinquished by:	Date/Time:	Received by:	Date/Time:
Rotometer/Primary Calibrator ID and Expiration:			
Analysis: NIOSH 7400 AHERA TEM OTHER _____ Turnaround Time: 4 Hrs - 6 Hrs - 24 Hrs - 2 Days - 3 Days - 5 Days - Other _____		Instructions:	

Asbestos Bulk Sample Log & Chain of Custody Form

Lab Use Only:

Select a Laboratory:

Lab Location:

New Orleans: 524 Elmwood Park Blvd., Ste. 170, New Orleans, LA 70123 (504) 818 3638

Project Name:		Project Number:		Project Manager:	
Project Address:		City/State / Zip:		Email Results To:	
Site/Building:					

HA	Sample Number	Sample Location	HA Description (Color, Dimensions, Descriptor, then Type)	HA General Location/Notes	Condition[1]	Friable?[1]	Estimated Quantity
					G D SD	Y/N	SF / LF / Units
					G D SD	Y/N	SF / LF / Units
					G D SD	Y/N	SF / LF / Units
					G D SD	Y/N	SF / LF / Units
					G D SD	Y/N	SF / LF / Units

Sampling Date:	Collected by (print):	Inspector's Signature:
Relinquished by:	Date/Time:	Received by: Date/Time:
Analysis: PLM EPA 600/R-93/116 - PLM 400 Point Count - TEM - Other _____		Instructions:
Turnaround Time: 6 Hrs - 24 Hrs - 2 Days - 3 Days - 5 Days - Other _____		Positive Stop: ☐ Number of samples: _____

[1] G = Good (no damage); D = Damaged (<10% distributed or <25% localized); or SD = Significantly Damaged (>10% distributed or >25% localized), F=Friable NF=Non-Friable

Terracon

Asbestos Bulk Sample Log & Chain of Custody Form

Lab Use Only:

Select a Laboratory:

Lab Location:

New Orleans: 524 Elmwood Park Blvd., Ste. 170, New Orleans, LA 70123 (504) 818 3638

HA	Sample Number	Sample Location	HA Description (Color, Dimensions, Descriptor, then Type)	HA General Location/Notes	Condition[1]	Friable?[1]	Estimated Quantity
					G D SD	Y/N	SF / LF / Units
					G D SD	Y/N	SF / LF / Units
					G D SD	Y/N	SF / LF / Units
					G D SD	Y/N	SF / LF / Units
					G D SD	Y/N	SF / LF / Units
					G D SD	Y/N	SF / LF / Units
					G D SD	Y/N	SF / LF / Units

[1] G = Good (no damage); D = Damaged (<10% distributed or <25% localized); or SD = Significantly Damaged (>10% distributed or >25% localized), F=Friable NF=Non-Friable

Lead Sample Log & Chain of Custody

Lab Use Only: EMSL

Lab Location:

New Orleans: 524 Elmwood Park Blvd., Ste. 170, New Orleans, LA 70123 (504) 818 3638

Project Name:		Project Number:		Project Manager:	
Project Address:		City/State / Zip:		Email Results To:	

Site/Building:	

Sample ID	Sample Description/Location	Sample Volume/Area	Sample Date and Time

Sampling Date:	Collected by (print):	Signature:
Relinquished by:	Date/Time:	Received by: Date/Time:
Rotometer/Primary Calibrator ID and Expiration:		
Analysis: Flame FAA (SW-846-7000B) NIOSH 7082 TCLP – Lead OTHER _____ Turnaround Time: 4 Hrs - 6 Hrs - 24 Hrs - 2 Days - 3 Days - 5 Days - Other _____		Instructions: