QUALITY SYSTEMS MANUAL FOR ENVIRONMENTAL ANALYTICAL SERVICES

eurofins | Calscience

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Prepared By

Eurofins Calscience, Inc.
7440 Lincoln Way
Garden Grove, CA 92841-1427
Telephone: 714-895-5494
Facsimile: 714-894-7501
Internet: www.calscience.com

Based On

The NELAC Institute (TNI)
National Environmental Laboratory Accreditation Program (NELAP)
Management and Technical Requirements for Laboratories Performing Environmental Analysis
TNI Standard (EL-V1-2009) Effective September 09, 2009

Larry Lem
QUALITY ASSURANCE MANAGER

Linda Scharpenberg
QUALITY ASSURANCE / TECHNICAL DIRECTOR

Virginia Huang
OPERATIONS DIRECTOR

Elizabeth Winger
LABORATORY DIRECTOR

Steven L. Lane
VICE-PRESIDENT / BUSINESS UNIT MANAGER

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PREFACE TO THE QUALITY SYSTEMS MANUAL

Purpose

The purpose of this document is to provide implementation guidance on the establishment and management of quality systems for Eurofins Calscience, Inc (ECI) and is based on the National Environmental Laboratory Accreditation Conference's (NELAC) Quality System requirements, the Department of Defense / Energy Environmental Laboratory Accreditation Program (DOD/DOE ELAP) and International Organization for Standardization / International Electrotechnical Commission (ISO/IEC) 17025:2005.

These three programs are built upon one another and are mutually reinforcing in their Quality Assurance programs and protocols.

Background

To be accredited and in compliance under the following three programs:

1. The National Environmental Laboratory Accreditation Program (NELAP). Accredited laboratories shall have a comprehensive quality system in place, the requirements for which are outlined in The NELAC Institute (TNI) 2009 Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis (EL-V1-2009). This manual was written with guidance primarily from Volume 1: Modules 2, 3, 4, 5, and 7.

   Additional information may be found at:

   - http://www.nelac-institute.org/

2. The Department of Defense Environmental Laboratory Accreditation Program (DOD/DOE ELAP) will provide a means for laboratories to demonstrate conformance to the DOD/DOE Quality Systems Manual for Environmental Laboratories (DOD/DOE QSM) as authorized by DOD Instruction 4715.15.

   The DOD/DOE QSM Revision 5.0 (July 2013) is based on the National Environmental Laboratory Accreditation Conference (NELAC) Quality Systems standard which provides guidelines for implementing the international standard, ISO/IEC 17025.

   Additional information may be found at:

   - http://www.denix.osd.mil/edqw/Accreditation/
   - http://www.denix.osd.mil/edqw/upload/QSM-Version-5-0-FINAL.pdf

3. ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories.

   Additional information may be found at:

   - http://www.iso.org/iso/home.html

Project Specific Requirements

Project-specific requirements or regulations may supersede requirements contained in this manual. The laboratory bears the responsibility for meeting all **State requirements**. Nothing in this document relieves the laboratory from complying with contract requirements, or with **Federal, State, and/or local regulations**.

Results and Benefits

- **Standardization of Processes** – Because this manual provides the laboratory with a comprehensive set of requirements that meet the needs of many clients, as well as the NELAP, the laboratory may use it to create a standardized quality system. Ultimately, this standardization saves laboratory resources by establishing one set of consistent requirements for all environmental work. Primarily, the laboratory bears the responsibility for meeting all State requirements as outlined in their respective certification programs.

- **Deterrence of Improper, Unethical, or Illegal Actions** – Improper, unethical, or illegal activities committed by only a few laboratories have implications throughout the industry, with negative impacts on all laboratories. This manual establishes a minimum threshold program for all laboratories to use to deter and detect improper, unethical, or illegal actions.

- **Foundations for the Future** – A standardized approach to quality systems, shared by laboratories and The NELAC Institute, paves the way for the standardization of other processes. For example, this manual might serve as a platform for a standardized strategy for Performance Based Measurement System (PBMS) implementation.

Document Format

This ECI Quality Systems Manual (QSM) is designed to implement the TNI 2009 (EL-V1-2009) standards along with the DOD/DOE QSM 5.0 and the ISO/IEC 17025:2005 standards.

The section numbering has been changed from that of these standards as the manual is meant to be a stand-alone document. Thus the numbering in this document is not consistent with the numbering in the above-mentioned standards; however, all required elements are covered, herein.
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ACROYNM LIST

°C: Degrees Celsius
ANSI/ASQC: American National Standards Institute / American Society for Quality Control
ASTM: American Society for Testing and Materials
CAS: Chemical Abstract Service
CCV: Continuing calibration verification
CFR: Code of Federal Regulations
CLP: Contract Laboratory Program
COC: Chain of Custody
CV: Coefficient of Variation
DO: Dissolved Oxygen
DOC: Demonstration of Capability
DOD/DOE: Department of Defense / Energy
DQOs: Data Quality Objectives
EPA: Environmental Protection Agency
g/L: Grams per Liter
GC/MS: Gas Chromatography / Mass Spectrometry
ICP-MS: Inductively Coupled Plasma / Mass Spectrometer
ICV: Initial Calibration Verification
ID: Identifier
ISO/IEC: International Standards Organization / International Electrotechnical Commission
LCS: Laboratory Control Sample
LCSD: Laboratory Control Sample Duplicate
LOD: Limit of Detection
LOQ: Limit of Quantitation
LQMP: Laboratory Quality Management Plan
MDL: Method Detection Limit
ME: Marginal Exceedance
mg/kg: Milligrams per Kilogram
MS: Matrix Spike
MSD: Matrix Spike Duplicate
NELAC: National Environmental Laboratory Accreditation Conference
NELAP: National Environmental Laboratory Accreditation Program
NIST: National Institute of Standards and Technology
OSHA: Occupational Safety and Health Administration
PBMS: Performance Based Measurement System
PC: Personal Computer
PCBs: Polychlorinated Biphenyls
PT: Proficiency Testing
QA: Quality Assurance
QAD: Quality Assurance Division (EPA)
QAMS: Quality Assurance Management Section
QAPP: Quality Assurance Project Plan
QSM: Quality Systems Manual
QC: Quality Control
RL: Reporting Limit
RPD: Relative Percent Difference
RSD: Relative Standard Deviation
SD: Serial Dilutions
SOP: Standard Operating Procedure
TNI: The NELAC Institute
TSS: Total Suspended Solids
UV: Ultraviolet
VOC: Volatile Organic Compound

QUALITY SYSTEMS

Quality Systems include all quality assurance (QA) policies and quality control (QC) procedures that are delineated in a Quality Systems Manual (QSM) and followed to ensure and document the quality of the analytical data. Eurofins Calscience, Inc. (ECI), accredited under the National Environmental Laboratory Accreditation Program (NELAP), assures implementation of all QA policies and the applicable QC procedures specified in this Manual. The QA policies, which establish essential QC procedures, are applicable to all areas of ECI, regardless of size and complexity.

The intent of this document is to provide sufficient detail about quality management requirements so that all accrediting authorities evaluate laboratories consistently and uniformly.

The NELAC Institute (TNI) is committed to the use of Performance Based Measurement Systems (PBMS) in environmental testing and provides the foundation for PBMS implementation in these standards. While this standard may not currently satisfy all the anticipated needs of PBMS, NELAC will address future needs within the context of State statutory and regulatory requirements and the finalized EPA implementation plans for PBMS.

Chapter 5 is organized according to the structure of ISO/IEC 17025, 2005. Where deemed necessary specific areas within this Chapter may contain more information than specified by ISO/IEC 17025.

All items identified in this QSM shall be available for on-site inspection or data audit.

1.0 SCOPE

a) This QSM sets the general requirements that ECI must successfully demonstrate to be recognized as competent to perform specific environmental tests.

b) This QSM includes additional requirements and information for assessing competence or for determining compliance by the organization or accrediting authority that grants approval.

   If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory demonstrates that such requirements are met. If it is not clear which requirements are more stringent, the standard from the method or regulation is to be followed.

c) ECI uses this QSM in the development and implementation of its quality systems. Accreditation authorities use this NELAC based standard to assess the competence of environmental laboratories.

2.0 REFERENCES

See Appendix A.

3.0 DEFINITIONS

The relevant definitions from ISO/IEC Guide 2, ANSI/ASQC E-4, 1994, the EPA “Glossary of Quality Assurance Terms and Acronyms,” and the *International vocabulary of basic and general terms in metrology (VIM*) are applicable. The most relevant is quoted in Appendix A, Glossary, of Chapter 1 of NELAC, together with further definitions applicable for the purposes of this Standard.

4.0 ORGANIZATION AND MANAGEMENT

4.1 Legal Definition of Laboratory

ECI is legally definable as evidenced by its business license, and current California State Water Resources Control Board (SWRCB) Services Environmental Laboratory Accreditation Program (ELAP) certificate. It is organized and operates in such a way that its facilities meet the requirements of the Standard. See the graphical presentations of the Organization and QA responsibility in Figures 1 and 2, respectively.

4.2 Organization

Eurofins Calscience Inc.:

a) Has a managerial staff with the authority and resources necessary to discharge their duties;

b) Has processes to ensure that its personnel are free from any commercial, financial and other undue pressure that adversely affect the quality of their work;

c) Is organized in such a way that confidence in its independence of judgment and integrity is maintained at all times;

d) Specifies and documents the responsibility, authority, and interrelationship of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

   Such documentation includes:

   1) A clear description of the lines of responsibility in the laboratory, and is proportioned such that adequate supervision is ensured, and

   2) Job descriptions for all positions.

e) Provides supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test, and the assessment of the results.

   The ratio of supervisory to non-supervisory personnel ensures adequate supervision and adherence to laboratory procedures and accepted techniques.

f) Has a technical director who has overall responsibility for the technical operation of ECI.

   The technical director certifies that personnel who perform the tests for which the laboratory is accredited have the appropriate educational and/or technical background. Such certification is documented.

   The technical director meets the requirements specified in the Accreditation Process. (See NELAC Section 4.1.1.1.)

g) Has a quality assurance manager who has responsibility for the quality system and its implementation.

   The quality assurance officer has direct access to the technical director and to the highest level of management at which decisions are made regarding laboratory policy or resources.

   The quality assurance manager (and/or his/her designees):

   1) Serves as the focal point for QA/QC activities, and is responsible for the oversight and/or review of quality control data;

2) Has functions independent from laboratory operations for which she/he has quality assurance oversight;

3) Is able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence;

4) Has documented training and/or experience in QA/QC procedures and is knowledgeable in the quality system, as defined under NELAC;

5) Has a general knowledge of the analytical test methods for which data review is performed;

6) Arranges for and conducts internal audits as per ECI QSM section 5.3 annually; and

7) Notifies ECI management of deficiencies in the quality system and monitors corrective action.

h) Nominates, by way of the "Alternates List," deputies in case of absence of the Technical Director and/or the Quality Assurance Director;

i) ECI makes every effort to ensure the protection of its clients' information as confidential and proprietary.

ii) ECI is sensitive to the fact that much of the analytical work performed for clientele may be subject to litigation processes. ECI, therefore, holds all information in strict confidence with laboratory release only to the client.

iii) Information released to entities other than the client is performed only upon written request from the client.

iv) Due to the investigative nature of most site assessments, analytical information may become available to regulatory agencies or other evaluating entities during site assessment of the laboratory for the specific purpose of attaining laboratory certifications, accreditations, or evaluation of laboratory qualification for future work. During these occurrences, the laboratory will make every effort to maintain the confidence of client specific information.

j) For purposes of qualifying for and maintaining accreditation, participates in a proficiency test program as outlined in Chapter 2 of NELAC. Results of ECI's performance in rounds of proficiency testing are available by request or on the web site.

5.0 QUALITY SYSTEM – ESTABLISHMENT, AUDITS, ESSENTIAL QUALITY CONTROLS, AND DATA VERIFICATION

5.1 Establishment

ECI establishes and maintains quality systems based on the required elements contained in this Manual and appropriate to the type, range and volume of environmental testing activities it undertakes.

a) The elements of this quality system are documented in this quality manual.

b) The quality documentation is available for use by all laboratory personnel.

c) The laboratory defines and documents its policies and objectives for, and its commitment to accepted laboratory practices and quality of testing services.

d) The laboratory management ensures that these policies and objectives are documented in the quality manual and are communicated to, understood and implemented by all laboratory personnel concerned.

i. All staff members are given access to a controlled copy of the Quality Systems Manual (QSM) for review at the commencement of employment. However, the individual Standard Operating Procedures are the training documents that have precedence. The QSM is provided as a general overview.

ii. A controlled copy of the quality manual is also available in each department.

e) The quality manual is maintained current under the responsibility of the quality assurance department. This manual is reviewed on an annual basis or more frequently, and revised as necessary.

5.2 Quality Systems Manual (QSM) Elements

This Quality Systems Manual (QSM) and related quality documentation state ECI's policies and operational procedures established in order to meet the requirements of this Standard.

This manual lists on the title page: a document title; the laboratory's full name and address; the name, address, and telephone number of individuals responsible for the laboratory and the effective date of the version.

This quality manual and related quality documentation also contains:

a) A quality ***policy statement***, including objectives and commitments, by top management;

i. Eurofins Calscience, Inc. (ECI) is committed to providing the highest quality environmental analytical services available. To ensure the production of scientifically sound, legally defensible data of known and proven quality, an extensive Quality Assurance program has been developed and implemented. This document, ECI's Quality Systems Manual for Environmental Analytical Services, presents an overview of the essential elements of our Quality Assurance program. ECI has modeled this systems manual after EPA guidelines as outlined in "Guidance for Quality Assurance Project Plans (EPA QA/G-5)", Office of Monitoring Systems and Quality Assurance, Office of Research and Development, U.S. EPA, EPA/240-R-02/009 December 2002. ECI's QA Program is closely monitored at the Corporate, Divisional, and Group levels, and relies on clearly defined objectives, well-documented procedures, a comprehensive quality assurance/quality control system, and management support for its effectiveness.

ii. This QA Program Systems Manual is designed to control and monitor the quality of data generated at ECI. The essential elements described herein are geared toward generating data that is in compliance with federal regulatory requirements specified under the Clean Water Act, the Safe Drinking Water Act, the Resource Conservation and Recovery Act, the Comprehensive Environmental Response, Compensation, and Liability Act, and applicable amendments, and state and DOD/DOE/DoE equivalents. Although the quality control requirements of these various programs are not completely consistent, each of the programs base data quality judgments on the following three types of information, the operational elements of each being described elsewhere in this manual.

⇨ Data which indicates the overall qualifications of the laboratory to perform environmental analyses;
⇨ Data which measures the laboratory's daily performance using a specific method; and
⇨ Data which measures the effect of a specific matrix on the performance of a method.

iii. It is important to note that the QA guidelines presented herein will always apply unless adherence to specific Quality Assurance Project Plans (QAPPs) or client and/or regulatory agency specific requirements are directed. In these cases, the elements contained within specified direction or documentation shall supersede that contained herein.

iv. This manual is a living document subject to periodic modifications to comply with regulatory changes and technological advancements. All previous versions of this document are obsolete. Users are urged to contact ECI to verify the current revision of this document.

b) The organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

See Figure 1 Organizational Chart, and Figure 2 and 3 Responsibility Charts.

c) The relationship between management, technical operations, support services and the quality system;

d) Procedures to ensure that all records required under the NELAP are retained, as well as procedures for control and maintenance of documentation through a document control system which ensures that all standard operating procedures, manuals, or documents clearly indicate the time period during which the procedure or document was in force;

i. Ensuring a high quality work product in the environmental laboratory not only requires adherence to the quality issues discussed in the previous sections, but also requires the ability to effectively archive, restore, and protect the records that are generated.

ii. Procedures are in place to ensure that all records are retained. In addition, a documentation control system is employed to clearly indicate the time period during which a standard operating procedure, manual, or document was in force. These procedures are outlined in the laboratory standard operating procedure SOP-T002.

iii. All laboratory logbooks, instrument response printouts, completed analytical reports, chain-of-custodies, and laboratory support documentation are stored for a minimum of five years. Project specific data are stored in sequentially numbered project files and include copies of the applicable laboratory logbooks, instrument response printouts, completed analytical reports, chain-of-custodies, and any other pertinent supporting documentation.

iv. When complete, the project specific data are high speed optically scanned and transformed into digital CD media. Additional copies of these records are created at the time of scanning and are stored off-site for protection of the data. These records are stored for a minimum of five years.

v. Access to all systems is limited by use of log-in and password protection and is maintained by the system administrator.

vi. There are four forms of electronic data that are generated in the laboratory. Refer to Table 1 – Data Archiving Schedule below for a synopsis of general data archiving schedules.

vii. All electronic records are stored for a minimum of five years.

TABLE 1 – DATA ARCHIVING SCHEDULE

<u>LIMS Database</u>	
Backup frequency:	Daily
Backup media:	Hard Disk
Backup software:	MS SQL Server Backup
Backup versions kept:	Ten previous versions
Onsite copy:	Redundancy by using mirrored hard drive
Offsite copy:	One (Replicate to Lampson Facility)
<u>Instrument Data</u>	

Backup frequency:	Daily
Backup media:	Hard Disk
Backup software:	NT Backup
Backup versions kept:	All versions
Offsite copy:	One (Replicate to Lampson Facility)

e) Job Descriptions, Roles and Responsibilities

In order for the Quality Assurance Program to function properly, all members of the staff must clearly understand and meet their individual responsibilities as they relate to their job function and the quality program as a whole.

The responsibility for quality lies with every employee at ECI. As such, all employees have access to the Quality Assurance Manual and are responsible for knowing the content of this manual and upholding the standards therein. Each employee is expected to conduct themselves in accordance with the procedures in this manual and the laboratory's SOPs.

The following descriptions define the primary roles and their relationship to the Quality Assurance Program. Members of the key staff include the following:

- Management (e.g., President, Vice-President, Business Unit Manager, Laboratory Director);
- Technical managers (e.g., Technical Director, Section Supervisors);
- Quality managers;
- Support systems and administrative managers (e.g., IT manager, Facilities manager, project managers); and
- Other staff

In these positions, members of the key staff are responsible for assuring compliance with the National Environmental Laboratory Accreditation Program (NELAP), California Environmental Laboratory Accreditation Program (ELAP), Department of Defense / Energy (DOD/DOE) ELAP, State and Federal Agencies, and ISO 17025:2005 Standard requirements. In these roles, key personnel may set or enforce quality policies, monitor compliance, initiate corrective actions, interface with laboratory, client, and regulatory personnel, and provide general program oversight.

Business Unit Manager:

ECI's Business Unit Manager represents ECI to the Eurofins US and Global Corporate entities.

- ⇨ Ensures that ECI's financial and production performance meets assigned metrics.
- ⇨ Determines need for capital and employee resources and allocates as appropriate.
- ⇨ Serves as the legal representative for ECI.
- ⇨ Responsible for yearly budget and overruns.
- ⇨ Point person for major new initiatives

Laboratory Director:

ECI's Laboratory Director, through its Business Unit Manager, is the final authority on all issues dealing with data quality and has the authority to require that procedures be amended or discontinued, or analytical results voided or repeated. He or she also has the authority to suspend or terminate employees on the grounds of non-compliance with QA/QC procedures. In addition, the Laboratory Director:

- ⇨ Ensures that ECI remains current with all regulations which affect operations and disseminate all such changes in regulatory requirements to the QA Director, Technical Director, QA Manager, and Group Leaders;
- ⇨ Provides one or more Technical Directors for the appropriate fields of testing. The name(s) of the Technical Director are included in the national database. (The Laboratory Director may also act in the Technical Director capacity.) If the Technical Director is absent for a period of time exceeding 15 consecutive calendar days, the Laboratory Director will designate another full time staff member meeting the qualifications of the Technical Director to temporarily perform this function. If the absence exceeds 35 consecutive calendar days, the primary accrediting authority will be notified in writing;
- ⇨ Ensures that all analysts and supervisors have the appropriate education and training to properly carry out the duties assigned to them and ensures that this training has been documented;
- ⇨ Ensures that personnel are free from any commercial, financial and other undue pressures which might adversely affect the quality of their work;
- ⇨ Oversees the development and implementation of the QA Program which assures that all data generated will be scientifically sound, legally defensible, and of known quality;
- ⇨ In conjunction with the QA Manager, conducts annual reviews of the QA Program;
- ⇨ Oversees the implementation of new and revised QA procedures to improve data quality;
- ⇨ Ensures that appropriate corrective actions are taken to address analyses Identified as requiring such actions by internal and external performance or procedural audits. Procedures that do not meet the standards set forth in the QAM or laboratory SOPs may be temporarily suspended by the Laboratory Director;
- ⇨ Reviews and approves all SOPs prior to their implementation and ensures all approved SOPs are implemented and adhered to;
- ⇨ Oversees all laboratory accreditation efforts

Operations Director:

The Operations Director manages and directs the analytical production sections of the laboratory. He or she reports directly to the Laboratory Director and assists in determining the most efficient instrument utilization. More specifically, he/she:

- ⇨ Evaluate the level of internal/external non-conformances for all departments;
- ⇨ Continuously evaluate production capacity and improves capacity utilization;
- ⇨ Continuously evaluate turnaround time and addresses any problems that may hinder meeting the required and committed turnaround time from the various departments;
- ⇨ Develop and improve the training of all analysts in cooperation with the Laboratory Director, QA Director, QA Manager and Group Leaders, and in compliance with regulatory requirements;
- ⇨ Ensure that scheduled instrument maintenance is completed;
- ⇨ Are responsible for efficient utilization of supplies;
- ⇨ Constantly monitor and modify the processing of samples through the departments; and
- ⇨ Maintain sufficient personnel, equipment and supplies to achieve production goals.

Technical Director:

The Technical Director reports to the Business Unit Manager and is responsible for all laboratory, client, and project technical issues. More specifically, he/she:

- ⇨ For major projects and/or clients, act as a technical resource for the client and the laboratory in matters of method selection or QC criteria.
- ⇨ Company-wide, maintains all training-related documentation in a single secure location. Develops training guides and other training documentation as needed;

- ⇨ Interface directly with Project Management staff in response to questions pre-release or from the client post-release. Determine causation and interface with QA staff to prevent recurrences;
- ⇨ Interface directly with clients, or other client representatives in matters related to technical data quality requests.
- ⇨ Attend client, Business Development, or industry meetings with or without management when a 'technical representative' is required or would be beneficial to ECI.
- ⇨ Provide support to Business Development through the review of DOD/DOE-related SAPs, QAPPs, and work plans. Provide comment and alternative solutions if unable to meet specific requirements. Populate DOD/DOE UFP QAPP tables for client SAPs/QAPPs when needed;
- ⇨ Support QA and Operations with SOP revisions, where needed;
- ⇨ Perform full QA reviews and/or data validation where required;
- ⇨ Provide technical solutions to QA with regard to laboratory procedures, data quality issues, possible solutions, and appropriate corrective actions;
- ⇨ Provide technical opinions and support to Operations with regard to current procedures or new method development;
- ⇨ Interface with QA staff as necessary to ensure continuous improvement in all areas of ECI's operations.
- ⇨ Provide LIMS input; and
- ⇨ As may be necessary, act as Program Director for DOD/DOE or other high profile projects.

Quality Assurance Director:

The Quality Assurance (QA) Director has full authority through the Business Unit Manager in all matters relating to quality assurance and quality control systems. The QA Director can make recommendations to the Business Unit Manager and/or Laboratory Director regarding the suspension analytical activities or the suspension or termination of employees on the grounds of non-compliance with QA/QC systems or procedures. An alternate QA Director is always assigned. In the absence of the primary designate, the alternate will act in the QA Director's capacity with the full authority of the position as allowed by ECI governing documents. In addition, the QA Director performs the following:

- ⇨ Oversight and monitoring of and compliance with ECI's QA program;
- ⇨ Ensuring continuous improvement in all aspects of ECI's QA program such as:
  - o accreditations/certifications;
  - o analytical method management;
  - o internal and external audits;
  - o documentation;
  - o training;
  - o proficiency evaluation studies;
- ⇨ Ensuring ECI's QA program remains up-to-date consistent with current regulatory requirements and ECI's QA policies;
- ⇨ Supervision and direction of all QA staff; and
- ⇨ Serving as a technical resource for analytical chemistry or QA matters;
- ⇨ Provide support and oversight to QA staff with regard to external audit responses. Provide input on, and define appropriate corrective actions for the laboratory. Document corrective action responses, and monitor the required audit response time frames, as needed.
- ⇨ Oversees in-house training on quality assurance and control.

Quality Assurance Manager:

The Quality Assurance (QA) Manager has full authority through the Quality Assurance Director in matters dealing within the laboratory. The QA Manager can make recommendations to the Quality Assurance Director and/or Laboratory Director regarding the suspension or termination of employees on the grounds of

non-compliance with QA/QC procedures. An alternate QA Manager is always assigned. In the absence of the primary designate, the alternate will act in the QA Manager's capacity with the full authority of the position as allowed by ECI governing documents. In addition, the QA Manager performs the following:

- ⇨ Maintains and updates the QAM on an annual basis;
- ⇨ Implements ECI's QA Program;
- ⇨ Monitors the QA Program within the laboratory to ensure complete compliance with its objectives, QC procedures, holding times, and compliance with client or project specific data quality objectives;
- ⇨ Distributes performance evaluation (PE) samples on a routine basis to ensure the production of data that meets the objectives of its QA Program;
- ⇨ Maintains all SOPs used at ECI;
- ⇨ Maintains records and archives of all PE results, audit comments, and customer inquiries concerning the QA program;
- ⇨ Performs statistical analyses of QC data and establish controls that accurately reflect the performance of the laboratory;
- ⇨ Conducts periodic performance and system audits to ensure compliance with the elements of ECI's QA Program;
- ⇨ Prescribes and monitors corrective action;
- ⇨ Serves as in-house client representative on all project inquiries involving data quality issues;
- ⇨ Coordinates data review process to ensure that thorough reviews are conducted on all project files;
- ⇨ Develops revisions to existing SOPs;
- ⇨ Reports the status of in-house QA/QC to the Laboratory Director;
- ⇨ Maintains records and archives of all QA/QC data including but not limited to method detection limit (MDL) studies, accuracy and precision control charts, and completed log books; and
- ⇨ Conducts and/or otherwise ensures that an adequate level of QA/QC training is conducted within the laboratory.

Quality Assurance Assistant:

The QA Assistant reports to the QA Manager and performs the following functions:

- ⇨ Assists the QA Manager and lab staff with internal audits, corrective action review, test method assessments and overall implementation of the QA program;
- ⇨ Generates and reviews, in conjunction with the QA Manager, Control Charts and Method Detection Limit (MDL) studies;
- ⇨ Reviews and revises SOPs as needed;
- ⇨ Distributes new SOPs to all applicable lab areas.
- ⇨ Writes and promulgates QA Directives.

Director of Business Development:

The Director of Business Development reports to the Laboratory Director and serves as the interface between the laboratory's technical departments and the laboratory's clients. The staff consists of the Project Management team, Business Development team and satellite office Operations Manager. With the overall goal of total client satisfaction, the functions of this position are outlined below:

- ⇨ Technical training and growth of the Project Management team;
- ⇨ Business liaison for the Project Management team;
- ⇨ Human resource management of the Project Management team;
- ⇨ Responsible for the review and negotiation of client contracts and terms and conditions;

- ⇨ Responsible for establishing standard fee schedules for the laboratory;
- ⇨ Responsible for preparation of proposals and quotes for clients and client prospects;
- ⇨ Accountable for response to client inquiries concerning sample status;
- ⇨ Responsible for assistance to clients regarding the resolution of problems concerning Chains-of-Custody;
- ⇨ Ensuring that client specifications, when known, are met by communicating project and quality assurance requirements to the laboratory;
- ⇨ Notifying the department managers of incoming projects and sample delivery schedules;
- ⇨ Accountable to clients for communicating sample progress in daily status meeting with agreed-upon due dates;
- ⇨ Responsible for discussing with client any project-related problems, resolving service issues, and coordinating technical details with the laboratory staff;
- ⇨ Responsible for staff familiarization with specific quotes, sample log-in review, and final report completeness; and
- ⇨ Ensure that all non-conformance conditions are reported to the QA Manager, Operations Manager, and/or Laboratory Director via the Corrective Action process.

Technical Managers (at ECI known as Group Leaders):

The Group Leaders report directly to the Operations Director. They have the authority to accept or reject data based on pre-defined QC criteria. In addition, with the approval of the QA Manager, the Group Leaders may accept data that falls outside of normal QC limits if, in his or her professional judgment, there are technical justifications for the acceptance of such data. The circumstances must be well documented and any need for corrective action identified must be defined and initiated. The authority of the Group Leaders in QC related matters results directly from the QA Manager. The Group Leaders also

- ⇨ Coordinating, writing, and reviewing test methods and SOPs, with regard to quality, integrity, regulatory requirements and efficient production techniques;
- ⇨ Monitoring the validity of the analyses performed and data generated in the laboratory. This activity begins with reviewing and supporting all new business contracts, insuring data quality, analyzing internal and external non-conformances to identify root cause issues and implementing the resulting corrective and preventive actions, facilitating the data review process and providing technical and troubleshooting expertise on routine and unusual or complex problems;
- ⇨ Providing training and development programs to applicable laboratory staff as new hires and, subsequently, on a scheduled basis; and
- ⇨ Coordinates audit responses with supervisors and QA Manager.
- ⇨ Actively support the implementation of ECI's QA Program;
- ⇨ Ensure that their employees are in full compliance with ECI's QA Program;
- ⇨ Maintain accurate SOPs (by reviewing and implementing updates) and enforce routine compliance with SOPs;
- ⇨ Conduct technical training of new staff and when modifications are made to existing procedures;
- ⇨ Maintain a work environment which emphasizes the importance of data quality;
- ⇨ Ensure all logbooks are current, reviewed and properly labeled or archived;
- ⇨ Ensure that all non-conformance conditions are reported to the QA Manager, Operations Manager, and/or Laboratory Director via Corrective Action reports;
- ⇨ Provide guidance to analysts in resolving problems encountered daily during sample prep/analysis in conjunction with the Technical Director, Operations Manager, and/or QA Manager. Each is responsible for 100% of the data review and documentation, nonconformance issues, and the timely and accurate completion of performance evaluation samples and MDLs, for his/her department;.

- ⇨ Encourage the development of analysts to become cross-trained in various methods and/or operate multiple instruments efficiently while performing maintenance and using appropriate documentation techniques;.
- ⇨ Ensure that preventive maintenance is performed on instrumentation as detailed in the QA Manual or SOPs. He or she is responsible for developing and implementing a system for preventive maintenance, troubleshooting, and repairing or arranging for repair of instruments;
- ⇨ Provide written responses to external and internal audit issues; and
- ⇨ Provide support to all levels of ECI Management.

Technical Managers (Sample Control Group Leader):

The Sample Control Group Leader reports to the Operations Manager. The responsibilities are outlined below:

- ⇨ Direct the receipt, handling, labeling and proper storage of samples in compliance with laboratory procedures and policies;
- ⇨ Oversee the training of Sample Control Technicians regarding the above items;
- ⇨ Direct the logging of incoming samples into the LIMS and ensure the verification of data entry from login;
- ⇨ Oversee all sample courier operations;
- ⇨ Acts as a liaison between Project Managers and Analytical departments in respect to handling rush orders and resolving inconsistencies and problems with chain-of-custody forms, and routing of subcontracted analyses; and
- ⇨ Oversees the handling of samples in accordance with the Waste Disposal SOP, the Hazardous Waste Contingency Plan in the Chemical Hygiene/Safety Manual, and the U. S. Department of Agriculture requirements.

Laboratory Analysts

Laboratory analysts are responsible for conducting analysis and performing all tasks assigned to them by the group leader or supervisor. The responsibilities of the analysts are listed below:

- ⇨ Perform analyses by adhering to analytical and quality control protocols prescribed by current SOPs, this QA Manual, the Data Integrity Policy, and project-specific QA plans honestly, accurately, timely, safely, and in the most cost-effective manner.
- ⇨ Document standard and sample preparation, instrument calibration and maintenance, data calculations, sample matrix effects, and any observed non-conformance on work sheets, bench sheets, preparation logbook, and/or a Non-Conformance report;
- ⇨ Report all non-conformance situations, instrument problems, matrix problems and QC failures, which might affect the reliability of the data, to the Group Leader and/or the QA Manager;
- ⇨ Perform 100% review of the data generated prior to entering and submitting for secondary level review; and
- ⇨ Work cohesively as a team in their department to achieve the goals of accurate results, optimum turnaround time, cost effectiveness, cleanliness, complete documentation, and personal knowledge of environmental analysis.

Laboratory Technicians:

- ⇨ Prepare samples for analysis by weighing, extracting or digesting, filtering, or concentrating samples; and

- ⇨ Prepare method specific QC Samples with each preparation batch. All personnel must adhere to all QC procedures specified in the analytical method and in accordance to procedures or policies and are responsible for the full documentation of these procedures.

Project Managers:

The Project Manager normally reports to the Senior Project Manager and/or Business Development Director. Typical responsibilities include:

- ⇨ Serving as the laboratories' primary point of contact for assigned clients;
- ⇨ Working with laboratory chemists to resolve questions on data;
- ⇨ Scheduling of courier deliveries and pick-ups;
- ⇨ Tracking the progress of all laboratory production efforts;
- ⇨ Advising clients of any scheduling conflicts, possible delays, or other problems which may arise;
- ⇨ Resolving any questions or issues that clients may have with regard to our services, especially our reports;
- ⇨ Preparation of bottle kits for use by clients in their sampling efforts (as necessary);
- ⇨ Reviewing of reports/EDDs (Electronic Data Deliverables) as necessary prior to release;
- ⇨ Invoice preparation and review prior to release to client;
- ⇨ Serving as back-up contact person for other Project Managers in the event of his/her absence;
- ⇨ Coordination of all subcontracting efforts for projects assigned;
- ⇨ Preparation and implementation of program QAPPs (Quality Assurance Project Plans), if needed;
- ⇨ Preparation of project Case Narratives, as needed; and
- ⇨ Assembly of full data packages in accordance with company or client protocol, as needed.

Project Management Assistant:

The Project Management Assistant normally receives direction from the Project Manager(s) for which he/she is assigned. Typical responsibilities include:

- ⇨ Working with laboratory chemists to resolve questions on data;
- ⇨ Scheduling of courier deliveries and pick-ups;
- ⇨ Tracking the progress of all laboratory production efforts;
- ⇨ Advising clients of any scheduling conflicts, possible delays, or other problems which may arise;
- ⇨ Resolving any questions or issues that clients may have with regard to our services, especially our reports;
- ⇨ Preparation of bottle kits for use by clients in their sampling efforts;
- ⇨ Reviewing of reports/EDDs (Electronic Data Deliverables) prior to release;
- ⇨ Invoice preparation and review prior to release to client;
- ⇨ Serving as back-up contact person for the project managers in the event of his/her absence;
- ⇨ Coordination of all subcontracting efforts for projects assigned; and
- ⇨ Preparation and implementation of program QAPPs (Quality Assurance Project Plans), if needed.
- ⇨ As part of the administrative staff, this person may also be required to answer phones, do occasional filing, mailing, etc.

Health, Safety, and Respiration Protection Manager:

The Health and Safety Manager reports to the Laboratory Director and ensures that systems are maintained for the safe operation of the laboratory. The EHS Manager is responsible for:

- ⇨ Conducting ongoing, necessary safety training and conducting new employee safety orientations;
- ⇨ Assisting in developing and maintaining the Chemical Hygiene/Safety Manual;
- ⇨ Oversees the inspection and maintenance of general safety equipment – fire extinguishers, safety showers, eyewash fountains, etc. and ensure prompt repairs as needed; and
- ⇨ Completes accident reports, follows up on root causes and defines corrective actions.

Hazardous Waste Coordinator:

The Hazardous Waste Coordinator reports directly to the Environmental Health & Safety Manager. The duties of the HWC consist of:

- ⇨ Staying current with the hazardous waste regulations and continuing training on hazardous waste issues;
- ⇨ Contacting the hazardous waste subcontractors for review of procedures and opportunities for minimization of waste;
- ⇨ Supervise the recording of the transfer of samples from refrigerated conditions to ambient conditions [in the sample disposal log sheets (SDLS)];
- ⇨ Check the records in SDLS against the logbook (LIMS) records;
- ⇨ Coordinate the collection of waste throughout the laboratory that will be disposed of through “Lab Packs”;
- ⇨ Coordinate and supervise Hazardous Waste Technician(s);
- ⇨ Dispose of solid waste to an assigned Tote;
- ⇨ Supervise the recording and disposal of acid and soil with methylene chloride extracts into appropriate drums;.
- ⇨ Prepare and discharge treated wastewater to the sewer system;
- ⇨ Maintain Uniform Hazardous Waste Manifest files;
- ⇨ Prepare weekly sample disposal schedules;
- ⇨ Coordinate and schedule waste pick-up;
- ⇨ Check all waste containers for appropriate labels; and
- ⇨ Maintain safe housekeeping and practices.

Education and Experience

ECI makes every effort to hire analytical staff that posses a college degree (AA, BA, BS) in an applied science with some chemistry in the curriculum. Exceptions are made based upon experience and an individual’s ability to learn as there are many in the industry that are more than competent, experts perhaps, who have not earned a college degree.

Selection of qualified individuals for employment begins with documentation of minimum education, training, and experience prerequisites needed to perform the prescribed task. Experience and specialized training may be accepted in lieu of a college degree (basic lab skills such as using a balance, aseptic or quantitation techniques, etc. are also considered).

Included in Section 5.2 (e) of this Quality Assurance Manual are the basic job titles and personnel responsibilities for anyone who manages, performs or verifies work affecting the quality of the laboratory’s environmental sample testing. Minimum education and training requirements are summarized in the following table:

When an analyst does not meet these minimum requirements, they can perform a task under the direct supervision of a qualified analyst, peer reviewer or Group Leader, and are considered an analyst in training. The person supervising an analyst in training is directly accountable for the quality of the analytical data and must review and approve data and associated corrective actions.

Job Type	Education	Experience
Extractions, Digestions, some electrode methods (pH, DO, Redox, etc.), Titrimetric and Gravimetric Analyses,	H.S. Diploma or GED	On the job training
GFAA, CVAA, FLAA, Single component or short list Chromatography (e.g., Fuels, BTEX-GC, IC	A college degree in an applied science or 2 years of college with at least 1 year of college chemistry, or	2 years prior analytical experience is required
ICP, ICPMS, Long List or complex chromatography (e.g., Pest, PCB, Herb, HPLC, etc.), GCMS	A college degree in an applied science or 2 years of college chemistry, or	5 years of prior analytical experience is required
Spectra Interpretation	A college degree in an applied science or 2 years of college Chemistry, and	2 years relevant experience, or 5 years of prior analytical experience is required
Group Leaders – Advanced Instrumentation	Bachelors Degree in an applied science with 16 semester hours in chemistry. An advanced (MS, PhD.) degree may substitute for one year of experience, and	2 years experience in the analytical technique for environmental analysis of representative analytes for which they will oversee
Group Leaders – Wet Chemistry (Basic Skills)	Associates degree in an applied science or 2 years of college with 16 semester hours in Chemistry, and	2 years relevant experience

f) Identification of the laboratory's approved signatories; at a minimum, the title page of the quality manual has the signed and dated concurrence (with appropriate titles) of all responsible parties including the QA Manager, Operations, QA, Technical, Laboratory and Operations Directors.

g) The laboratory's procedures for achieving traceability of measurements;

h) A list of all test methods under which the laboratory performs its accredited testing may be found in the Index of Standard Operating Procedures, a separate document.

i) Mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

j) Reference to the calibration and/or verification test procedures used;

Calibration procedures and verification of acceptability for each set of required calibrations are defined in Section 13 (Calibration) and Section 12 (Quality Control) of each standard operating procedure.

k) Procedures for handling samples received;

The generation of quality analytical data begins with the collection of the sample and, therefore, the integrity of the sample collection process is of importance to ECI. Samples must be collected in such a way that foreign material is not introduced into the samples and that analytes of interest do not escape from the samples or degrade prior to their analysis. To ensure sample integrity and representativeness, the following items must be considered:

- ⇨ Samples must be collected in appropriate containers. In general, glass containers are used for organic analytes and polyethylene for inorganic/metal analytes;
- ⇨ Only new sample containers which are certified and documented clean in accordance with U.S. EPA OSWER Directive No. 9240.0-0.05 specifications shall be provided by ECI for sample collection;
- ⇨ Certain extremely hazardous samples or samples that have the potential to become extremely hazardous will not be accepted. These include (but are not limited to)

    1. Radioactive samples that significantly exceed background levels
    2. Biohazardous samples (medical wastes, body fluids, etc.)
    3. Explosive samples in pure form (Semtex, Flash or gunpowder, ammunition, flares, etc.)
    4. Neurological or other toxic agents (Sarin, Anthrax, Ricin, etc.)

ECI's chain-of-custody document is used to forward samples from the client to the laboratory. As the basic elements of most all chain-of-custody (COC) documents are similar, clientele may choose to use their own chain-of-custody document to forward samples to ECI.

Any discrepancies in the COC must be documented on the Sample Receipt Form and resolved prior to analysis of samples. Further guidance may be found in SOP T100 “Sample Receipt and Log-In Procedures”.

Upon receipt by ECI, samples proceed through an orderly processing sequence designed to ensure continuous integrity of both the sample and its documentation from sample receipt through its analysis and beyond.

All coolers that are received by the Sample Control Group undergo a preliminary examination in accordance of the Sample Receipt Form. Specifically, each sample is carefully examined for label identification, proper container (type and volume), chemical preservation when applicable, container condition, and chain-of-custody documentation consistency with sample labels. Discrepancies are noted on both the Sample Receipt Form and the Sample Anomaly Form and, if possible, discussed with the client prior to his or her departure. If this is not possible, the discrepancies are communicated to the client for resolution prior to the completion of the log-in process. The temperature of the cooler is measured and, with other observations, is recorded.

During the log-in process each sample is assigned a unique laboratory identification number through a computerized Laboratory Information Management System (LIMS), which stores all essential project information. ECI maintains multiple security levels of access into LIMS to prevent unauthorized tampering/release of sample and project information.

Once all analyses for a sample have been completed and the sample container is returned to Sample Control, it shall remain in refrigerated storage for a period not less than 14 days following sample receipt unless the client requests return/forwarding of the sample. Following the 14-day refrigerated storage period, the samples are placed into ambient storage for another period not less than 14 days after which the samples are bulked into drums for later disposal.

Extended storage may be requested at prevailing per sample rates.

l) Reference to the major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests;

A list of major equipment is kept up-to-date on the List of Major Assets, reference Appendix G. This, as well as a list of reference measurement standards and their certificates of calibration, is maintained by the QA Manager or the respective departments. In general, all calibrations and references should be traceable to NIST

m) Reference to procedures for calibration, verification and maintenance of equipment; Laboratory SOPs (T043 and T066) are available to staff for calibration, verification and maintenance of equipment. In general,

n) Reference to verification practices which may include inter-laboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes;

Instrument calibration is required to ensure that the analytical system is operating correctly and functioning at the proper sensitivity such that required reporting limits can be met. Each instrument is calibrated with standard solutions appropriate to the type of instrument and the linear range established for the analytical method. The manufacturer's guidelines, the analytical method, and/or the requirements of special contracts determine the frequency of calibration and the concentration of calibration standards, whichever is most applicable. The following are very general guidelines and are not meant to be all-inclusive. Detailed calibration procedures are specified in the SOP for each method performed.

Gas Chromatography/Mass Spectroscopy (GC/MS): Each day prior to analysis of samples, all GC/MS instruments are tuned with 4-bromofluorobenzene (BFB) for VOCs and decafluorotriphenylphosphine (DFTPP) for SVOCs in accordance with the tuning criteria specified in the applicable methods. Samples are not analyzed until the method-specific tuning requirements have been met.

After the tuning criteria are met, the instrument is then calibrated for all target analytes and an initial multipoint calibration curve established. The calibration curve is then validated by the analysis of a second source standard, referred to as the initial calibration verification (ICV). Alternatively, the previous calibration curve may be used if validated by a continuing calibration verification (CCV) standard. All target analytes are represented in the calibration and certain key target analytes referred to as system performance calibration compounds (SPCCs) and calibration check compounds (CCCs) are used for curve acceptance determination. For the initial calibration to be deemed acceptable, the SPCCs and CCCs must meet established acceptance criteria and must be re-evaluated and meet the acceptance criteria, at a minimum, every twelve (12) hours thereafter.

Non-GC/MS Chromatography: The field of chromatography involves a variety of instrumentation and detectors. While calibration standards and control criteria vary depending upon the type of system and analytical methodology required for a specific analysis, the general principles of calibration apply uniformly. Each chromatographic system is calibrated prior to sample analysis. An initial multipoint calibration curve is generated using all target analytes. All target analytes must meet the acceptance criteria for the calibration to be deemed acceptable. The calibration curve is then validated by the analysis of a second source standard, referred to as the initial calibration verification (ICV). The continued validity of the initial multipoint calibration is verified every 12 hours using continuing calibration verification (CCV) standard containing all target analytes. If the CCV fails to meet the acceptance criteria, the system is re-calibrated and all samples analyzed since the last acceptable CCV must be re-analyzed.

Inductively Coupled Plasma Emission Spectroscopy: Initial calibration consists of a calibration blank (CB) plus one calibration standard. The calibration is verified by the re-analysis of the standard and initial calibration verification (ICV) standard. If the standard and the ICV fail to meet the acceptance criteria, the initial calibration is considered invalid and is re-performed.

Continuing calibration verification (CCV) consists of a mid-concentration standard plus a calibration blank (CB) analyzed every 10 samples and at the end of the sequence. If the CCV and/or CB fail to meet the acceptance criteria, the instrument must be re-calibrated and all samples analyzed since the previous acceptable CCV and/or CB must be re-analyzed.

ICP/MS Spectroscopy: Each day prior to the analysis of samples, all ICP/MS instruments undergo mass calibration and resolution checks prior to initial calibration. Initial calibration consists of a calibration blank (CB) and at least one calibration standard. The calibration is verified by the re-analysis of the standard and initial calibration verification (ICV) standards. If the standard and the ICV fail to meet the acceptance criteria, the initial calibration is considered invalid and is re-performed.

Continuing calibration verification (CCV) consists of a mid-concentration standard plus a calibration blank (CB) analyzed every 10 samples and at the end of the sequence. If the CCV and/or CB fail to meet the acceptance criteria, the instrument must be re-calibrated and all samples analyzed since the previous acceptable CCV and/or CB must be re-analyzed.

Cold Vapor Atomic Absorption Spectroscopy: Initial calibration consists of a calibration blank plus a series of at least 5 standards. The calibration curve is then validated by the analysis of a second source standard, referred to as the initial calibration verification (ICV). Continuing calibration verification (CCV) consists of midpoint calibration standard plus a continuing calibration blank (CCB) analyzed every 10 samples and at the end of the sequence. If the CCV and/or CCB fail to meet the acceptance criteria, the instrument must be re-calibrated and all samples analyzed since the previous acceptable CCV and/or CCB must be re-analyzed. If the calibration blanks contain target analyte concentrations exceeding the acceptance limits, the cause must be determined and corrected.

Flame and Graphite Furnace Atomic Absorption Spectroscopy: Initial calibration consists of a calibration blank plus a low, medium, and high calibration standard. Continuing calibration verification (CCV) consists of midpoint calibration standard plus a continuing calibration blank (CCB) analyzed every 10 samples and at the end of the sequence. If the CCV and/or CCB fail to meet the acceptance criteria, the instrument must be re-calibrated and all samples analyzed since the previous acceptable CCV and/or CCB must be re-analyzed. If the calibration blanks contain target analyte concentrations exceeding the acceptance limits, the cause must be determined and corrected.

General Inorganic Analyses: General inorganic (non-metal) analyses involve a variety of instrumental and wet chemistry techniques. While calibration procedures vary depending on the type of instrumentation and methodology, the general principles of calibration apply universally. Each system or method is initially calibrated using standards prior to analyses being conducted with continual verification that the calibration remains acceptable throughout analytical processing. If continual calibration verification fails to meet the acceptance criteria, the instrument must be re-calibrated and all samples analyzed since the previous acceptable CCV must be re-analyzed.

o) Procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur;

These procedures may be found in SOP-T015 (Correction/Prevention of Errors in Test Records) and SOP-T022 (Corrective/Preventive Actions).

p) The laboratory management arrangements for permitting exceptions and departures from documented policies and procedures or from standard specifications;

ECI's SOPs are in substantial conformity with their corresponding published method references. Departure from approved SOPs shall be approved if necessary or appropriate due to the nature or composition of the sample or otherwise based on the reasonable judgment of ECI's Laboratory Director, Technical Director, or QA Manager.

Departures shall be made on a case-by-case basis consistent with recognized standards of the industry. In no case shall departures be approved without written communication between EC Iand the affected client.

q) Procedures for dealing with complaints;

Procedures for dealing with complaints may be found in SOP-T018, Handling of Inquiries and Complaints.

r) Procedures for protecting confidentiality (including national security concerns) and proprietary rights;

ECI is sensitive to the fact that much of the analytical work performed for clientele may be subject to litigatory processes. ECI, therefore, holds all information in strict confidence with laboratory release only to the client or designee. Information released to entities other than the client is performed only upon written, facsimile or e-mail request from the client.

Due to the investigative nature of most site assessments, analytical information may become available to regulatory agencies or other evaluating entities during site assessment of the laboratory for the specific purpose of attaining laboratory certifications, accreditations, or evaluation of laboratory qualification for future work. During these occurrences, the laboratory will make its best effort to maintain the confidence of client specific information.

s) Procedures for audits;

ECI participates in a wide variety of system and performance audits conducted by numerous federal and state agencies, as well as through its major clientele. These audits are conducted to verify that analytical data produced conforms to industry standards on a routine basis.

A System Audit is a qualitative evaluation of the measurement systems utilized at ECI, specifically, that ECI has, in place, the necessary facilities, staff, procedures, equipment, and instrumentation to generate acceptable data. This type of audit typically involves an on-site inspection of the laboratory facility, operations, and interview of personnel by the auditing agency.

A Performance Audit verifies the ability of ECI to correctly identify and quantitate compounds in blind check samples. This type of audit normally is conducted by the auditing agency through laboratory participation in round robin Performance Evaluation (PE) programs. Examples of current PE program involvement include those offered by commercial suppliers like ERA (WS/WP/SOIL and DMR-QA), or other inter-laboratory studies not required for certification but done to ensure laboratory performance, as well as programs administered by major industry.

Outliers in required PE samples will be investigated and corrective actions documented using the Corrective/Preventive Action Record.

Should the result of any audit detect a significant error, which has been identified to adversely affect released data, the situation shall be thoroughly investigated. Corrective measures shall be enacted to include system re-evaluation, the determined affect on released data and client notification, as necessary. These measures shall be documented using the Corrective/Preventive Action Record.

t) Processes/procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training;

Quality control begins prior to sample(s) receipt at the laboratory. The selection of well qualified personnel, based upon education and/or experience is the first step in successful laboratory management. A thorough screening of job applicants and selection of the best candidate to fulfill a well-defined need is as important an aspect of a successful QA/QC program as a careful review of analytical data.

Employee training and approval procedures used at ECI are specified in SOP-T010, "Employee Training", and includes but is not limited to the following:

- ⇨ A thorough understanding of the applicable regulatory method and ECISOP;
- ⇨ A review of ECI's QA Program Manual and thorough understanding of the specifics contained therein that are directly related to the analysis to be performed;
- ⇨ Instruction by the applicable Group Leader on all aspects of the analytical procedure;
- ⇨ Performance of analyses under supervision of experienced laboratory personnel, which shall include analysis of blind QC check samples, when deemed appropriate;
- ⇨ Participation in in-house seminars on analytical methodologies and procedures;
- ⇨ Participation in job related seminars outside of the laboratory; and
- ⇨ Participation in conventions and meetings, i.e., ACS, etc.

u) Ethics policy statement developed by the laboratory and processes/procedures for educating and training personnel in their ethical and legal responsibilities including the potential punishments and penalties for improper, unethical, or illegal actions;

A vital part of ECI's analytical laboratory services is their Laboratory Ethics Training Program. An effective program starts with an Ethics Policy Statement that is supported by all staff, and is reinforced with initial and ongoing ethics training.

"It shall be the policy of ECI to conduct all business with integrity and in an ethical manner. It is a basic and expected responsibility of each staff member and manager to hold to the highest ethical standard of professional conduct in the performance of all duties."

A proactive ethics training program is the most effective means of deterring and detecting improper, unethical, or illegal actions in the laboratory. There are six facets to the program: (1) clearly define improper, unethical, and illegal actions; (2) outline elements of prevention and detection programs for improper, unethical, or illegal actions; and (3) identify examples of inappropriate (i.e., potentially fraudulent) laboratory practices; (4) Annual Ethics and Data Integrity Training to be documented and maintained in the personnel file of each employee., (5) Documented training on new revisions of the Quality Systems Manual (QSM) and for new employees as needed. (6) Signed Ethics and Data Integrity Agreement (to be completed for new employees and annually thereafter)

Definition of Improper, Unethical, and Illegal Actions

Improper actions are defined as deviations from contract-specified or method-specified analytical practices and may be intentional or unintentional.

Unethical or illegal actions are defined as the deliberate falsification of analytical or quality assurance results, where failed method or contractual requirements are made to appear acceptable.

Prevention of laboratory improper, unethical, or illegal actions begins with a zero-tolerance philosophy established by management. Improper, unethical, or illegal actions are detected through the implementation of oversight protocols.

Prevention and Detection Program for Improper, Unethical, or Illegal Actions

ECI management has implemented a variety of proactive measures to promote prevention and detection of improper, unethical, or illegal activities. The following components constitute the basic program:

- ⇨ Data Integrity Standard Operating Procedure (SOP) T065
- ⇨ Data Integrity Documentation Procedures
- ⇨ An Ethics and Data Integrity Agreement that is read and signed by all personnel;
- ⇨ Initial and annual ethics training;

- ⇨ Internal audits;
- ⇨ Inclusion of anti-fraud language in subcontracts;
- ⇨ Analyst notation and sign-off on manual integration changes to data;
- ⇨ Active use of electronic audit functions when they are available in the instrument software; and
- ⇨ A "no-fault" policy that encourages laboratory personnel to come forward and report fraudulent activities. Alternately, employees may report ethics violations to a third party agent contracted by Eurofins USA c/o reports@lighthouse-services.com/eurofinsus

A proactive, "beyond the basics" approach to the prevention of improper, unethical, or illegal actions are a necessary part of laboratory management. As such, in addition to the requirements above, ECI has a designated ombudsman (data integrity officer) to whom laboratory personnel can report improper, unethical, or illegal practices, or provide routine communication of training, lectures, and changes in policy intended to reduce improper, unethical, or illegal actions.

Examples of Improper, Unethical, or Illegal Practices

Documentation that clearly shows how all analytical values were obtained are maintained by ECI and supplied to the data user as needed. To avoid miscommunication, ECI clearly documents all errors, mistakes, and basis for manual integrations within the project file and case narrative as applicable. Notification is also made to the appropriate supervisor so that appropriate corrective actions can be initiated. Gross deviations from specified procedures are investigated for potential improper, unethical, or illegal actions, and findings of fraud are fully investigated by senior management. Examples of improper, unethical, or illegal practices are identified below:

- ⇨ Improper use of manual integrations to meet calibration or method QC criteria (for example, peak shaving or peak enhancement are considered improper, unethical, or illegal actions if performed solely to meet QC requirements);
- ⇨ Intentional misrepresentation of the date or time of analysis (for example, intentionally resetting a computer system's or instrument's date and/or time to make it appear that a time/date requirement was met);
- ⇨ Falsification of results to meet method requirements;
- ⇨ Reporting of results without analyses to support (i.e., dry-labbing);
- ⇨ Selective exclusion of data to meet QC criteria (for example, initial calibration points dropped without technical or statistical justification);
- ⇨ Misrepresentation of laboratory performance by presenting calibration data or QC limits within data reports that are not linked to the data set reported, or QC control limits presented within QAPP that are not indicative of historical laboratory performance or used for batch control;
- ⇨ Notation of matrix inference as basis for exceeding acceptance limits (typically without implementing corrective actions) in interference-free matrices (for example, method blanks or laboratory control samples);
- ⇨ Unwarranted manipulation of computer software (for example, improper background subtraction to meet ion abundance criteria for GC/MS tuning, chromatographic baseline manipulations);
- ⇨ Improper alteration of analytical conditions (for example, modifying EM voltage, changing GC temperature program to shorter analytical run time) from standard analysis to sample analysis;
- ⇨ Misrepresentation of QC samples (for example, adding surrogates after sample extraction, omitting sample preparation steps for QC samples, over- or under-spiking); and
- ⇨ Reporting of results from the analysis of one sample for those of another.

v) Reference to procedures for reporting analytical results;

Standard operating procedures pertaining to the reporting of results are available to all laboratory personnel. They are: SOP-T009, Significant Figures, Rounding, and Reporting of Results; SOP-T025, Reporting of Tentatively Identified Compounds (TICs); and T-026, Reporting of Data Qualifiers.

All analytical data generated within ECI is thoroughly checked for accuracy and completeness. The data validation process consists of data generation, reduction, and four levels of review as described below.

The analyst generating the analytical data has the primary responsibility for its correctness and completeness. All data is generated and reduced following protocols specified in the appropriate SOPs. Each analyst reviews the quality of his or her work based upon an established set of guidelines specified in the SOPs or as specified by project requirements. The analyst reviews the data package to ensure that:

- ⇨ Holding times have not been exceeded;
- ⇨ Sample preparation information is correct and complete;
- ⇨ Analysis information is correct and complete;
- ⇨ The appropriate procedures were employed;
- ⇨ Analytical results are correct and complete;
- ⇨ All associated QC is within established control limits and, if not, out-of-control forms are completed thoroughly explaining the cause and corrective action taken;
- ⇨ Any special sample preparation and analytical requirements have been met; and
- ⇨ Documentation is complete, i.e., all anomalies in the preparation and analysis have been documented; out-of-control forms, if required, are complete, etc.

The data reduction and validation steps are documented, signed, and dated by the analyst on the QC Review coversheet accompanying each data package. This initial review step, performed by the analyst, is designated as primary review. The analyst then forwards the data package to his or her Group Leader, or designated data reviewer, who performs a secondary review. Secondary reviews consist of an independent check equivalent to that of the primary review and are designed to ensure that:

- ⇨ Calibration data is scientifically sound, appropriate to the method, and completely documented;
- ⇨ QC data is within established guidelines or reported with appropriate clarification/qualification;
- ⇨ Qualitative identification of sample components is correct;
- ⇨ Quantitative results are correct;
- ⇨ Documentation is complete and any anomalies properly addressed and documented;
- ⇨ The data is ready for incorporation into the final report package; and
- ⇨ The data package is complete and ready for archiving.

A significant component of the secondary review is the documentation of any errors that have been identified and corrected during the review process. ECI believes that the data package that is submitted for a secondary review should be free from errors. Errors that are discovered are documented and formally transmitted to the appropriate Group Leader. The cause of the errors is then addressed by additional training or clarification of procedures (SOP revisions) to ensure that similar errors do not recur and high quality data will be generated.

Signature of Data Reviewer and the date of review document the completion of secondary reviews on the QC Review coversheet. These constitute approval for data release and generation of analytical report.

During both of the QC review processes, 100% of the raw data associated with the entire project is available to the reviewer. Data packages are checked back to the raw data as deemed necessary by the reviewer.

Following draft report generation, the report is reviewed by the Project Manager to ensure that the data set and quality control data is complete and meets the specific requirements of the project. When available, the data is also evaluated against historical site information. Once all requested analytical work has been verified as complete, a final report is generated and signed by the Project Manager.

Following approval for release by the Project Manager, the Quality Assurance Manager or other qualified personnel may review 10% of the project files back to the raw data as an additional check, if a situation so warrants.

A variety of reporting formats, from Portable Document File (PDF), normal typed reports to computerized data tables to complex reports discussing regulatory issues are available. In general, ECIreports contain the following information.

Analytical Data

Analytical data is reported by sample identification (both client and laboratory) and test. Pertinent information including date(s) sampled, received, prepared, and analyzed; any required data qualifiers are included on each results page. The reporting limit for each method analyte is also listed. Additional data may include Method Detection Limits (MDLs).

QC Data

A QC Summary is provided with each final report. Unless otherwise specified in a QAPP or requested by the client, QC Summaries include results for method blanks, matrix spikes, matrix spike duplicates, and surrogate spikes. Laboratory control sample and method blank surrogates are routinely included if matrix interference results in a QC outlier. The effective control limits for the reported QC values are also provided on the QC Summary as well as explanations for any QC outliers. Case Narratives may be included as appropriate.

As required for the project, data reports from “results only” through “full CLP-like” will be generated and provided. Included in this range are reports for the major DOD/DOE programs including NFESC, AFCEE, and USACE.

Methodology

References for the preparative and analytical methodology employed is included on all preliminary or final analytical reports.

Signatory

Final reports are ready for release to the client following review and approval by the Project Manager, as evidenced by his/her signature on the final report cover page. An approved signatories listing shall be maintained by the QA office.

Preliminary Data

Upon client request, preliminary data shall be released prior to completion of a full QC review. Preliminary data is subject to change pending QC review and, therefore, shall be clearly marked as “Preliminary”. This qualification is provided as notification to the client that the data review process has not been completed yet and that the data is subject to possible modification resulting therefrom.

Revised Data

Analytical reports that have been revised for any reason from the original sent report shall be noted as being revised with a report note, case narrative or indication as to the revision.

Formatting

At a minimum, an analytical report shall consist of the Report Cover Page, Analytical Results, QA/QC Data (Default), Footnotes/Comments Page, Sample Receipt Form and COC. Paginated reports shall be employed for all reports unless used for non-NELAP analysis.

w) A Table of Contents and applicable lists of references and glossaries, and appendices.

FIGURE 1:

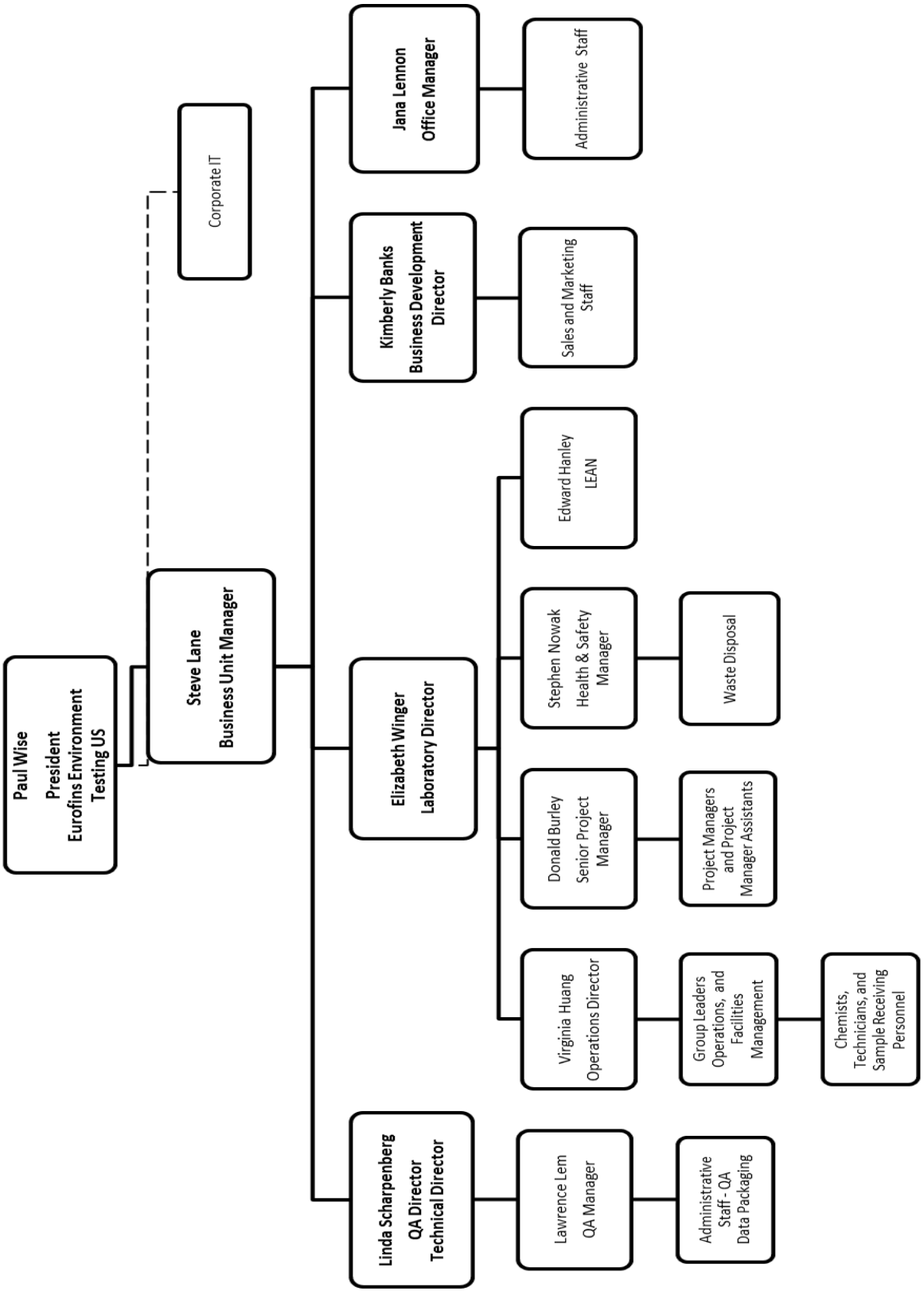
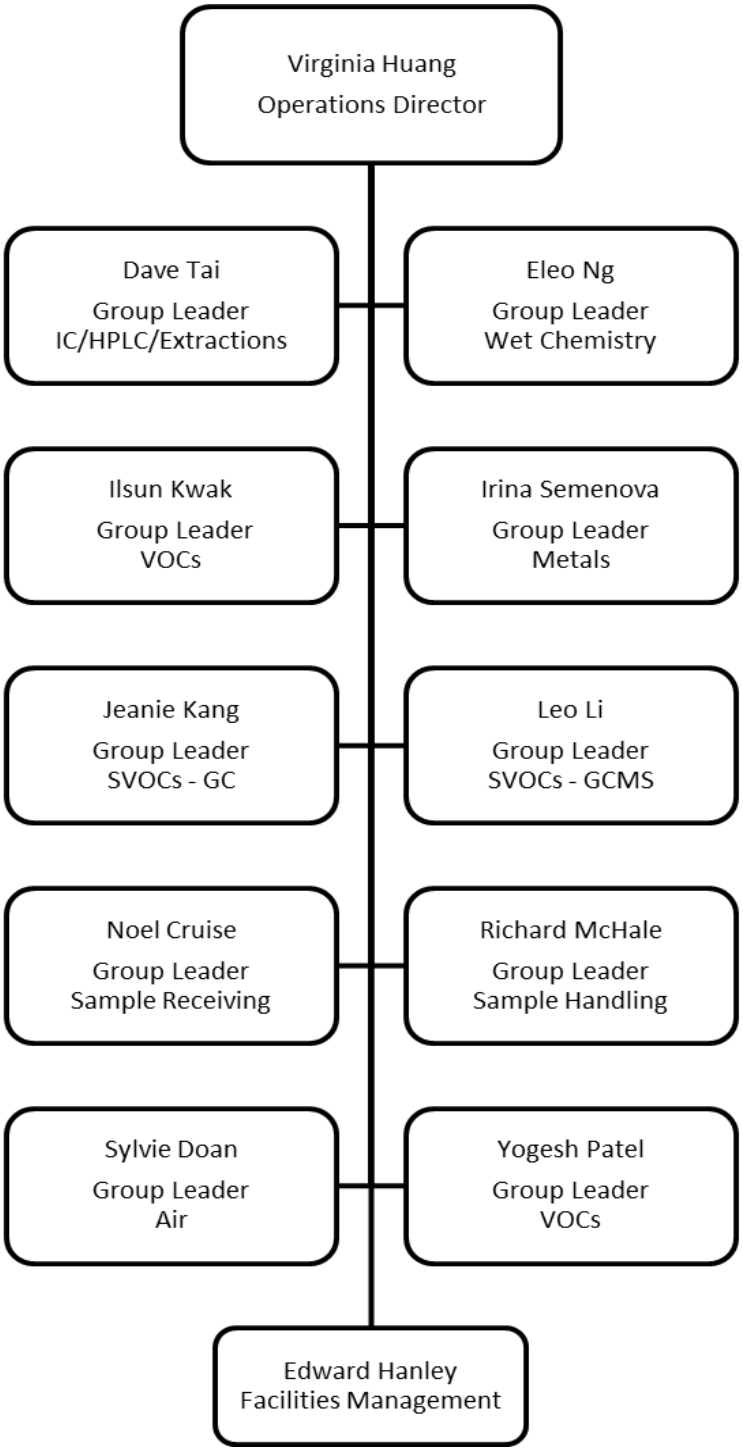

Paul Wise
President
Eurofins Environment Testing US
Steve Lane
Business Unit Manager
Corporate IT
Jana Lennon
Office Manager
Administrative Staff
Kimberly Banks
Business Development Director
Sales and Marketing Staff
Elizabeth Winger
Laboratory Director
Edward Hanley
LEAN
Stephen Nowak
Health & Safety Manager
Waste Disposal
Donald Burley
Senior Project Manager
Project Managers and Project Manager Assistants
Virginia Huang
Operations Director
Group Leaders Operations, and Facilities Management
Chemists, Technicians, and Sample Receiving Personnel
Linda Scharpenberg
QA Director
Technical Director
Lawrence Lem
QA Manager
Administrative Staff - QA Data Packaging

FIGURE 2:


Virginia Huang
Operations Director
Dave Tai
Group Leader
IC/HPLC/Extractions
Eleo Ng
Group Leader
Wet Chemistry
Ilsun Kwak
Group Leader
VOCs
Irina Semenova
Group Leader
Metals
Jeanie Kang
Group Leader
SVOCs - GC
Leo Li
Group Leader
SVOCs - GCMS
Noel Cruise
Group Leader
Sample Receiving
Richard McHale
Group Leader
Sample Handling
Sylvie Doan
Group Leader
Air
Yogesh Patel
Group Leader
VOCs
Edward Hanley
Facilities Management

5.3 Audits

5.3.1 Internal Audits

The laboratory arranges comprehensive annual internal audits to verify that its operations continue to comply with the requirements of the laboratory's said quality system. The Quality Assurance Manager or the Quality Assurance Assistant plans and organizes audits as required by a predetermined schedule and requested by management. The internal audits are buttressed by regular and scheduled Test Method Assessments (TMA).

The Quality Assurance Assistant or other qualified personnel, independent of the activity to be audited, will carry out such audits following the procedures noted in SOP T028, Internal Audit Procedures.

Personnel do not audit their own activities except when it can be demonstrated that an effective audit will be carried out.

Where the audit findings cast doubt on the correctness or validity of the laboratory's calibrations or test results, the laboratory takes immediate corrective action and immediately notifies, in writing, any client whose work was involved.

i. List of available qualified personnel for internal audits include:
   - QA Director
   - QA Manager
   - QA Assistant
   - Department Manager
   - Assistant Department Manager
   - Group Leader (For departments other than their own)
   - Program Manager
   - Health and Safety Manager (For non-analytical departments)
   - Any Senior Chemist (With documented training in proper internal auditing procedures from a qualified source).

ii. The minimum qualifications for an internal auditor shall be:
   - Education: A Bachelors (BS) Degree in an applied science with 16 semester hours in chemistry.
   - Experience: Two years' experience in an instrumental analytical technique for environmental analysis of representative environmental samples. Training to the most current revision of ECISOP T028 (Internal Audits). The training to be overseen by an individual that is ISO 17025 / 9001 trained in internal auditing procedures, or equivalent.
   - An advanced (MS, PhD.) degree may be substituted for one year of experience.

Any outside audit findings will also be included in the Internal Audits.

5.3.2 Management Review

ECI management conducts an annual review of its quality system and its testing and calibration activities to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements in the quality system and laboratory operations.

This review takes account of reports from managerial and supervisory personnel, the outcome of recent internal audits, assessments by external bodies, the results of inter-laboratory comparisons or proficiency tests, any changes in the volume and type of work undertaken, feedback from clients, senior lab personnel, corrective actions, and other relevant factors.

The laboratory shall have a procedure for review by management, and maintain records of review findings and actions. For more detailed descriptions Reference section 18.1 of this QSM and SOP T030.

5.3.3 Audit Review

All audit and review findings and any corrective actions that arise from them are documented. The laboratory management ensures that these actions are discharged within the agreed time frame as indicated in the quality manual and/or SOPs.

5.3.4 Performance Audits

In addition to periodic audits, the laboratory ensures the quality of results provided to clients by implementing checks to monitor the quality of the laboratory's analytical activities. Examples of such checks are:

a) Internal quality control procedures using statistical techniques (see Section 5.4 below);

b) Participation in proficiency testing or other inter-laboratory comparisons;

c) Use of certified reference materials and/or in-house quality control using secondary reference materials as specified in ECIQSM Section 5.4;

d) Replicate testing using the same or different test methods;

g) Re-testing of retained samples;

h) Correlation of results for different but related analysis of a sample (for example, total phosphorus should be greater than or equal to orthophosphate).

5.3.5 Corrective / Preventive Actions

a) In addition to providing acceptance criteria and specific protocols for corrective/preventive actions in SOP-T022, the laboratory implements general procedures to be followed to determine when departures from documented policies, procedures and quality control have occurred. These procedures include but are not limited to the following:

    1) Identify the individual(s) responsible for assessing each QC data type;

    2) Identify the individual(s) responsible for initiating and/or recommending corrective/preventive actions;

    3) Define how the analyst shall treat a data set if the associated QC measurements are unacceptable;

    4) Specify how out-of-control situations and subsequent corrective actions are to be documented; and

    5) Specify procedures for management (including the QA officer) to review corrective/preventive action reports.

b) To the extent possible, sample results are reported only if all quality control measures are acceptable. If a quality control measure is found to be out of control, and the data are to be reported, all samples associated with the failed quality control measure are reported with the appropriate data qualifier(s).

5.4 Essential Quality Control Procedures

These general quality control principles apply, where applicable, to all testing at ECI. The manner in which each is implemented is dependent on the types of tests performed by the laboratory and is further described in Appendix D and in SOP-T020, Internal Quality Control Checks. The standards for any given test type assures that the applicable principles are addressed:

a) All laboratories have detailed written protocols in place to monitor the following quality controls:

   1) Positive and negative controls (blanks, spikes, reference toxicants, etc.) to monitor tests;

   2) Tests to define the variability and/or repeatability of the laboratory results such as replicates;

   3) Measures to assure the accuracy of the test method including calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures;

   4) Measures to evaluate test method capability, such as detection limits and quantitation limits or range of applicability such as linearity;

   5) Selection of appropriate formulae to reduce raw data to final results such as regression analysis, comparison to internal/external standard calculations, and statistical analyses;

   6) Selection and use of reagents and standards of appropriate quality;

   7) Measures to assure the selectivity of the test for its intended purpose; and

   8) Measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the test method, such as temperature, humidity, light or specific instrument conditions.

b) All quality control measures are assessed and evaluated on an on-going basis, and quality control acceptance criteria are used to determine the usability of the data. (See Appendix D.)

c) The laboratory has procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist. (See ECI QSM Section 11.2, Sample Acceptance Policy.)

d) The quality control protocols specified in the method manual (ECI QSM Section 10.1.2) is followed. ECI ensures that the essential standards outlined in NELAC 5, Appendix D, or mandated methods or regulations (whichever are more stringent) are incorporated into the method manuals. When it is not apparent which is more stringent the QC in the mandated method or regulations is to be followed.

   The essential quality control measures for testing are found in Appendix D.

6.0 PERSONNEL

6.1 General Requirements for Laboratory Staff

ECI's testing departments have a sufficient level of personnel with the necessary education, training, technical knowledge and experience to perform the assigned functions.

All personnel are responsible for complying with all quality assurance/quality control requirements that pertain to their organizational/technical function. Each technical staff member must have a combination of experience and education to adequately demonstrate a specific knowledge of their particular function and a general knowledge of laboratory operations, test methods, quality assurance/quality control procedures and records management.

6.2 Laboratory Management Responsibilities

In addition to ECI QSM Section 4.2.d, the laboratory management:

a) Defines the minimum level of qualification, experience and skills necessary for all positions in the laboratory. In addition to education and/or experience, basic laboratory skills such as using a balance and quantitative techniques, are considered.

b) Ensures that all technical laboratory staff members demonstrate capability in the activities for which they are responsible. Such demonstration is documented (See Appendix C). Note: In departments with specialized "work cells" (a well-defined group of analysts that together perform the method analysis), the group as a unit meets the above criteria and this demonstration is fully documented.

c) Ensures that the training of each member of the technical staff is kept up-to-date (on-going) by the following:

    1) Keeping evidence on file that demonstrates that each employee has read, understood, and is using the latest version of the laboratory's in-house quality documentation that relates to his/her job responsibilities.

    2) Documenting training courses or workshops on specific equipment, analytical techniques, or laboratory procedures.

    3) Documenting employee attendance at training courses on ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions. Keeping on file evidence that demonstrates that each employee has read, acknowledges, and understands their personal ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions.

    4) Maintains up-to-date analyst training records that contain a certification that technical personnel have read, understood and agreed to perform the most recent version of the test method (the approved method or SOP as defined by the laboratory document control system, ECI QSM Section 5.2.d) and documentation of continued proficiency by at least one of the following once per year:

        i. Acceptable performance of a blind sample (single blind to the analyst);

        ii. Another demonstration of capability;

        iii. Successful analysis of a blind performance sample on a similar test method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624, or 5035/8260) would only require documentation for one of the test methods;

        iv. At least four consecutive laboratory control samples with acceptable levels of precision and accuracy;

        v. If subsections i-iv cannot be performed, analysis of authentic samples with results statistically indistinguishable from those obtained by another trained analyst.

d) Documents all analytical and operational activities of the laboratory;

e) Supervises all personnel employed by the laboratory;

f) Ensures that all sample acceptance criteria (ECI QSM Section 11.0) are verified and that samples are logged into the sample tracking system and properly labeled and stored.

g) Documents the quality of all data reported by the laboratory.

h) Develops a proactive program for the prevention and detection of improper, unethical, or illegal actions. Components of this program could include: internal proficiency testing (single and double blind); post-analysis electronic and magnetic tape audits; effective reward program to improve employee vigilance and co-monitoring; and separate SOPs identifying appropriate and inappropriate laboratory and instrument manipulation practices.

6.2.1 Ownership Transfer / Out of Business

a) In the event that the laboratory transfers ownership or goes out of business, ECI will ensure that the records are maintained or transferred according to client instruction.

b) Upon ownership transfer, record retention requirements shall be addressed in the ownership transfer agreement and the responsibility for maintaining archives will be clearly established. In cases of bankruptcy, appropriate regulatory and state legal requirements concerning laboratory records will be followed.

c) In the event that the laboratory goes out of business, all records will revert to the control of the client or regulatory agency, as applicable. As much notice as possible will be given to clients and the accrediting bodies who have worked with the laboratory during the previous 5 years of such action.

6.3 Personnel Records

Records on the relevant qualifications, training, skills and experience of the technical personnel are maintained by the laboratory (see EC IQSM Section 6.2.c), including records on demonstrated proficiency for each laboratory test method, such as the criteria outlined in ECI QSM Section 10.5 for chemical testing.

7.0 PHYSICAL FACILITIES – ACCOMMODATION AND ENVIRONMENT

7.1 Environment

a) Laboratory accommodations, test areas, energy sources, lighting, heating and ventilation are such that they facilitate proper performance of tests.

b) The environment in which these activities are undertaken does not invalidate the results or adversely affect the required accuracy of the measurements. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

c) The laboratory shall provide for the effective monitoring, control and recording of environmental conditions as appropriate. Such environmental conditions may include biological sterility, dust, electromagnetic interference, humidity, main voltage, temperature, and sound and vibration levels.

d) In instances where monitoring or control of any of the above-mentioned items is specified in a test method or by regulation, the laboratory meets and documents adherence to the laboratory facility requirements.

7.2 Work Areas

a) There is effective separation between neighboring areas when the activities therein are incompatible including volatile organic chemicals handling areas.

b) Access to and use of all areas affecting the quality of these activities are defined and controlled.

c) Adequate measures are taken to ensure good housekeeping in the laboratory and to ensure that any contamination does not adversely affect data quality.

d) Workspaces are available to ensure an unencumbered work area. Work areas include:

   1) Access and entryways to the laboratory;

   2) Sample receipt areas;

   3) Sample storage areas;

   4) Chemical and waste storage areas; and

   5) Data handling and storage areas.

8.0 EQUIPMENT AND REFERENCE MATERIALS

a) ECI is furnished with all items of equipment (including reference materials) required for the correct performance of tests for which accreditation is maintained. Note that ECI does not use equipment outside its permanent control.

b) All equipment is properly maintained, inspected, and cleaned. Maintenance procedures are documented.

c) Any equipment item that has been subjected to overloading or mishandling, or that gives suspect results, or has been shown by verification or otherwise to be defective, is taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

d) When appropriate, each item of equipment, including reference materials, is labeled, marked, or otherwise identified to indicate its calibration status.

e) Records are maintained of each major item of equipment and all reference materials significant to the tests performed. These records include documentation on all routine and non-routine maintenance activities in assigned log books and reference material verifications.

   The records include:

   1) The name of the item of equipment;

   2) The manufacturer's name, type identification, and serial number or other unique identification;

   3) Date received and date placed in service (if available);

   4) Current location, where appropriate;

5) If available, condition when received (e.g., new, used, reconditioned);

6) Copy of the manufacturer's instructions, where available;

7) Dates and results of calibrations and/or verifications and date of the next calibration and/or verification;

8) Details of maintenance carried out to date and planned for the future; and

9) History of any damage, malfunction, modification or repair.

9.0 MEASUREMENT TRACEABILITY AND CALIBRATION

9.1 General Requirements

All measuring operations and testing equipment having an effect on the accuracy or validity of tests are calibrated and/or verified before being put into service and on a continuing basis. The laboratory has an established program for the calibration and verification of its measuring and test equipment. This includes balances, thermometers and control standards.

9.2 Traceability of Calibration

a) The overall program of calibration and/or verification and validation of equipment is designed and operated so as to ensure that measurements made by the laboratory are traceable to national standards of measurement.

b) Calibration certificates indicate the traceability to national standards of measurement and provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification. The laboratory maintains records of all such certification in the QA office.

c) Where traceability to national standards of measurement is not applicable, the laboratory provides satisfactory evidence of correlation of results, for example, by participation in a suitable program of inter-laboratory comparisons, proficiency testing, or independent analysis.

9.3 Reference Standards

a) Reference standards of measurement held by the laboratory (such as Class S or equivalent weights, or traceable thermometers) are used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated. A body that can provide traceability calibrates reference standards of measurement. Where possible, this traceability is to a national standard of measurement.

b) There is a program of calibration and verification for reference standards.

   i. Two weeks prior to their date of calibration expiration, individual thermometers are removed from service and replaced by newly calibrated units from the supplier.

   ii. ECI keeps two sets of Class S weights on hand for use in the laboratory. One set is used for daily calibration checks, and the second set is kept for back up use should the first set be damaged, lost or otherwise compromised. The second set of weights is also place in service when the daily use set is shipped off site for recalibration.

iii. Analytical balances are serviced and calibrated on a routine, annual schedule.

c) Where relevant, reference standards and measuring and testing equipment are subjected to in-service checks between calibrations and verifications. Reference materials are traceable. Where possible, traceability is to national or international standards of measurement, or to national or international standard reference materials.

d) NIST-Traceable Weights and Thermometers

i. Reference standards of measurement shall be used for the purposes of calibration only. NIST traceable thermometers and NIST-traceable weights shall not be used for routine testing. If NIST traceable reference sources are used for routine testing they shall not be used for calibration purposes unless it can be shown that their performance as reference standards would not be invalidated.

ii. For NIST-traceable weights and thermometers, ECI requires that all calibrations be conducted by a calibration laboratory accredited by ACLASS, A2LA or other recognized accrediting body.

a. The calibration laboratory must hold ISO 17025 or ISO 9001 accreditation for the services rendered. Prior to use, QA verifies that the selected vendor holds the appropriate scope of accreditation for the services required.

b. The calibration certificate or report supplied by the calibration laboratory must contain a traceability statement, the conditions under which the calibrations were made, a compliance statement with an identified metrological specification and the pertinent clauses when applicable, and a clearly identified record of the quantities and functional test results before and after re-calibration.

c. The certificate and scope of accreditation is kept on file at the laboratory and is reviewed yearly.

iii. If significant amendments are made to a calibration certificate, it must have its own unique report identifier and must reference the one it is replacing. The piece of equipment must be identified in the amended report using its unique serial number or other laboratory defined identifier. The amended report is maintained with the original calibration report.

iv. Laboratory balances are recalibrated annually by an external, certified vendor that is certified to ISO 17025 / ISO 9001 standards for calibration. Prior to use, QA verifies that the selected vendor holds the appropriate scope of accreditation for the services required. This service is documented on each balance with a signed and dated certification sticker.

v. NIST mercury thermometers are sent out for recalibration every five years, or are replaced. All working mercury thermometers are calibrated annually against a NIST-traceable reference thermometer. All digital temperature measuring devices (min/max thermometers, IR guns) are calibrated quarterly. Equipment that does not meet acceptance criteria is removed from service and repaired or replaced. Calibration reports are maintained by the QA Manager

vi. Balance calibrations and temperature readings of ovens, refrigerators, and incubators are checked on each day of use. Min/Max thermometers are used for refrigerators and freezers to continually monitor temperature performance.

e) Traceable Reference Standards and Materials

i. Reference standards and materials are traceable to certified reference materials, where available. Commercially prepared standard materials are purchased from vendors accredited by A2LA, NVLAP (National Voluntary Lab Accreditation Program) or other recognized vendor, and come with a Certificate of Analysis that documents the purity of the standard and expiration date, if assigned. If a standard cannot be purchased from a vendor that supplies a Certificate of Analysis, the purity of the standard is documented by analysis against a known reference.

ii. Analytical reagents must be at a minimum the purity required by or stated in the test method. Commercial materials that are purchased for the preparation of calibration, verification or spiking solutions, are usually accompanied by an assay certificate or the purity is noted on the label. If the purity is ≥96%, the weight provided by the vendor may be used without correction. If the purity is <96%, a correction will be made to solution concentrations prepared from that material.

iii. The receipt of all reference standards and materials, including received date and expiration date, is documented by the laboratory at the time of receipt, in chemical receiving logbooks. All documentation received with the reference standard or material (Certificate of Analysis or Purity Certificates) is retained by the laboratory. To prevent contamination and/or deterioration in quality, all standards and materials are handled and stored according to the method or manufacturer's requirements.

iv. Preparation of standard or reference materials are documented in Standard Preparation Logbooks maintained in each department. These records show the traceability to the purchased standards or materials, and include the method of preparation, date of preparation, expiration date, and preparer's initials, at a minimum. Reference standards are assigned a unique identifier and are then labeled with the identifier and expiration date. Refer to ECISOP, T003, Standards and Reagents Login, Preparation, Storage and Disposal, for additional information.

v. All standards, reference, primary and working, whether purchased from a commercial vendor or prepared by the laboratory, must be checked regularly to ensure that the variability of the standard from the 'true' value does not exceed method requirements. Calibration standards are checked by comparison with a standard from a second source, usually another manufacturer and vendor. In cases where a second manufacturer is not available, a different lot, with vendor certification, may be used as a second source.

vi. Quality control (QC) criteria for primary and second source standards are defined in laboratory SOPs. The Reagent and Chemicals SOP, T107, gives a general overview of the requirements with the determinative SOPs for each process further defining the QC acceptance criteria. In most cases, the analysis of an Initial Calibration Verification (ICV) or LCS/LCSD (where there is no sample preparation) is used as the second source verification of a primary calibration source.

9.4 Calibration

Calibration requirements are divided into two parts: (1) requirements for analytical support equipment, and (2) requirements for instrument calibration. In addition, the requirements for instrument calibration are divided into initial calibration and second source or initial calibration verification, and continuing calibration verification.

9.4.1 Support Equipment

These standards apply to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, thermometers, and volumetric dispensing devices (such as Eppendorf®, or automatic dilutor/dispensing devices) if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume.

a) All support equipment is maintained in proper working order. The records of all repair and maintenance activities, including service calls is kept.

b) All support equipment is calibrated or verified at least annually, using NIST traceable references when available, over the entire range of use. The results of such calibration are within the specifications required of the application for which this equipment is used or:

   1) The item is removed from service until repaired; or

   2) The laboratory maintains records of established correction factors to correct all measurements.

c) Raw data records are retained to document equipment performance.

d) Prior to use on each working day, balances, ovens, refrigerators, freezers, and water baths are checked in the expected use range, with NIST traceable calibrated references. The acceptability for use or continued use is according to the needs of the analysis or application for which the equipment is being used.

e) Mechanical volumetric dispensing devices including burettes (except Class A glassware) are checked for accuracy on at least a quarterly use basis. Glass microliter syringes are to be considered Class A glassware, and come with a certificate from the manufacturer attesting to established accuracy or the accuracy is initially demonstrated and documented by the laboratory.

9.4.2 Instrument Calibration

This manual specifies the essential elements that define the procedures and documentation for initial instrument calibration and continuing instrument calibration verification to ensure that the data are of known quality and be appropriate for a given regulation or decision. This manual does not specify detailed procedural steps ("how to") for calibration, but establishes the essential elements for selection of the appropriate technique(s). This approach allows flexibility and permits the employment of a wide variety of analytical procedures and statistical approaches currently applicable for calibration. If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory demonstrates that such requirements are met. If it is not apparent which standard is more stringent, then the requirements of the regulation or mandated test method are to be followed.

Note: In the following sections, initial instrument calibration is directly used for quantitation and continuing instrument calibration verification is used to confirm the continued validity of the initial calibration, unless otherwise stipulated by the analytical method.

9.4.2.1 Initial Instrument Calibrations

The following items are essential elements of initial instrument calibration:

a) The details of the initial instrument calibration procedures including calculations, integrations, acceptance criteria and associated statistics are included or referenced in the test method SOP. When initial instrument calibration procedures are referenced in the test method, the referenced material is retained by the laboratory and is available for review.

b) Sufficient raw data records are retained to permit reconstruction of the initial instrument calibration, e.g., calibration date, test method, instrument, analysis date, each analyte name, analyst's initials or signature; concentration and response, calibration curve or response factor; or unique equation or coefficient used to reduce instrument responses to concentration.

c) Sample results are quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification unless specifically stated in a mandated test method.

d) All initial instrument calibrations are verified with a standard obtained from a second manufacturer or lot. Traceability shall be to a national standard, when available.

e) Criteria for the acceptance of an initial instrument calibration is established, e.g., correlation coefficient or relative percent difference. The criteria used are appropriate to the calibration technique employed.

f) Results of samples not bracketed by initial calibration standards (within calibration range) are reported as having less certainty, e.g., defined qualifiers or flags or explained in the case narrative. As determined by the method, the lowest calibration standard is at or above the method detection limit and at or below the reporting limit.

g) If the initial instrument calibration results are outside established acceptance criteria, corrective actions are performed. Data associated with an unacceptable initial instrument calibration is not reported.

h) Calibration standards include concentrations at or below the regulatory limit/decision level, if the laboratory knows these limits/levels, unless these concentrations are below the laboratory's demonstrated detection limits (See ECI QSM Section Appendix D.1.5 Detection Limits).

i) If a reference or mandated method does not specify the number of calibration standards, the minimum number is two, not including blanks or a zero standard. The laboratory's standard operating procedure defines the number of points for establishing the initial instrument calibration.

9.4.2.2 Continuing Instrument Calibration Verification

When an initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration is verified prior to sample analyses by analyzing a continuing calibration verification standard with each analytical batch. The following items are essential elements of continuing calibration verification:

a) The details of the continuing calibration procedure, calculations and associated statistics must be included or referenced in the test method SOP.

b) A continuing calibration verification standard must be analyzed at the beginning and end of each analytical batch, and where required by method or project, at a specific frequency, every 10 or 20 samples or 12 hours, within the batch. The concentrations of the calibration verification shall be varied within the established calibration range. If an internal standard is used, only one continuing calibration verification standard must be analyzed, prior to sample or QC analysis, per analytical batch.

c) Sufficient raw data records must be retained to permit reconstruction of the continuing calibration verification, e.g., test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor, or unique equations or coefficients used to convert instrument responses into concentrations. Continuing calibration verification records must explicitly connect the continuing calibration verification data to the initial calibration.

d) Criteria for the acceptance of a continuing calibration verification must be established, e.g., relative percent difference.

e) If the continuing calibration verification results obtained are outside established acceptance criteria, corrective actions must be performed. If routine corrective action procedures fail to produce a second (consecutive and immediate) calibration verification within acceptance criteria, then the laboratory shall demonstrate performance after corrective action with two consecutive successful calibration verifications, or a new instrument calibration must be performed. If the laboratory has not demonstrated acceptable performance, sample analyses shall not occur until a new initial calibration curve is established and verified.

As an exception, sample data associated with an unacceptable continuing calibration verification may be reported as qualified data under the following special conditions:

i. 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. Otherwise the samples affected by the unacceptable calibration verification are reanalyzed after a new calibration curve has been established, evaluated and accepted.

ii. 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. Otherwise the samples affected by the unacceptable verification are reanalyzed after a new calibration curve has been established, evaluated and accepted.

10.0 TEST METHODS AND STANDARD OPERATING PROCEDURES

10.1 Methods Documentation

a) The laboratory has documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests.

b) All instructions, standards, manuals, and reference data relevant to the work of the laboratory are maintained up-to-date and be readily available to the staff.

10.1.1 Standard Operating Procedures (SOPs) Administrative

ECI maintains standard operating procedures that accurately reflect all phases of current laboratory activities such as instrument operation, assessing data integrity, corrective actions, handling customer complaints, reporting of test results, etc.

a) These documents, for example, may be equipment manuals provided by the manufacturer or internally written documents.

b) The test methods may be copies of published methods as long as any changes or selected options in the methods are documented and included in the SOP (See 10.1.2.)

c) Copies of all SOPs are accessible to all personnel.

d) The SOPs are organized.

e) Each SOP clearly indicates the effective date of the document, the revision number and the signatures of the approving authorities.

10.1.2 Standard Operating Procedures (SOPs) Analytical

a) The laboratory has and maintains SOPs for each accredited analyte or test method.

b) This SOP may consist of copies of published or referenced test methods or standard operating procedures that have been written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced test method is ambiguous or provides insufficient detail, these changes or clarifications are clearly described. Each test method includes or references where applicable:

1) Identification of the test method;
2) Applicable matrix or matrices;
3) Detection limit;
4) Scope and application, including components to be analyzed;
5) Summary of the test method;
6) Definitions;
7) Interferences;
8) Safety;
9) Equipment 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 measures;
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) Modifications
25) Revision History

Laboratory procedures other than preparative or analytical procedure may use a shortened format as outlined in SOP T001.

10.2 Exceptionally Permitting Departures from Documented Policies / Procedures

a) If it is necessary to depart from a documented procedure or policy due to circumstances outside of ECI's control or due to conditions encountered while preparing or analyzing a sample, the following will be documented.

    1) The nature of the exception
    2) How the data or procedure may be impacted
    3) Any Corrective Action that may be needed.
    4) Any approval from a client that may be required.
    5) Approval by management to report or proceed with the exception.
    6) A Case Narrative with the Final Report explaining the exception.

10.3 Test Methods

The laboratory uses appropriate test methods and procedures for all tests and related activities within its responsibility (including, as applicable, sample collection, sample handling, transport and storage, sample preparation and sample analysis). The method and procedures shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

a) When the use of specific test methods for a sample analysis is mandated or requested, only those methods are used.

b) Where test methods are employed that are not required, as in the Performance Based Measurement System approach, the methods are fully documented and validated (see ECIQSM Section 10.1.2 and Appendix C), and are available to the client and other recipients of the relevant reports.

10.4 Test Method Assessment

The laboratory will periodically conduct a Test Method Assessment (TMA) on the analytical methods in use. These TMAs will be conducted under the guidance of SOP T029. The purpose is to evaluate the compliance between bench performances of the method versus the current ECI Standard Operating Procedure versus the promulgated or published method. Discrepancies will need to be addressed and resolved. Note that some methods are totally prescriptive while others may contain prescriptive aspects, and still others are performance based. In many cases, modifications to the published method may be required due to circumstances outside the laboratories' control.

10.5 Demonstration of Capability

a) Prior to acceptance and institution of any test method, satisfactory demonstration of method capability is required. (See ECI QSM Section Appendix C and 6.2.b.) This demonstration does not test the performance of the method in real world samples, but in the applicable and available clean matrix (sample of a matrix is which no target analytes or interferences are present at concentrations that impact the results of a specific test method), e.g., water, solids and air. In addition, for analytes that do not lend themselves to spiking, the demonstration of capability may be performed using quality control samples.

b) Continuing demonstration of method performance, as per the quality control requirements in Appendix D (such as laboratory control samples) is required.

c) In all cases, the appropriate forms, such as the Certification Statement (Appendix C), is completed and retained by the laboratory to be made available upon request. The laboratory retains all associated supporting data necessary to reproduce the analytical results summarized in the Certification Statement. (See Appendix C for an example of a Certification Statement.)

d) Demonstration of capability is completed each time there is a significant change in instrument type, personnel, or test method.

e) In departments with specialized "work cell(s)" (a group consisting of analysts with specifically defined tasks that together perform the test method), the group as a unit must meet the above criteria and this demonstration of capability is fully documented.

f) When a work cell is employed, and the members of the cell change, the new employee(s) must work with an experienced analyst in that area of the work cell where they are employed. This new work cell must demonstrate acceptable performance through acceptable continuing performance checks (appropriate sections of Appendix D, such as laboratory control samples). Such performance is documented and the four preparation batches following the change in personnel must not result in the failure of any batch acceptance criteria, e.g., method blank and laboratory control sample, or the demonstration of capability must be repeated. In addition, if the entire work cell is changed or replaced, the new work cell must perform the demonstration of capability (Appendix C).

g) Performance of the work cell is linked to the training records of the individual members of the work cell (See ECI QSM Section 6.2).

10.6 Sample Aliquots

Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, the laboratory shall use documented procedures and appropriate techniques to obtain representative subsamples. Reference SOP M230, Homogenization and Compositing of Solid, Soil and Sediment Samples for further guidance.

10.7 Data Verification

Calculations and data transfers are subject to appropriate checks.

a) The laboratory has Standard Operating Procedures that ensure that the reported data are free from transcription and calculation errors.

b) The laboratory has Standard Operating Procedures that ensure that all quality control measures are reviewed, and evaluated before data are reported. Refer to SOPs T020, internal Quality Control Checks and T062, Project Management and Analytical Report Review

c) The laboratory has Standard Operating Procedures that address manual calculations including manual integrations. Refer to SOPs T065, Data Integrity and T023, Peak Integration Procedures.

10.8 Documentation and Labeling of Standards and Reagents

Documented procedures exist for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory.

a) The laboratory retains records for all standards, reagents and media including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if supplied), the date of receipt, recommended storage conditions, and an expiration date after which the material is not used, unless the laboratory verifies its suitability for testing use.

b) Original containers (such as those provided by the manufacturer or vendor) are labeled with an expiration date.

c) Records are maintained on reagent and standard preparation. These records indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials.

d) All containers of prepared reagents and standards bear a unique identifier and expiration date and are linked to the documentation requirements in ECIQSM Section 10.8.c above.

10.9 Computers and Electronic Data Related Requirements

Where computers, automated equipment, or microprocessors are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, ECI ensures that:

a) All requirements of the NELAC Standard (i.e., Chapter 5 of NELAC) are met;

b) Computer software is tested and documented to be adequate for use, e.g., internal audits, personnel training, focus point of QA and QC;

c) 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, data storage, data transmission and data processing;

d) 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; and,

e) It establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

11.0 SAMPLE HANDLING, SAMPLE ACCEPTANCE POLICY AND SAMPLE RECEIPT

While ECI does not have control of field sampling activities, the following are essential to ensure the validity of the laboratory's data.

11.1 Sample Tracking

a) The laboratory has a documented system for uniquely identifying the items to be tested, to ensure that there can be no confusion regarding the identity of such items at any time. This system includes identification for all samples, subsamples and subsequent extracts and/or digestates. The laboratory assigns a unique identification (ID) code to each sample container received in the laboratory. (The use of container shape, size, or other physical characteristic, such as amber glass, or purple top, is not an acceptable means of identifying the sample.)

b) This laboratory code is maintained as an unequivocal link with the unique field ID code assigned each container.

c) The laboratory ID code is placed on the sample container as a durable label.

d) The laboratory ID code is entered into the laboratory records (see ECIQSM Section 11.3.d) and is the link that associates the sample with related laboratory activities such as sample preparation or calibration.

e) In cases where the sample collector and analyst is the same individual or the laboratory pre-assigns numbers to sample containers, the laboratory ID code may be the same as the field ID code.

11.2 Sample Acceptance Policy

The laboratory has a written sample acceptance policy that clearly outlines the circumstances under which samples are accepted or rejected. Data from any samples that do not meet the following criteria are flagged in an unambiguous manner, and the nature of the variation is clearly defined. The sample acceptance policy is available to sample collection personnel and includes, but is not limited to, the following areas of concern:

a) Proper, full, and complete documentation, that includes sample identification, the location, date and time of collection, collector's name, preservation type, sample type and any special remarks concerning the sample;

b) Proper sample labeling that includes a unique identification and a labeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink;

c) Use of appropriate sample containers;

d) Adherence to specified holding times;

e) Adequate sample volume. Sufficient sample volume must be available to perform the necessary tests; and,

f) Procedures to be used when samples show signs of damage, contamination or inadequate preservation.

g) Samples are NOT accepted if classified as extremely hazardous, reference section 5.2 k for examples.

11.3 Sample Acceptance Policy (Posted)

This sample acceptance policy outlines the circumstances in which received samples are accepted or rejected by Eurofins Calscience, Inc. (ECI). If any of the below criteria are not met, it may delay ECI's processing of samples, possibly compromising "short" holding time analyses. Where received

samples do not meet these criteria, ECI will contact the client. If immediate client contact cannot be made, and hold times are not an issue, samples will be appropriately stored until the situation is clarified with the client. If a delay in sample processing will result in missed holding times, and ECI deems there is sufficient information provided on the Chain-of-Custody (COC), the lab will proceed with sample log-in and processing; however, ECI will not assume any liability for samples processed under these circumstances.

Data from samples that do not meet the sample acceptance criteria are flagged and/or addressed in a case narrative, with the nature of the deviation clearly defined. Samples must have written authorization to proceed if not in compliance with this guidance.

1. Complete COC with the following information:

   Unique sample identification, date and time of collection, sample matrix, analysis requested, sampler's name, preservation type (if applicable), client name and address, any additional comments, signature of relinquishing party and date and time that samples were relinquished.

2. Sample temperature upon receipt of >0°C to 6°C, as applicable to the method.

   In the event that samples are collected on the same day that they are received by the laboratory, they are deemed acceptable if they are received on ice and the cooling process has begun.

3. Sample containers and preservatives must be appropriate for the test and method being requested on the COC.

4. Sample labels must include a unique identification written with indelible ink on water resistant labels that correspond with the COC.

5. Adequate sample volume must be provided for the analyses requested on the COC, and containers for volatile analyses must be free of headspace. This includes Tedlar bags and Summa canisters.

6. Sufficient holding time available to perform the analyses requested:

   Samples shall be received at the laboratory within 72 hours of sampling, or with at least 1/2 of the holding time left for the analysis, whichever is less. ECI always makes a best effort to ensure that holding times are not exceeded under these circumstances. In the event that a preparation or analysis is performed outside of the associated holding time, the data will be qualified in the report.

7. Coolers and samples must be received in good condition, with no obvious signs of damage or tampering.

8. Received with a copy of ECI's Foreign Soil Permit, if applicable.

9. Please note, mixed waste, or samples classified as extremely hazardous are **NOT** accepted.

If you require additional information or clarification, please do not hesitate to contact ECI, or your Project Manager at (714) 895-5494.

11.4 Sample Receipt Protocols

a) Upon receipt, the condition of the sample, including any abnormalities or departures from standard condition as prescribed in the relevant test method, is recorded. All items specified in ECIQSM Section 11.2 above are checked.

   1) All samples that require cold temperature preservation are considered acceptable if the arrival temperature is within 2°C of the required temperature or the method-specified range. For samples with a specified temperature of 4°C, samples with a temperature ranging from just above the freezing temperature of water to 6°C shall be acceptable. Samples that are hand delivered to the laboratory

immediately after collection may not meet these criteria. In these cases, the samples shall be considered acceptable if there is evidence that the chilling process has begun, such as arrival on ice.

2) The laboratory shall implement procedures for checking chemical preservation using readily available techniques, such as pH or free chlorine, prior to or during sample preparation or analysis.

With the exception of residual chlorine measurements in aquatic toxicity samples, certain measurements, such a pH, are performed and recorded just prior to analysis.

Field filtration for dissolved metals, Perchlorate and others may also be required. If there is no documentation of field filtration on the Chain of Custody when required, the Project Manager is notified and the client asked. If samples are not field filtered, they are sent to the lab for filtration within 24 or 48 hours depending on the analysis.

b) The results of all checks are recorded on Sample Receipt and, as needed, Sample Anomaly forms.

c) When there is any doubt as to the item's suitability for testing, when the sample does not conform to the description provided, and when the test required is not fully specified, the laboratory makes every attempt to consult the client for further instruction before proceeding. The laboratory establishes whether the sample has received all necessary preparation, or whether sample preparation has yet to be performed. If the sample does not meet the sample receipt acceptance criteria listed in this standard, the laboratory:

1) Retains correspondence and/or records of conversations concerning the final disposition of rejected samples; or

2) Fully documents any decision to commence with the analysis of samples not meeting acceptance criteria.

i. The condition of these samples is, at a minimum, noted on the chain of custody record or transmittal form, and laboratory receipt documents.

ii. The analysis data is/are appropriately "qualified" on the final report.

d) The laboratory utilizes a permanent chronological record such as a logbook or electronic database to document receipt of all sample containers.

1) This sample receipt log records the following:

i. Client/Project Name;

ii. Date and time of laboratory receipt;

iii. Unique laboratory ID code (see ECIQSM Section 11.1); and

iv. Signature or initials of the person making the entries.

2) During the login process, the following information is linked to the log record or included as a part of the log. If such information is recorded/documented elsewhere, that document becomes part of the laboratory's permanent records, easily retrievable upon request, and readily available to individuals who will process the sample. Note: The placement of the laboratory ID number on the sample container is not considered a permanent record.

i. The field ID code that identifies each container is linked to the laboratory ID code in the sample receipt log.

ii. The date and time of sample collection is linked to the sample container and to the date and time of receipt in the laboratory.

iii. The requested analyses (including applicable approved test method numbers) are linked to the laboratory ID code.

iv. Any comments resulting from inspection for sample rejection are linked to the laboratory ID code.

e) All documentation (i.e., memos or transmittal forms) that are conveyed to the laboratory by the sample submitter is retained.

f) A complete chain of custody record form is maintained.

11.5 Storage Conditions

The laboratory has documented procedures and appropriate facilities to avoid deterioration, contamination, and damage to the sample during storage, handling, preparation, and testing; any relevant instructions provided with the item are followed. Where items must be stored or conditioned under specific environmental conditions, these conditions are maintained, monitored, and recorded.

a) Samples are stored according to the conditions specified by preservation protocols:

1) Samples that require thermal preservation are stored under refrigeration at +/-2° of the specified preservation temperature unless method-specified criteria exist. For samples with a specified storage temperature of 4°C, storage at a temperature above the freezing point of water to 6°C is acceptable.

2) Samples are stored away from all standards, reagents, food, and other potentially contaminating sources. Samples are stored in such a manner to prevent cross contamination.

b) Sample fractions, extracts, leachates, and other sample preparation products are stored according to ECIQSM Section 11.4.a above or according to specifications in the test method.

c) When a sample or portion of a sample needs to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory has storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

11.6 Sample Disposal

The laboratory has standard operating procedures for the disposal of samples, digestates, leachates and extracts or other sample preparation products. Refer to SOP T005, Disposal of Laboratory Samples and Wastes.

12.0 RECORDS

The laboratory maintains a record system to suit its particular circumstances and comply with any applicable regulations. The system produces unequivocal, accurate records that document all laboratory activities. The laboratory retains all original observations, calculations and derived data, calibration records and a copy of the test report for a minimum of five years.

There are two levels of sample handling: 1) sample tracking and 2) legal chain of custody protocols that are used for evidentiary or legal purposes. All essential requirements for sample tracking (e.g., chain of custody form) are outlined in ECIQSM Sections 12.1, 12.2 and 12.3. ECI details the Legal/Evidentiary and Internal Chain of Custody procedures in SOP T100, Sample Receipt and Log-In Procedures.

12.1 Record Keeping System and Design

The ECI record keeping system allows historical reconstruction of all laboratory activities that produced the analytical data. The history of the sample is readily understood through the documentation. This includes inter-laboratory transfers of samples and/or extracts.

a) The records include the identity of personnel involved in sampling, sample receipt, preparation, and calibration or testing.

b) All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, are documented.

c) The record keeping system facilitates the retrieval of all working files and archived records for inspection and verification purposes, e.g., set format for naming electronic files.

d) All changes to records are signed or initialed by responsible staff. The reason for the signature or initials is clearly indicated in the records such as “sampled by,” “prepared by,” or “reviewed by.”

e) All generated data, except those that are generated by automated data collection systems, are recorded directly, promptly, and legibly in permanent ink.

f) Entries in records are not be obliterated by methods such as erasures, overwritten files or markings. All corrections to record-keeping errors are made by one line marked through the error. The individual making the correction signs (or initials) and dates the correction. These criteria also apply to electronically maintained records.

g) Refer to 10.9 for Computer and Electronic Data.

12.2 Records Management and Storage

a) All records (including those pertaining to calibration and test equipment), certificates and reports are safely stored, and held secure and in confidence to the client. NELAP-related records are available to the accrediting authority.

b) All records, including those specified in ECIQSM Section 12.3, are retained for a minimum of five years from generation of the last entry in the records. The laboratory maintains all information necessary for the historical reconstruction of data. Records stored only on electronic media are supported by the hardware and software necessary for their retrieval.

c) Records that are stored or generated by computers or personal computers have hard copy or write-protected backup copies.

d) The laboratory has an established record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation storage and reporting.

e) Access to archived information is documented with an access log. These records are protected against fire, theft, loss, environmental deterioration, vermin, and in the case of electronic records, electronic or magnetic sources.

f) The laboratory has a plan to ensure that the records are maintained or transferred according to the clients’ instructions (see 4.1.8.e of NELAC) in the event of Laboratory Transfer of Ownership, Going out of Business or Bankruptcy. In all cases, appropriate regulatory and state legal requirements concerning laboratory records will be followed. For detailed policies and procedures for handling of client records and data in these situations, reference QSM Section 6.2.1 and SOP T-002, Document Control.

12.3 Laboratory Sample Tracking

12.3.1 Sample Handling

A record of all procedures to which a sample is subjected while in ECI's possession is maintained. These include but are not limited to all records pertaining to:

a) Sample preservation, including appropriateness of sample container and compliance with holding time requirement;

b) Sample identification, receipt, acceptance or rejection, and log-in;

c) Sample storage and tracking, including shipping receipts, sample transmittal forms (chain of custody form); and

d) Documentation procedures for the receipt and retention of test items, including all provisions necessary to protect the integrity of samples.

12.3.2 Laboratory Support Activities

In addition to documenting all the above-mentioned activities, the following is retained:

a) All original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts work sheets and data output records (chromatograms, strip charts, and other instrument response readout records);

b) A written description or reference to the specific test method used, which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value;

c) Copies of final reports;

d) Archived standard operating procedures;

e) Correspondence relating to laboratory activities for a specific project;

f) All corrective/preventive action reports, audits and audit responses;

g) Proficiency test results and raw data; and,

h) Results of data review, verification, and cross-checking procedures.

12.3.3 Analytical Records

The essential information associated with analyses, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs, include:

a) Laboratory sample ID code;

b) Date of analysis and time of analysis if the method-specified holding time is 72 hours or less, or when time critical steps are included in the analysis, e.g., extractions, and incubations;

c) Instrument identification and instrument operating conditions/parameters (or reference to such data);

d) Analysis type;

e) All manual calculations e.g., manual integrations;

f) Analyst's or operator's initials/signature or chemist ID number;

g) Sample preparation including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;

h) Sample analysis;

i) Standard and reagent origin, receipt, preparation, and use;

j) Calibration criteria, frequency and acceptance criteria;

k) Data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;

l) Quality control protocols and assessment;

m) Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries; and,

n) Method performance criteria including expected quality control requirements.

12.3.4 Administrative Records

The following are maintained:

a) Personnel qualifications, experience and training records;

b) Ethics Statements;

c) Records of demonstration of capability for each analyst; and

d) A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.

13.0 LABORATORY REPORT FORMAT AND CONTENTS

The results of each test, or series of tests carried out by the laboratory must be reported accurately, clearly, unambiguously and objectively. The results normally 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. Some regulatory reporting requirements or formats, such as monthly operating reports may not require all items listed below, however, ECI will provide all the required information to their client for use in preparing such regulatory reports.

a) Except as discussed in 13.b, each report to an outside client includes at least the following information (those prefaced with “where relevant” are not mandatory):

    1) A title, e.g., "Analytical Report," or "Test Certificate," "Certificate of Results" or "Laboratory Results”;

    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 identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

   This requirement may be presented in several ways:

   i. The total number of pages may be listed on the first page of the report as long as the subsequent pages are identified by the unique report identification and consecutive numbers, or

   ii. Each page is identified with the unique report identification, the pages are identified as a number of the total report pages (example: 3 of 10, or 1 of 20).

   Other methods of identifying the pages in the report may be acceptable as long as it is clear to the reader that discrete pages are associated with a specific report, and that the report contains a specified number of pages.

4) Name and address of client, where appropriate 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 NELAC sample acceptance requirements such as improper container, holding time, or temperature;

7) Date of receipt of sample, date and time of sample collection, date(s) of performance test, and time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to 72 hours;

8) Identification of the test method used, or unambiguous description of any nonstandard method used;

9) If the laboratory collected the sample, reference to sampling procedure;

10) Any deviations from (such as failed quality control), additions to or exclusions from the test method (such as environmental conditions), and any nonstandard conditions that may have affected the quality of results, and including the use and definitions of data qualifiers.

11) Measurements, examinations and derived results, supported by tables, graphs, sketches, and photographs as appropriate, and any failures identified; identify whether data are calculated on a dry weight or wet weight basis; identify the reporting units such as µg/l or mg/kg;

12) When required, a statement of the estimated uncertainty of the test results;

13) A signature and title, or an equivalent electronic identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;

14) At the ECI's discretion, a statement to the effect that the results relate only to the items tested or to the sample as received by the laboratory;

15) At the ECI's discretion, a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory;

16) Clear identification of all test data provided by outside sources, such as subcontracted laboratories, clients, etc.; and

17) Clear identification of numerical results with values outside of quantitation limits.

b) Where the certificate or report contains results of tests performed by subcontractors, these results are clearly identified by subcontractor name or applicable accreditation number and the entirety of the subcontract report is included with the final ECI report.

c) After issuance of the report, the laboratory report remains unchanged. Material amendments to a calibration certificate, test report or test certificate after issue may be made only in the form of a further document, or data transfer, including the statement "Supplement to Test Report or Test Certificate, serial number . . . [or as otherwise identified]", or equivalent form of wording. Such amendments meet all the relevant requirements of the NELAC Standard.

d) ECI notifies clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate.

e) The laboratory will, where clients require transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, follow documented procedures that ensure that the requirements of this Standard are met and that confidentiality is preserved.

f) ECI will certify that all its NELAC-certified test results reported meet all requirements of NELAC or provide reasons and/or justification if they do not.

14.0 SUBCONTRACTING ANALYTICAL SAMPLES

When ECI subcontracts work whether because of unforeseen circumstances (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through client direction, contractual arrangement or permanent subcontracting), this work shall be placed with a laboratory accredited under NELAP, or other appropriate certification, for the tests to be performed or with a laboratory that meets applicable statutory and requirements for performing the tests and submitting the results of tests performed. All subcontracted work shall be referenced and so noted in the final ECI analytical report.

Subcontract laboratories will provide or make available, current copies of the following documents prior to ECI submitting samples. This information will be updated annually or on an as needed basis.

a) Laboratory accreditations / certifications

b) Upon request, any Proficiency Testing (PT) or Performance Evaluation (PE) results relevant to the subcontracted samples.

c) Insurance Certificates

d) Quality Assurance Manual

e) Subcontract laboratories will also submit statements affirming that ECI will be notified if any of the following occur.

- There is a change or loss in accreditation for the applicable analysis.
- Most recent PT or PE study results for the applicable analysis are unacceptable *AND* are not able to be addressed via Corrective Action.
- There is a need to subcontract ECI project samples. Prior ECI approval is required in writing for subcontracting samples.

f) The client project requirements will be used to evaluate the subcontract laboratories and to determine their acceptability. Approval by either: the QA Manager, Laboratory Director or Client Services Director (or designee) is required.

g) A master list of approved laboratories will be created and distributed to Sample Control and all Project Managers. All subcontracting must utilize a laboratory from this list.

The procedure for subcontracting samples will follow these guidelines:

a) ECI will advise its client via written, facsimile or e-mail notification of its intention to subcontract any portion of the testing to another party in cases when unforeseen circumstances occur. ECI shall gain approval by the client in writing, facsimile or via e-mail response.

b) ECI may subcontract samples on a continuing basis without written, facsimile or e-mail notification under the following (but not limited to) cases:

- Standing Client direction or instruction
- Contractual specification or requirement
- Project historical precedent

c) A separate Chain of Custody will be created specifically for the subcontracted sample(s). This (or a copy) will be included with the full and complete subcontract report in the final ECI analytical report.

d) ECI shall retain records demonstrating that the above requirements have been met.

e) If the samples to be subcontracted are submitted to ECI under special regulatory, agency or governmental accreditation, Example: Department of Defense / Energy, that have more comprehensive or differing quality criteria, Example: DOD/DOE QSM for Environmental Laboratories Version 5.0 July 2013, then the subcontract laboratory MUST have certification for the subcontracted analysis from the same entity and MUST have undergone similar assessment as the primary laboratory for the subcontracted component. Written authorization from the client or authorizing body must be obtained prior to usage of each subcontract laboratory.

15.0 OUTSIDE SUPPORT SERVICES AND SUPPLIES

ECI does not procure outside services and supplies, other than those referred to in this Manual.

Service providers and vendors are evaluated in accordance with ISO/IEC 17025:2005 or ISO 9001 guidelines prior to use by ECI, reference SOP T019 and T107 for additional information.

16.0 INQUIRIES AND COMPLAINTS

ECISOP-T018 addresses the policies and procedures for the resolution of inquiries and complaints received from clients or other parties about the laboratory's activities. Where an inquiry or complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this manual or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with NELAC Section 5.3.1. Records of the complaint and subsequent actions are maintained and are available for audits.

17.0 REVIEW OF WORK REQUESTS, CONTRACTS AND TENDERS

ECI has established procedures for the review of work requests contracts and tenders. Projects, proposals and contracts are reviewed for adequately defined requirements and the ability of ECI to meet those requirements. A thorough review of all technical and quality control requirements contained in these requests is performed to ensure a project's success. The appropriateness of requested methods, and the lab's capability to perform them must be established. A review of the laboratory's capability to analyze non-routine analytes is also part of this review process. Additionally, alternate test methods that are capable of meeting the clients' requirements may be proposed by the lab.

All projects, proposals and contracts are reviewed for the client's requirements in terms of compound lists, test methodology requested, detection and reporting levels, and quality control limits. During the review process, the laboratory determines whether it has the necessary physical, personnel and information resources to meet the project requirements, and if the personnel have the expertise needed to perform the required testing. Each proposal is also checked for its impact on the overall capacity of the laboratory. The proposed turnaround time will be checked for feasibility. Electronic or hard copy deliverable requirements are evaluated against the laboratory's ability to produce such documentation.

This review process ensures that the laboratory's test methods are suitable to achieve regulatory and/or client requirements and that the laboratory holds the appropriate certifications to perform the work. In the event that the use of a subcontract laboratory is needed, also confirming that they meet all project requirements and maintain the appropriate certifications for the proposed subcontract analyses. If the laboratory cannot provide all services and therefore intends to use the services of a subcontract laboratory, this will be documented and discussed with the client prior to project or contract approval.

Following the review process, the laboratory informs the client of the results of the review and notes any potential conflict, lack of accreditation, or inability of the lab to complete the work satisfactorily. Any discrepancy between the client's requirements and the capability of the laboratory to meet those requirements is resolved in writing before acceptance of the project or contract. It is necessary that the project requirements or contract be acceptable to both the client and the laboratory prior to the start of the work. The review process is repeated when there are amendments to the original contract by the client.

All contracts, Quality Assurance Project Plans (QAPPs), Sampling and Analysis Plans (SAPs), contract amendments, and documented communications become part of the project record.

Review Personnel

Depending upon the scope of a project or contract, one or more key persons may review and accept work on behalf of the laboratory. For routine projects, a review by the Project Manager (PM) is considered adequate. The PM confirms that the laboratory has the necessary certifications, that it can meet the clients' data quality, reporting and turn-around time requirements.

For new, complex or large projects, the proposed project proposal or contract is given to the Business Development Director for an initial review that encompasses all facets of the operation. The scope of work is then distributed to the following personnel, as needed based on scope of contract, to evaluate all of the project related requirements:

- Laboratory Director
- Operations Director
- Technical Director
- Quality Assurance Director
- Quality Assurance Manager
- Group Leaders

- Project Manager(s)

Appropriate records are maintained for every contract or work request. Copies of the agreed-upon contract will be distributed to key personnel as needed and the signed copies maintained by the Business Development Director and/or Laboratory Director.

Project Kick-off and Status Meetings

For routine project work, project managers ensure that specific technical and QC requirements are effectively evaluated and communicated to laboratory personnel through the use of the LIMS system: special requirements section of the chemist's worksheet.

Prior to work on a new or complex project, project managers or key personnel will hold meetings with operations personnel to discuss schedules and any unique aspects of the project. Items discussed include the project technical profile, turnaround times, holding times, methods, analyte lists, reporting limits, deliverables, sample hazards, and any other special requirements.

Project requirements are given to the laboratory staff during project kick-off meetings or the daily status meetings. Information disseminated during these meetings provides direction to the laboratory staff in order to maximize production, maintain high quality and ensure client satisfaction.

During the project, changes to the scope of work may occur due to client, sampling or regulatory reasons. If these changes impact the laboratory's role in the project (use of a non-standard method or modification of a method to comply with revised requirements) then the changes need to be discussed with and agreed upon with the client prior to continuing with the work. These changes must be documented prior to implementation and communicated to the laboratory staff during a status or project specific meeting. Documentation of the modification is made in the analytical report narrative.

And at all times, records of all pertinent discussions with a client relating to the project or contract are documented and maintained as a part of the project record.

18.0 MANAGEMENT REVIEW, MANAGEMENT OF CHANGE AND CONTINUOUS IMPROVEMENT

18.1 Management Review

A comprehensive Management Review of the entire ECI Quality System will be conducted by the Laboratory Director on an annual basis, no later than the end of the first quarter for the previous year's review. The SOP T-030 may be consulted for detailed guidance. All major stakeholders will be given an opportunity to provide comment or input for the review. These will include:

- Laboratory Director
- Client Services Director
- Operations Director
- Technical Director
- Senior Project Manager
- Other Operational / Project Management personnel as appropriate.
- Clients

The purpose and goal of the Management Review will identify weaknesses, areas requiring more resources or oversight, opportunities for continuous improvement and follow up on previous recommendations.

The final completed review is part of the NELAP laboratory documentation requirements and may be submitted to ECI authorized auditing agencies or clients upon request.

18.2 Management of Change

Whenever a change is made in a controlled environment (not just production) the laboratory is put at risk. However, one needs to constantly make changes to keep pace with business / regulatory requirements. The challenge to the laboratory is to minimize the risk and impact of that change.

An organization must have an operating process in place for which an evaluation has been conducted, and that allows proper lead times and approvals to ensure that the laboratory is unaffected when changes are made. But to successfully implement a change, one also needs to have a comprehensive understanding of the infrastructure that supports the services to determine the overall impact. The Management of Change process will facilitate, as referenced in SOP T030, this evaluation.

The Management of Change process will track and implement the following types of changes:

a) Permanent Change: – A change that is considered long term and durable. Any change which is not categorized as a Temporary Change.

b) Temporary Change: – A change which has a defined lifetime and which will be removed before a defined date (usually no more than six months). All temporary changes must have a specified removal date that is documented on the approved MOC form.

c) Emergency Change: – An emergency change path that allows the change to be implemented and commissioned immediately in order to address an immediate safety, operational, health, environmental, or product quality situations.

The functional categories that will be managed include:

a) Laboratory Facility Acquisition
b) Laboratory Instrument Acquisition
c) Analytical Method Development and Validation
d) Laboratory Operations Process Change
e) Department Relocation
f) Activation of Analytical Method
g) Information Technology (Major Initiatives)
h) New Accreditation or Certification

18.3 Continuous Improvement

In order for ECI to be proactive and a leader in the industry, the entire ECI Quality system is designed to ensure the production of scientifically sound, legally defensible data of known and proven quality. The addition of the Management Review and Management of Change processes enhances ECI's ability to foster continuous improvement.

Continuous improvement is an ongoing effort to improve data integrity, services or processes. These efforts can seek "incremental" improvement over time or "breakthrough" improvement all at once. All staff at ECI participates in continuous improvement, from the Laboratory Director down to the beginning technician, as well as external stakeholders when applicable.

The following procedures / inputs have direct involvement in the continuous improvement process:

a) External Audits (Regulatory and Client Based)
b) Internal Audits
c) Corrective / Preventive Actions
d) Statistical Quality Control (SQC) Monitoring
e) Proficiency Testing Performance
f) Client Feedback – Complaints and Commendations
g) Management Review
h) Management of Change

The Management of Change process will guide and document the major improvements. The Corrective / Preventive Action procedure will enable and record the more incremental changes.

The principal elements are commitment to quality, focused effort, involvement of all employees, willingness to change, and communication.

NELAC APPENDICES

APPENDIX A - REFERENCES

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EPA/503/8-91/001 Evaluation of Dredged Material Proposed for Ocean Disposal – Testing Manual. Office of Water, Washington, DC, 1991.

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EPA/600/4-91/002 Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, 3rd Ed., Office of Research and Development, Washington, DC, 1994.

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ISO/IEC 17025: 2005. General requirements for the competence of calibration and testing laboratories.

“Laboratory Biosafety Manual,” World Health Organization, Geneva, 1983.

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Performance Based Measurement System, EPA EMMC Method Panel, PBMS Workgroup, 1996.

APPENDIX B - GLOSSARY

The following definitions are used in the text of Quality Systems. In writing this document, the following hierarchy of definition references was used: ISO 8402, ANSI/ASQC E-4, EPA's Quality Assurance Division Glossary of Terms, and finally definitions developed by NELAC. The source of each definition, unless otherwise identified, is the Quality Systems Committee.

Acceptance Criteria: Specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQC)

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 a voluntary one. (NELAC)

Accrediting Authority: The Territorial, State, or Federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation. (NELAC) [1.5.2.3]

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)

Analysis Duplicate: The second measurement of the target analyte(s) performed on a single sample or sample preparation.

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. (NELAC)

Analytical Reagent (AR) Grade: Designation for the high purity of certain chemical reagents and solvents given by the American Chemical Society. (Quality Systems)

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 NELAC). (NELAC)

Audit: A systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity. (EPA-QAD)

Batch: Environmental samples, which 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 NELAC-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. (NELAC 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. (ASQC)

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. (NELAC)

Calibration: To determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements. (NELAC)

Calibration Curve: The graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response. (NELAC)

Calibration Method: A defined technical procedure for performing a calibration. (NELAC)

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: A 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; collector; time of collection; preservation; and requested analyses. (NELAC)

Compromised Samples: Those samples which are improperly sampled, insufficiently documented (chain of custody and other sample records and/or labels), improperly preserved, collected in improper containers, or exceeding holding times when delivered to a laboratory. Under normal conditions compromised samples are not analyzed. If emergency situations require analysis, the results must be appropriately qualified. (NELAC)

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. (NELAC)

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)

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)

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)

Demonstration of Capability: A procedure to establish the ability of the analyst to generate acceptable accuracy. (NELAC)

Desorption Efficiency: The mass of target analyte recovered from sampling media, usually a sorbent tube, divided by the mass of target analyte spiked on to the sampling media expressed as a percentage. Sample target analyte masses are usually adjusted for the desorption efficiency. (NELAC)

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. (NELAC)

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)

Duplicate Analyses: The analyses or measurements of the variable of interest performed identically on two subsamples 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. (EPA- QAD)

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)

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. (NELAC)

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: 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. (NELAC)

Laboratory Duplicate: Aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently. (NELAC)

Limit of Detection (LOD): Limit of Detection (LOD): The smallest concentration of a substance that must be present in a sample in order to be detected at the DL with 99% confidence. At the LOD, the false negative rate (Type II error) is 1%. (NELAC)

Limit of Quantitation (LOQ): The smallest concentration that produces a quantitative result with known and recorded precision and bias. (NELAC)

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. (NELAC)

Matrix: The component or substrate that contains the analyte of interest. For purposes 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% 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: 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. (NELAC)

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. (NELAC)

Media: Material that supports the growth of a microbiological culture.

Method 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. (NELAC)

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)

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. (NELAC)

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. (NELAC)

National Environmental Laboratory Accreditation Program (NELAP): The overall National Environmental Laboratory Accreditation Program of which NELAC is a part. (NELAC)

Negative Control: Measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results. (NELAC)

Objective Evidence: Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measures, or tests that can be verified. (ASQC)
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. (NELAC)

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. (NELAC)

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. (NELAC)

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. (NELAC)

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. (NELAC)

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. (NELAC) [2.1]

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. (NELAC)

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, and analysis) which must be strictly followed. (EPA- QAD)

Pure Reagent Water: Shall be water (defined by national or international standard) in which no target analytes or interferences are detected as required by the analytical method. (NELAC)

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)

Quality Control Sample: An uncontaminated sample matrix 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. (NELAC)

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 specific degree of confidence. (NELAC)

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)

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)

Record Retention: The systematic collection, indexing and storing of documented information under secure conditions. (EPA-QAD)

Reference Material: A material or substance 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. (NELAC)

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 2.1.f). (NELAC)

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. (NELAC)

Requirement: Denotes a mandatory specification; often designated by the term "shall". (NELAC)

Sampling Media: Material used to collect and concentrate the target analytes(s) during air sampling such as solid sorbents, filters, or impinger solutions.

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. (NELAC)

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)

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 NELAC procedures and policies. (ASQC)

Standard Operating Procedure (SOP): 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)

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. (NELAC)

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)

Systems Audit (also Technical Systems Audit): A thorough, systematic, qualitative on-site assessment of the facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system. (EPA-QAD)

Technical Director: Individual(s) who has overall responsibility for the technical operation of the environmental testing laboratory. (NELAC)

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. (NELAC)

Testing Laboratory: 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 (see Chapter 5, Appendix D, Section 2.4.a). (NELAC)

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)

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)

Validation: The process of substantiating specified performance criteria. (EPA- QAD)

Verification: Confirmation by examination and provision of evidence that specified requirements have been met. (NELAC)

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.

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. (NELAC)

Sources:

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

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)

National Environmental Laboratory Accreditation Conference (NELAC), July 1998 Standards

Random House College Dictionary

U.S. EPA Quality Assurance Management Section (QAMS), Glossary of Terms of Quality Assurance Terms, 8/31/92 and 12/6/95

U.S. EPA Quality Assurance Division (QAD)

40 CFR, Part 136

Webster's New World Dictionary of the American Language

APPENDIX C - DEMONSTRATION OF CAPABILITY

C.1 PROCEDURE FOR DEMONSTRATION OF CAPABILITY

A demonstration of capability (DOC) must be made prior to using any test method, and at any time there is a change in instrument type, personnel or test method. (See NELAC 10.2.1.)

Note: Where tests are performed by specialized "work cells" (a well-defined group of analysts that together perform the method analysis), the work cell as a unit meets the above criteria and this demonstration is fully documented.

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), e.g., water, solids and air. However, before any results are reported using this method, actual sample spike results may be used to meet this standard, i.e., at least four consecutive matrix spikes within the last twelve months. In addition, for analytes that do not lend themselves to spiking, e.g., TSS, the demonstration of capability may be performed using quality control samples.

All demonstrations shall be documented through the use of the form in this appendix.

The following steps, which are adapted from the EPA test methods published in 40 CFR Part 136, Appendix A, are performed if required by mandatory test method or regulation. Note: For analytes for which spiking is not an option and for which quality control samples are not readily available, the 40 CFR approach is one way to perform this demonstration. The laboratory documents that other approaches to DOC are adequate, and this is documented in the laboratory's Quality Manual.

a) A quality control sample is obtained from an outside source. If not available, the QC sample may be prepared by the laboratory using stock standards that are prepared independently from those used in instrument calibration.

b) The analyte(s) is diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified, or if unspecified, to a concentration approximately 10 times the method-stated or laboratory-calculated method detection limit.

c) At least four aliquots are prepared and analyzed according to the test method either concurrently or over a period of days.

d) Using all of the results, the mean recovery ($\overline{X}$) is calculated in the appropriate reporting units (such as µg/L) and the standard deviations of the population sample (n-1) (in the same units) for each parameter of interest. When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, the laboratory will assess performance against established and documented criteria.

e) Compare the information from (d) above to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-generated acceptance criteria (if there are no established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.

f) When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst must proceed according to 1) or 2) below.

1) Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with c) above.

2) Beginning with c) above, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, will confirm a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with c).

C.2 CERTIFICATION STATEMENT

The following certification statement shall be used to document the completion of each demonstration of capability. A copy of the certification statement shall be retained in the personnel records of each affected employee (see ECIQSM Section 6.3 and 12.3.4.b.).

Demonstration of Capability
Certification Statement

Date: Page __of __
Laboratory Name:
Laboratory Address:
Analyst(s) Name(s):

Matrix: _____
Examples: laboratory pure water, soil, air, solid, biological tissue)

Method number, SOP#, Rev #, and Analyte, or Class of Analytes or Measured Parameters:
_____ (examples: barium by 200.7, trace metals by 6010, benzene by 8021, etc.)

We, the undersigned, CERTIFY that:

1. The analysts identified above, using the cited test method(s), which is in use at this facility for the analyses of samples under the National Environmental Laboratory Accreditation Program, have met the Demonstration of Capability.

2. The test method(s) was performed by the analyst(s) identified on this certification.

3. A copy of the test method(s) and the laboratory-specific SOPs are available for all personnel on-site.

4. The data associated with the demonstration capability are true, accurate, complete and self-explanatory (1).

5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized assessors.

_____	_____	_____
Technical Director's Name and Title	Signature	Date
_____	_____	_____
Quality Assurance Officer's Name	Signature	Date

This certification form must be completed each time a demonstration of capability study is completed.

(1) True: Consistent with supporting data.
Accurate: Based on good laboratory practices consistent with sound scientific principles/practices.
Complete: Includes the results of all supporting performance testing.
Self-explanatory: Data properly labeled and stored so that the results are clear and require no additional explanation.

(Note: Form may be modified so long as the essential items are included in the revised form)

APPENDIX D - ESSENTIAL QUALITY CONTROL REQUIREMENTS

The quality control protocols specified by the laboratory's method manual (10.1.2) shall be followed. The laboratory shall ensure that the essential standards outlined in Appendix D are incorporated into their method manuals.

All quality control measures shall be assessed and evaluated on an ongoing basis and quality control acceptance criteria shall be used to determine the validity of the data. The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exists.

The requirements from the body of Chapter 5, e.g., Section 5.4, apply to all types of testing. The specific manner in which they are implemented is detailed in each of the sections of this Appendix, i.e., chemical testing.

The Standard Operating Procedure (SOP) T020 "Internal Quality Control Checks" and the specific analytical method SOPs have a more detailed outline of the quality control procedures.

D.1 CHEMICAL TESTING

D.1.1 Positive and Negative Controls

a) Negative Controls

1) Method Blanks - Shall be performed at a frequency of one per preparation batch of samples per matrix type. The results of this analysis shall be one of the QC measures to be used to assess the batch. The source of contamination must be investigated and measures taken to correct, minimize or eliminate the problem if

i) the blank contamination exceeds a concentration greater than 1/10 of the measured concentration of any sample in the associated sample batch or

ii) the blank contamination exceeds the concentration present in the samples and is greater than 1/10 of the specified regulatory limit.

Any sample associated with the contaminated blank shall be reprocessed for analysis or the results reported with appropriate data qualifying codes.

b) Positive Controls

1) Laboratory Control Sample (LCS) - (QC Check Samples) Shall be analyzed at a minimum of 1 per preparation batch of 20 or less samples per matrix type, except for analytes for which spiking solutions are not available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. The results of these samples shall be used to assess the batch. NOTE: The matrix spike (see 2 below) may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS.

a. The NELAC requirements (2009 Standard, Section 1.7.4.2 b) allow the usage of LCS Marginal Exceedance control limits for those analyses with multiple reporting analytes.

b. The NELAC standards state that if a large number of analytes are in the LCS, it becomes statistically likely that a few will be outside control limits. This may not indicate that the system is out of control; therefore, corrective action may not be necessary. Upper and lower marginal exceedance (ME) limits can be established to determine when corrective action is necessary. ME is defined as being beyond the LCS control limit but within the ME limits. ME limits are between 3 and 4 standard deviations around the mean.

c. The number of allowable marginal exceedance is based on the number of analytes in the LCS. If there is any analyte that exceed the LCS control limits, it does not necessary mean the LCS fails. The NELAC standard states if the number of analytes fails LCS control limits but is within the ME limits, it is acceptable.

2) Matrix Spikes (MS) - Shall be performed at a frequency of one out of every 20 samples per matrix type prepared over time, except for analytes for which spiking solutions are not available such as, total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. The selected sample(s) shall be rotated among client samples so that various matrix problems may be noted and/or addressed. Poor performance in a matrix spike may indicate a problem with the sample composition and shall be reported to the client whose sample was used for the spike.

3) Surrogates - Surrogate compounds must be added to all samples, standards, and blanks, for all organic chromatography methods except when the matrix precludes its use or when a surrogate is not available. Poor surrogate recovery may indicate a problem with the sample composition and shall be reported to the client whose sample produced the poor recovery.

4) If the mandated or requested test method does not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample and Matrix Spike. However, in cases where the components interfere with accurate assessment (such as simultaneously spiking chlordane, toxaphene, and PCBs in Method 608), the test method has an extremely long list of components or components that are incompatible, a representative number (minimum of 10%) of the listed components may be used to control the test method. The selected components of each spiking mix shall represent all chemistries, elution patterns and masses, permit-specified analytes, and other client-requested components. However, the laboratory shall ensure that all reported components are used in the spike mixture within a two-year time period.

D.1.2 Analytical Variability/Reproducibility

Matrix Spike Duplicates (MSDs) or Laboratory Duplicates - Shall be analyzed at a minimum of 1 in 20 samples per matrix type per sample extraction or preparation method. The laboratory shall document its procedure to select the use of appropriate type of duplicate. The selected sample(s) shall be rotated among client samples so that various matrix problems may be noted and/or addressed. Poor performance in the duplicates may indicate a problem with the sample composition and shall be reported to the client whose sample was used for the duplicate.

D.1.3 Method Evaluation

In order to ensure the accuracy of the reported result, the following procedures shall be in place:

a) Demonstration of Analytical Capability - (Section 10.5) shall be performed initially (prior to the analysis of any samples) and with a significant change in instrument type, personnel, matrix or test method.

b) Calibration - Calibration protocols specified in Section 9.4 shall be followed.

c) Proficiency Test Samples - The results of such analyses (4.2.j or 5.3.4) shall be used by the laboratory to evaluate the ability of the laboratory to produce accurate data.

D.1.4 Analytical Measurement Uncertainty Estimation

Uncertainty is “a parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand” (as defined by the International Vocabulary of Basic and General Terms in Metrology, ISO Geneva, 1993, ISBN 92-67-10175-1).

Uncertainty is not error. Error is a single value, the difference between the true result and the measured result. For environmental samples, the true result is never known. The measurement is the sum of the unknown true value and the unknown error.

Unknown error is a combination of systematic error, or bias, and random error. Bias varies predictably, constantly, and independently from the number of measurements. Random error is unpredictable, assumed to have a Gaussian distribution, and be reducible by increasing the total number of measurements.

Knowledge of the uncertainty of a measurement provides additional confidence in the validity of a result as its value accounts for all the factors which could possibly affect the result. Certain test methods will specify limits to the values of sources of uncertainty of measurement (EPA 500 series methods, etc.) and will specify the form of presentation of calculated results.

When the method makes these stipulations, there is no need to provide a mechanism for calculating the uncertainty. Where this information is not provided within a method or other regulatory device, the uncertainty associated with results generated by the laboratory can be determined by using the Laboratory Control Sample (LCS) accuracy range for a given analyte because LCS recoveries incorporate all of the laboratory-related variables associated with a given test over time. It is recognized that other approaches exist; however, ECI's standard for estimating analytical data uncertainty uses this approach.

D.1.4.1 Using the Laboratory Control Sample (LCS) to Estimating Analytical Uncertainty

a) The estimated measurement uncertainty can be expressed as a range (±) around the reported analytical results at a specified confidence level. For methods that use statistically-derived LCS control limits based on historical LCS recovery data to assess the performance of the measurement system, these limits are considered an estimate of the minimum laboratory contribution to measurement uncertainty at a 99% confidence interval, The percent recovery of the LCS is compared either to the method-required LCS accuracy limits or to the statistical, historical, in-house LCS accuracy limits.

- Uncertainty values may be reported for specific projects upon request. In absence of alternate client-specified approaches or confidence levels,

  ECI will use the following procedure:

  > To calculate the uncertainty value of a reported analytical result, the lower uncertainty range value is calculated by subtracting the product of the result and the lower LCS percent recovery from the result; and the upper uncertainty value result is calculated by adding the product of the result and the upper LCS percent recovery.
  >
  > These calculated values represent approximately a 99% confidence level. In other words, approximated 99% of the measured values for the analyte will fall within this calculated range.

- Example: If the reported result is 1.0 mg/l, and the LCS percent recovery range is 75 to 125%. The uncertainty range would be 0.75 to 1.25 mg/l, which could also be written as 1.0 +/- 0.25 mg/l.

- The Laboratory Quality and Accreditation Office has made available to the public both a spreadsheet that calculates analytical measurement uncertainty and an SOP describing how to use it. This SOP applies to test methods that are within the scope of ISO/IEC 17025-1999 Standard: General Requirements for the Competence of Testing and Calibration Laboratories and it is based on the general rules outlined in Guide to the Expression of Uncertainty in Measurement (GUM).

The spreadsheet provides a QC-based nested approach for estimating measurement uncertainty using laboratory generated calibration and QC spike results. This spreadsheet has been authorized to be used on DOD/DOE projects, if requested.

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D.1.4.2 Additional Components to Estimating Analytical Uncertainty

When estimating analytical measurement uncertainty, all significant components of uncertainty must be identified and quantified. Components that affect analytical measurement uncertainty include sampling, handling, transport, storage, preparation and testing. A typical environmental laboratory will have the greatest contribution to uncertainty in the storage, preparation and testing portion of the analytical train, hence the estimation can be limited to those three areas, assuming all other factors are within recommended guidelines for sample size, container type, preservation (chemical, temperature, temporal) and handling/transport. If the latter are *NOT* within guidelines then these additional estimations of variability must be accounted for, and may supersede the laboratory contribution to uncertainty.

Definitive references and procedural manuals for calculating Analytical Measurement Uncertainty are listed below. Note that there are different theories on the "best" way to estimate uncertainty, it is up to the end user to determine that which best meets their project needs.

a) "Environmental Analytical Measurement Uncertainty Estimation – Nested Hierarchical Approach", William Ingersoll, Defense Technical Information Center # ADA396946, 2001

b) "Quantifying Uncertainty in Analytical Measurement", EuraChem / CITAC Guide CG 4, Second Edition, QUAM 2000.1

c) "Quantifying Measurement Uncertainty in Analytical Chemistry – A Simplified Practical Approach", Thomas W. Vetter, National Institute of Standards and Technology

d) ISO Guide to the Expression of Uncertainty in Measurement (GUM), 1993

e) "Estimation of Analytical Measurement Uncertainty - Laboratory Quality and Accreditation Office Uncertainty Calculator Standard Operating Procedure. Downloaded from http://www.denix.osd.mil/edqw/upload/UNCERTAINTY-SOP.PDF , 2013

f) QC-based Nested Approach for Estimating Measurement Uncertainty Spreadsheet, Microsoft Excel Spreadsheet, Ingersoll, William Stephen, 2002

The process in general involves the following steps:

1. Specify the Measurand – Write down a clear statement of what is being measured, including the relationship between the measurand and the input quantities, i.e., measured quantities, constants, calibration standard values, etc.

2. Identify uncertainty sources – This will include sources that contribute to the uncertainty on the parameters in the relationships identified in step 1, but may include other sources and must include sources arising from chemical assumptions.

3. Quantify uncertainty components – Measure or estimate the size of the uncertainty component associated with each potential source of uncertainty identified. It is often possible to estimate or determine a single contribution to uncertainty from the aggregate of multiple sources.

4. Calculate combined uncertainty – The information obtained in step 3 will consist of a number of quantified contributions to overall uncertainty, whether associated with individual sources or with the combined effects of several sources.

The process outlined above relates to the measurement of uncertainty for the preparative / analytical laboratory procedure. However, there are uncertainty contributions from other factors outside the preparative / analytical procedure. These can be controlled to a great extent by specifying uniform and standardized training or conditions.

Examples:

Human Factors

a) All personnel at ECI undergo documented training in the method and / or instrument used. Minimum levels of education or experience are required.

b) Initial and continuing Demonstrations of Capability (DOC) must be performed and documented prior to and in continuance of analytical work related to their areas of responsibilities.

c) Blind Proficiency Testing samples are analyzed twice a year to gauge each department, matrix and method.

d) Data Integrity and Ethics Training are provided to new employees and on an annual basis to all employees.

Accommodation and Environmental Conditions

a) ECI has standardized operating procedures for transport, storage and tracking of samples, extracts and digests throughout the laboratory. All incoming orders are logged into a Laboratory Information System that assigns a specific identifier code to each work order, sample container and analytical result.

b) The sample control areas are secured with restricted access using card key portals. Internal chain of custody is available if the project requires.
c) The laboratory has over 35,000 sq ft of laboratory space with temperature controlled and air positive or negative environmental controls.

d) Regular safety inspections are performed to identify potentially hazardous conditions and to ensure general cleanliness.

Environmental Test Methods and Method Validation

a) All methods in use have Standard Operating Procedures (SOPs) based upon published methods from the EPA, ASTM, Standard Methods or other established body. These are controlled documents assigned to each department. An annual review is performed.

b) Each method has internal and external quality control criteria for preparative efficiency, instrument performance, calibration, continuing method performance and possible matrix effects as appropriate.

c) Ongoing Proficiency Testing program.

Equipment and Instrumentation

a) Each instrument in use has performance parameters that must be evaluated to specific standards based on the established method prior to any analytical use.

b) Routine and preventative maintenance is performed to maintain optimum operational performance.

c) Complex instrument systems are covered under manufacturer service contracts as appropriate.

Measurement Traceability

a) Every reagent used must meet the indicated purity and fitness for usage as referenced in the method SOPs.

b) All calibration standards are certified by the manufacturer to meet or exceed purity levels as recorded in the accompanying Certificate of Traceability to NIST or other standards verification.

c) Each reagent, standard or working standard is recorded, assigned a tracking identifier. This is referenced in the analytical log book as needed to assure traceability to the original source.

d) All Balances, Dispensers, Pipettors, Refrigerators, Freezers and Thermometers are checked on a daily or other routine basis to specified tolerances.

D.1.5 Detection Limits

The laboratory shall utilize a test method that provides a detection limit that is appropriate and relevant for the intended use of the data. Detection limits shall be determined by the protocol in the mandated test method or applicable regulation, e.g., Method Detection Limit (MDL). If the protocol for determining detection limits is not specified, the selection of the procedure must reflect instrument limitations and the intended application of the test method. Refer to SOP T006, Determination of Detection Limits.

a) A detection limit study is not required for any component for which spiking solutions or quality control samples are not available such as temperature.

b) The detection limit shall be initially determined for the compounds of interest in each test method in a matrix in which there are not target analytes nor interferences at a concentration that would impact the results or the detection limit must be determined in the matrix of interest (see definition of matrix).

c) Detection limits must be determined each time there is a change in the test method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis.

d) All samples processing steps of the analytical method shall be included in the determination of the detection limit.

e) All procedures used must be documented. Documentation must include the matrix type. All supporting data must be retained.

f) The laboratory must have established procedures to relate detection limits with quantitation limits.

g) The test method's quantitation limits must be established and must be above the detection limits.

D.1.6 Data Reduction

The procedures for data reduction, such as use of linear regression, shall be documented.

D.1.7 Quality of Standards and Reagents

a) The source of standards shall comply with 9.3.

b) Reagent Quality, Water Quality and Checks:

1) Reagents - In methods where the purity of reagents is not specified, analytical reagent grade shall be used. Reagents of lesser purity than those specified by the test method shall not be used. The labels on the container should be checked to verify that the purity of the reagents meets the requirements of the particular test method. Such information shall be documented.

2) Water - The quality of water sources shall be monitored and documented and shall meet method specified requirements.

3) The laboratory will verify the concentration of titrants in accordance with written laboratory procedures.

D.1.8 Selectivity

a) Absolute retention time and relative retention time aid in the identification of components in chromatographic analyses and to evaluate the effectiveness of a column to separate constituents. The laboratory shall develop and document acceptance criteria for retention time windows.

b) A confirmation shall be performed to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory. Such confirmations shall be performed on organic tests such as pesticides, herbicides, or acid extractable or when recommended by the analytical test method except when the analysis involves the use of a mass spectrometer. Confirmation is required unless stipulated in writing by the client. All confirmation shall be documented.

c) The laboratory shall document acceptance criteria for mass spectral tuning.

D.1.9 Constant and Consistent Test Conditions

a) The laboratory shall assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used.

b) Glassware Cleaning - Glassware shall be cleaned to meet the sensitivity of the test method.

Any cleaning and storage procedures that are not specified by the test method shall be documented in laboratory records and SOPs.

D.1.10 Method Validation – Modified Procedures, Non-Standard Methods, Additional Analytes

Often times, modifications to published methods are promulgated to allow the laboratory flexibility, increased productivity and, in some cases, it allows for better hazardous waste management, all while maintaining the quality of the data generated. But, this cannot be done without following standard method validation procedures to guarantee that the results achieved from the modified version are equal to or greater than the actual published or routinely accepted method.

Validation procedures are done to make sure that the sensitivity and selectivity of the process is appropriate for the method or analytes chosen. Interference checks are performed to show that the changes or additions will not contribute interferences to previous analytes or on-going processes. Accuracy and precision requirements are established, or previously defined, and used to demonstrate the capability of an analyst to perform the method, initially and on-going.

In the event that a non-standard method (significantly modified or newly-developed) is needed to meet client requirements, the method specifications and how they impact the project requirements must be relayed to the client for approval prior to beginning work on project samples. The client must understand the limits of the method, why it was developed and when it will be used on their project samples, and they must agree to its use.

Any significantly modified or newly-developed method (including the addition of analytes to established procedures) must be fully defined in a Standard Operating Procedure. The validation must be performed by qualified personnel, using appropriate reagents, standards and equipment/instrumentation and that process must be documented. The following items must be performed (as applicable to the method) and the completed documentation with all raw data provided to the Operations Manager and QA Manager for review prior to granting approval for use. A new method cannot be put into production without Operations and QA approval. For situations where NELAP approval is being sought, the method cannot be used for client samples until the certification has been received from the State, unless approval is given by the client.

D.1.10.1 Significant Modification / New Method / Additional Analyte Documentation:

Prior to the acceptance of client samples for analysis, the following documentation, as applicable to the type of modification or method status, must be provided to both Operations and QA for review and approval.

1. Approved Standard Operating Procedure for Analytical or Preparation Processes. Include all related raw data for the SOP revision with the draft version.

    a) Modification of existing method: - Revised SOP with modifications clearly spelled out:

    b) New Method: - New SOP in NELAC format – QA will assign SOP number

    c) Additional Analytes: - Revised SOP with modifications clearly spelled out:

2. Method Detection Limit (MDL) Study: Compliant with 40CFR, Part 136.

    a) Include summary form and all raw data for the review

3. MDL Verification Standard spiked at 1-4x the MDL, or the level specified by the specific program or contract. Example: 1-2x the MDL, reference specific program requirements.

    b) Recovery within 30 -150%, or a minimum response distinguishable from the established instrument noise level.

4. Reporting Limit Verification (when an MDL verification is not performed)

    a) For analytical methods, reprocess the low calibration standard as percent recovery – recovery between 50% and 150% is acceptable.

    b) For extraction methods, or where required by project or program, spike a blank matrix at the reporting limit and process through all steps of the procedure. Note the spike level and percent recoveries. Method defined control limits are used for recovery evaluation, or default recoveries between 40% and 160% if method defined limits are not available.

5. Tuning Check (as applicable to the method)

6. Degradation Check (as applicable to the method)

7. A Valid Initial Calibration and Verification

    a) Minimum of 5 sequential points, unless otherwise stated in the method or in-house SOP.

    b) Low calibration standard at or below the Reporting/Quantitation Limit.

    c) Initial Calibration Verification Standard

8. Retention Time Window Study

9. Second Column Confirmation for all analytes (as applicable to the method)

10. Inter-element Correction (as applicable to the method)

11. Linear Range Study (as applicable to the method)

12. GCMS Spectral Profile(s) (as applicable to the method)

13. Interference Check – Method Blank

    a) Analysis of a blank matrix that has gone through all related steps, preparation and /or analysis, as applicable.

14. Acceptable PT Sample required for all new analytes where NELAP accreditation is being sought.

    a) At least one PT sample (preferably two) required for all new methods

    b) Where a PT sample is not available, or accreditation is not needed, accuracy can be measured through the use of a second source standard.

15. For California ELAP or State NELAP, process a real world sample for MS and MSD. The sample does not have to contain any target analytes but recoveries for surrogates, internal standards and spikes must be within lab or method defined criteria.

    a) Use Tap Water for drinking water only methods, tap or other clean water source for ground, surface, etc. methods

    b) Local Soil sample for SW-846 methods (if applying for soil or soil/water)

16. Initial Demonstration of Capability (IDOC) per analyst

    a) 4 LCS for each matrix, spiked with all associated new analytes – most acceptance criteria are in the methods, if none, use an initial recovery range of 40-160% and an RPD of 30%.

    b) Non-Standard methods – Follow the procedure in the 2003 NELAC Standards, Chapter 5 appendix C.3.3 (b).

17. Certification / Approval from Regulatory Agency where available.

APPENDIX E – LIST OF ACCREDITED METHODS

- **Arizona Department of Health Services – Laboratory ID AZ0781**

  a) View at: http://www.eurofinsus.com/media/161879/arizona-cert_scope_031216.pdf

- **California SWRCB ELAP – Laboratory ID 2944**

  a) View at: http://www.eurofinsus.com/media/162063/ca-elap_calscience.pdf

- **Guam Environmental Protection Agency – Laboratory ID E971101**

  a) View at: http://www.eurofinsus.com/media/161875/guam-cert_foas_103115.pdf

- **Hawaii Department of Health – Laboratory ID (None)**

  a) View at: http://eurofinsus.com/media/161878/hawaii-cert_093015.pdf

- **Kansas Department of Health & Environment – Laboratory ID E-10409**

  a) View at: http://www.eurofinsus.com/media/16055/kansas1.pdf
  b) View at: http://www.eurofinsus.com/media/16056/kansas2.pdf

- **Nevada Department of Conservation and Natural Resources – Laboratory ID CA001112013-1**

  a) View at: http://www.eurofinsus.com/media/162008/nevada-cert-2015.pdf

- **Oklahoma Department of Environmental Quality – Laboratory ID 1311**

  a) View at: http://www.eurofinsus.com/media/161882/oklahoma-cert_083115.pdf

- **Oregon Environmental Laboratory Accreditation Program (NELAP Primary) – Laboratory ID CA300001**

  a) View at: http://www.eurofinsus.com/media/161877/oregon-state-primary-nelap-cert_012916.pdf

- **Texas Commission of Environmental Quality – Laboratory ID T104704499-14-4**

  a) View at: http://www.eurofinsus.com/media/161881/texas-cert_073115.pdf

- **United States Department of Agriculture Certificate No. P330-10-00403, Permit to Receive Soil**

  a) View at: http://eurofinsus.com/media/16042/usda_soil_permit.pdf

- **United States Department of Agriculture – Authorization to Receive Plant Material**

  b) View at: http://www.eurofinsus.com/media/162229/usda-plant-import-authorization_050615.pdf

- **United States Army Corp of Engineers – Approval (EPA 8270 SIM – PCB Congeners)**

  a) View at: http://www.eurofinsus.com/media/16039/dmmo_epa8270sim.pdf

- **United States Department of Defense / Energy ANAB/ACLASS ELAP Certificate ADE-1864 and Fields of Accreditation**

  a) View at: http://www.eurofinsus.com/media/16049/dod_elap.pdf

- **United States Department of the Interior – Approval**

  b) View at: http://www.eurofinsus.com/media/16067/usbor.pdf

- **Utah Department of Health – Laboratory ID CA00111**

  a) View at: http://www.eurofinsus.com/media/161880/utah-cert_foas_103115.pdf

- **Washington Department of Ecology – Laboratory ID C916**

  a) View at: http://www.eurofinsus.com/media/16070/washington1.pdf
  b) View at: http://www.eurofinsus.com/media/16069/washington2.pdf

APPENDIX F – LIST OF PHYSICAL LOCATIONS

F.1 Main Laboratory

- 7440 Lincoln Way, Garden Grove, CA 92841-1427
- 714-895-5494 Fax 714-894-7501

F.2 Satellite Laboratory 1

- 7445 Lampson Avenue, Garden Grove, CA 92841-2903
- Fax 714-898-2036

F.3 Satellite Laboratory 2

- 11380 Knott Street, Garden Grove, CA 92841-1400

F.4 Concord, CA Service Center

- 5063 Commercial Circle, Suite H, Concord, CA 94520-8577
- 925-689-9022 Fax 925-689-9023

APPENDIX G – SPECIAL PROGRAM REQUIREMENTS

F.1 United States Department of Defense / Energy Environmental Laboratory Accreditation Program

1. ECI participates and is accredited in the United States Department of Defense / Energy Environmental Laboratory Accreditation Program (DOD/DOE-ELAP).

2. The DOD/DOE ELAP will provide a means for laboratories to demonstrate conformance to the DOD/DOE Quality Systems Manual for Environmental Laboratories (DOD/DOE QSM) as authorized by DOD/DOE Instruction 4715.15, Environmental Quality Systems, December 2006 and as required by the DOD/DOE Policy and Guidelines for Acquisitions Involving Environmental Sampling or Testing, December, 2007. The DOD/DOE QSM is based on the National Environmental Laboratory Accreditation Conference (NELAC) Quality Systems standard (Chapter 5), which provides guidelines for implementing the international standard, ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories.

3. The DOD/DOE ELAP will apply to environmental programs / projects at DOD/DOE operations, activities, and installations, including Government-owned, contractor-operated facilities and formerly used defense sites, where testing is being performed in support of environmental restoration programs. The program will apply to all laboratories, including permanent, temporary, or mobile facilities, that generate definitive data, regardless of their size, volume of business, or field of accreditation; the collection of screening data will be governed by project specific requirements.

4. The current DOD/DOE Quality Systems Manual for Environmental Laboratories is Version 5.0, dated June 2013

5. Implementation of the DOD/DOE Quality Systems Manual for Environmental Laboratories Version 5.0, dated July 2013, will be phased in over the 2014-2015 time period.

6. The ECI Management will provide sufficient training, resources and other measures to ensure compliance with the DOD/DOE QSM as appropriate. (including but not limited to):

    a. Specific Standard Operating Procedures (SOPs) and / or Appendicles
    b. DOD/DOE compliant Laboratory Information Management System (LIMS) analytical test codes
    c. Specialized technician and chemist training
    d. Enhanced Quality Assurance (QA) oversight
    e. Project specific instruments
    f. Assigned Project Management personnel
    g. Quality Assurance Project Plans (QAPP)
    h. DOD/DOE analytical data reporting qualifiers
    i. Calibration and reference materials that meet DOD/DOE requirements.

APPENDIX H – LISTING OF MAJOR ANALYTICAL INSTRUMENTATION

GC/MS SYSTEMS

Designation	Manufacturer/Model	Serial Number	Acquired	Department	OS
GC/MS-K	HP 6890	US00024158	1998	Air	XP
	HP5973	US82311263	1998		
	Entech 7100A	0063	1998		
	Entech 7016CA	00142	1998		
GC/MS-L	HP 6890	US00023714	1998	Volatiles	XP
	Agilent 5973	US82311287	1998		
	Tekmar Atomx	US09163001	2009		
GC/MS-M	HP 6890	US00028876	1999	Volatiles	XP
	HP 5973	US9192601	1999		
	Tekmar Stratum	US08283015	2010		
	Varian Archon	MS0903W013	2010		
GC/MS-O	Agilent 6890N	US00034260	2000	LUFT-TPPH	XP
	Agilent 5973	US94240048	2000		
	Tekmar 3100	US02261003			
	Varian Archon	13863	2002		
GC/MS-P	Agilent 6890	US00034661	2000	Semivolatiles	XP
	Agilent 5973N	US94240038	2000		
	Agilent G2613A (Injector)	CN35234549	2000		
	Agilent G2614A (Tray)	US04109505	2000		
GC/MS-Q	Agilent 6890	US00037519	2000	Volatiles	XP
	Agilent 5973	US03340458	2000		
	Tekmar Stratum	US13099007	2013		
	Varian Archon	13386	2000		
GC/MS-R	Agilent 6890	US00037782	2000	Volatiles	XP
	Agilent 5973	US03340489	2000		
	Tekmar Stratum	US12111001	2012		
	Varian Archon	14040	2003		
GC/MS-S	Agilent 6890	US00030897	2000	Summa QC	XP
	Agilent 5973	US03340414	2000		
	Tekmar Autocan	US06047025	2006		
GC/MS-T	Agilent 6890	US00039185	2000	Volatiles	XP
	Agilent 5973	US03940628	2000		
	Tekmar Atomx	US11048001	2011		
GC/MS-U	Agilent 6890	US00036171	2001	Summa QC	XP
	Agilent 5973	US02450134	2001		
	Tekmar Autocan	US08169005	2002		
GC/MS-V	Agilent 6890	US00036172	2001	Air	XP

	Agilent 5973	US02450131	2001		
	Entech 7100A	1092	2005		
	Entech 7016CA	1041	2005		
GC/MS-W	Agilent 6890	US00036170	2001	Volatiles	XP
	Agilent 5973	US02450128	2001		
	Tekmar Stratum	US09154005	2010		
	Varian Archon	13573	2001		
GC/MS-X	Agilent 6890N	US10203064	2002	Air	XP
	Agilent 5973	US10462129	2002		
GC/MS-Y	Agilent 6890	US10203153	2002	Semivolatiles	XP
	Agilent 5973	US10442209	2002		
	Agilent G2613A (Injector)	US00211064	2002		
	Agilent G2614A (Tray)	CN64942239	2002		
GC/MS-Z	Agilent 6890N	US10225110	2002	Volatiles	XP
	Agilent 5973	US21842958	2002		
	Tekmar Stratum	US12115008	2012		
	Varian Archon	15278	2008		
GC/MS-AA	Agilent 6890N	US10225149	2002	Air	XP
	Agilent 5973N	US21843250	2002		
	Entech 7100A	1045	2003		
	Entech 7016CA	1183	2004		
	Entech 7016CA	1212	2004		
GC/MS-BB	Agilent 6890N	US1023004	2002	Volatiles	XP
	Agilent 5973N	US21843288	2002		
	Tekmar Stratum	US08283014	2012		
	Varian Archon	15208	2007		
GC/MS-CC	Agilent 6890N	US10233039	2002	Volatiles	XP
	Agilent 5973N	US21843272	2002		
	Tekmar Stratum	US10272001	2011		
	Varian Archon	13431	2002		
GC/MS-DD	Agilent 6890N	US10239018	2002	Air	XP
	Agilent 5973N	US21843913	2002		
	Entech 7100A	1432			
	Entech 7016CA	1018	2002		
	Entech 7016CA	1187			
GC/MS-EE	Agilent 6890N	US10248096	2003	Summa QC	XP
	Agilent 5973N	US21844395	2003		
	Tekmar Autocan	US99362027	1999		
GC/MS-GG	Agilent 6890N	CN10337014	2003	Marine Lab	XP
	Agilent 5973N	US33246020	2003		

	Agilent GC 80 SPME	CH00213565	2011		
GC/MS-HH	Agilent 6890N	CN10337015	2003	Air	XP
	Agilent 5973	US30945837	2003		
	Entech 7100A	1081	2003		
	Entech 7016CA	1012	2003		
	Entech 7016CA	1038	2003		
GC/MS-II	Agilent 6890	CN10517039	2005	Air	XP
	Agilent 5973	US44647341	2005		
	Entech 7100A	1458	2008		
	Entech 7016CA	1098	2005		
	Entech 7016CA	1225	2008		
GC/MS-JJ	Agilent 6890N	CN10547073	2005	Volatiles	XP
	Agilent 5973	US53941344	2005		
	Tekmar Stratum	US10230002	2010		
	Varian Archon	14529	2005		
GC/MS-KK	Agilent 6890	CN10545117	2005	Air	XP
	Agilent 5973	US53941343	2005		
	Entech 7100A	1221	2005		
	Entech 7016CA	1207			
	Entech 7016CA	1210			
GC/MS-LL	Agilent 6890N	CN10651084	2007	Volatiles	XP
	Agilent 5975B	US63214670	2007		
	Tekmar 3100	US01317008	2002		
	Varian Archon	MS0902W026	2006		
GC/MS-MM	Agilent 6890N	CN10651076	2007	Semivolatiles	XP
	Agilent 5975B	US62715103	2007		
	Agilent G2913A (Injector)	CN51825044	2007		
	Agilent G2614A (Tray)	CN51833057	2007		
GC/MS-NN	Agilent 7890A	CN10717056	2007	Air	XP
	Agilent 5975C	US71215995	2007		
	Entech 7100A	1291	2012		
	Entech 7016CA	1211			
	Entech 7150	45	2010		
	Entech 7410	138	2010		
GC/MS-OO	Agilent 7890A	CN10745139	2007	Volatiles	XP
	Agilent 5975C	US73317841	2007		
	Tekmar Stratum	US07277008	2009		
	Varian Archon	14697	2008		
GC/MS-PP	Agilent 7890A	CN10744086	2007	Volatiles	XP
	Agilent 5975C	US73317584	2007		

	Tekmar Stratum	US07277012	2009		
	Tekmar SOLATek	US09051008	2009		
GC/MS-QQ	Agilent 7890A	CN10742034	2007	Volatiles	XP
	Agilent 5975C	US71216778	2007		
	Tekmar Stratum	US07277018	2008		
	Tekmar SOLATek	US08032004	2008		
GC/MS-RR	Agilent 7890A	CN10730015	2007	Volatiles	XP
	Agilent 5975C	US73317844	2007		
	Tekmar Stratum	US08032004	2008		
	Tekmar SOLATek	US08032006	2008		
GC/MS-SS	Agilent 7890A	CN10803049	2007	Semivolatiles	XP
	Agilent 5975C	US80618497	2007		
	Agilent G2613A (Injector)	US81801206	2007		
	Agilent G2614A (Tray)	CN80246945	2007		
GC/MS-TT	Agilent 7890A	CN10806032	2007	Semivolatiles	XP
	Agilent 5975C	US80618456	2007		
	Agilent G2613A (Injector)	CN80246390	2007		
	Agilent G2614A (Tray)	CN80246936	2007		
GC/MS-UU	Agilent 7890A	CN10805004	2007	Volatiles	XP
	Agilent 5975C	US71215984	2007		
	Tekmar Stratum	US08087006	2008		
	Varian Archon	15287	2008		
GC/MS-VV	Agilent 7890A	CN10805094	2007	Volatiles	XP
	Agilent C5975	US80118376	2007		
	Tekmar 3100	US02203002	2001		
	Tekmar SOLATek	US09050003	2008		
GC/MS-WW	Agilent 7890A	CN10803015	2007	Volatiles	XP
	Agilent 5975C	US80118375	2007		
	Tekmar Atomx	US11034002	2011		
GC/MS-XX	Agilent 7890A	CN10815050	2008	Volatiles	XP
	Agilent 5975C	US80828968	2008		
	Tekmar Stratum	US14097001	2014		
	Varian Archon	15273	2008		
GC/MS-YY	Agilent 7890A	CN10814115	2008	Air	XP
	Agilent C5975	US80828967	2008		
	Entech 7100A	1431	2008		
	Entech 7016CA	1208	2008		
	Entech 7016CA	1214	2008		
GC/MS-ZZ	Agilent 7890A	CN10814050	2008	Air	XP
	Agilent 5975C	US80828953	2008		

	Markes TD-100	GB00K10173	2011		
GC/MS-AAA	Agilent 7890A	CN10812068	2008	Semivolatiles	XP
	Agilent 5975C	US80828988	2008		
	Agilent G2613A (Injector)	CN70438717	2008		
	Agilent G2614A (Tray)	CN64942222	2008		
GC/MS-BBB	Agilent 7890A	CN10947130	2009	Semivolatiles	XP
	Agilent 5975C	US93414124	2009		
	Agilent 7693 (Tray)	CN94701470	2009		
	Agilent 7693 (Injector)	CN11200098	2009		
GC/MS-CCC	Agilent 7890A	CN10947129	2009	Semivolatiles	XP
	Agilent 5975C	US93414097	2009		
	Agilent 7693 (Tray)	CN94901515	2009		
	Agilent 7693 (Injector)	CN95002678	2009		
GC/MS-DDD	Agilent 7890A	CN10031142	2009	Semivolatiles	XP
	Agilent 5975C	US10197302	2009		
	Agilent 7693 (Tray)	CN10210002	2009		
	Agilent 7693 (Injector)	CN10140077	2009		
GC/MS-EEE	Agilent 7890A	CN10241112	2009	Semivolatiles	XP
	Agilent 5975C	US10257401	2009		
	Agilent 7693 (Tray)	CN10210100	2009		
	Agilent 7693 (Injector)	CN10230009	2009		
GC/MS-FFF	Agilent 7890A	CN10391179	2010	Volatiles	XP
	Agilent 5975C	US10407502	2010		
	Tekmar Atomx	US10200002	2010		
GC/MS-GGG	Agilent 7890A	CN10401096	2010	Volatiles	XP
	Agilent 5975C	US10287508	2010		
	Tekmar Atomx	US10246002	2010		
GC/MS-HHH	Agilent 7890A	CN10521074	2010	Semivolatiles	Win 7
	Agilent 5975C	CN11030007	2010		
	Agilent 7693 (Tray)	US11077507	2010		
	Agilent 7693 (Injector)	CN11050288	2010		
GC/MS-III	Agilent 7890A	CN10521075	2010	Semivolatiles	Win 7
	Agilent 5975C	US11077506	2010		
	Agilent 7693 (Tray)	CN11030009	2010		
	Agilent 7693 (Injector)	CN11050291	2010		
GC/MS-JJJ	Agilent 7890A	CN11441070	2011	Semivolatiles	Win 7
	Agilent 5975C	US11447702	2011		
	Agilent 7693 (Tray)	CN11440045	2011		
	Agilent 7693 (Injector)	CN11390136	2011		
GC/MS-KKK	Agilent 7890A	CN11441059	2011	Air	Win 7
	Agilent 5975C	US11447704	2011		

	Entech 7100A	1384	2008		
	Entech 7016CA	1212	2008		
	Entech 7016CA	1183	2007		
GC/MS-LLL	Agilent 7890A	CN12031151	2012	Air	Win 7
	Agilent 5975C	US12097802	2012		
	Entech 7100A	1290	2012		
	Entech 7016CA	1041	2005		
GC/MS-MMM	Agilent 7890A	CN12261027	2012	Air	Win 7
	Agilent 5975C	US12262A09	2012		
	Markes TD-100	GB00k10257	2012		
GC/MS-NNN	Agilent 7890A	CN14073088	2014	Semivolatiles	Win 7
	Agilent 5975C	US14052222	2014		
	Agilent 7693 (Tray)	CN13500019	2014		
	Agilent 7693 (Injector)	CN14020017	2014		
GC/MS-OOO	Agilent 7890B	CN14103035	2014	Air	Win 7
	Agilent 5977A	US1410J201	2014		
	Entech 7200	1161	2014		
	Entech 7016D	1421	2014		

GC TRIPLEQUAD SYSTEMS

Designation	Manufacturer/Model	Serial Number	Acquired	Department	OS
GC/TQ-1	Agilent 7890A	US11041024	2011	Marine Lab	Win 7
	Agilent 7000 TQ/MS	US11046401	2011		
	Agilent 7693 (Tray)	CN11030015	2011		
	Agilent 7693 (Injector)	CN11050297	2011		
GC/TQ-2	Agilent 7890A	US11291011	2011	Marine Lab	Win 7
	Agilent 7000 TQ/MS	US11196604	2011		
	Agilent 7693 (Tray)	CN11180027	2011		
	Agilent 7693 (Injector)	CN95002669	2011		

GC SYSTEMS

Designation	Manufacturer/Model	Serial Number	Acquired	Department	OS
GC-1	HP 5890 Series II Detector(s): PID/FID	3310A48771	1987	LUFT-GRO	2000
	Tekmar 3100	US01362002	2004		
	Varian Archon	15301	2008		
GC-4	HP 5890 Detector(s): PID/FID	2750A17251	1989	LUFT-GRO	XP
	OI 4560	B239040			
	Varian Archon	13142	1999		

GC-8	HP 5890 Series II PID/FID	3033A31219	1990	LUFT-GRO	XP
	Tekmar 3100	US02249008	2002		
	Varian Archon	MS1010W015	2008		
GC-9	HP 5890 Series II Detector(s): FID/FID	3033A32951	1991	Semivolatiles	NT
GC-12	HP 5890 Series II Detector(s): FID/TCD	3118A35448	1991	Semivolatiles	NT
GC-13	HP 5890 Series II FID/TCD	3033A32929	1990	Air	XP
GC-14	HP 5890 Series II Detector(s): FPD	3126A36770	1991	Air	XP
GC-18	HP 5890 Series II Detector(s): PID/FID	3235A44156	1992	LUFT-GRO	2000
	EST Encon	512080906			
	Varian Archon	15307	2008		
GC-21	HP 5890 Series II Detector(s): PID/FID	3336A51475	1994	LUFT-GRO	XP
	Tekmar 3100	US02331005	2007		
	Varian Archon	MS0902W025	2008		
GC-22	HP 5890 Series II+ Detector(s): PID/FID	3336A61360	1994	LUFT-GRO	XP
	Tekmar 3100	US02233006	2008		
	Varian Archon	14699	2006		
GC-24	HP 5890 Series II+ Detector(s): PID/FID	3336A53949	1994	LUFT-GRO	2000
	Tekmar 3000	98194007	1998		
	Varian Archon	13864	2004		
GC-25	HP 5890 Series II+ Detector(s): PID/FID	2921A23805	1994	LUFT-GRO	XP
	Tekmar 3100	314009			
	Varian Archon	13470	2001		
GC-26	HP 6890 Detector(s): NPD/NPD	US00001017	1995	Semivolatiles	XP
	G1513A (Injector)	CN12620285	1995		
	G1514A (Tray)	US83304659	1995		
GC-29	HP 5890 Series II Detector(s): PID/FID	3310A47430	2000	LUFT-GRO	XP
	Tekmar 3100	US02249004	2002		
	Varian Archon	13874	2002		
GC-31	HP 6890 Detector(s): ECD/ECD	US00037979	2000	Semivolatiles	XP
	G2613A (Injector)	CN43138313	2000		
	G2614A (Tray)	CN71543642	2000		

GC-34	HP 5890 Series II Detector(s): FID	3033A32699	2000	Air	XP
GC-35	Agilent 6890N Detector(s): NPD/NPD	US10206061	2002	Semivolatiles	XP
	G2613A (Injector)	US81501043	2002		
	G2614A (Tray)	US83501663	2002		
GC-36	Agilent 6890N Detector(s): FID/TCD	US10346058	2004	Air	XP
GC-37	Agilent 6890N Detector(s): ECD/ECD	CN10350094	2004	Marine Lab	XP
GC-38	HP 5890 Series II Detector(s): FID	3029A30188	1995	Air	XP
GC-40	Agilent 7890N Detector(s): ECD/ECD	CN10647089	2007	Semivolatiles	XP
	G2913A (Injector)	CN715400009	2007		
	G2614A (Tray)	CN64842106	2007		
GC-41	Agilent 7890N Detector(s): ECD/ECD	CN10650013	2007	Semivolatiles	XP
	G2913A (Injector)	CN70538721	2007		
	G2614A (Tray)	CN43130148	2007		
GC-42	Agilent 6890N Detector(s): PID/FID	CN10647056	2007	LUFT-GRO	XP
	Tekmar 3100	US01274007			
	Varian Archon	14370	2004		
GC-43	Agilent 6890N Detector(s): FID	CN10720004	2007	Air	XP
GC-44	Agilent 6890N Detector(s): FID/FID	CN10721103	2007	Semivolatiles	XP
	G2913A (Injector)	CN71840418	2007		
	G2614A (Tray)	CN71843829	2007		
GC-45	Agilent 7890A Detector(s): FID/FID	CN10808107	2007	LUFT-DRO	XP
	G2913A (Injector)	CN81949025	2007		
	G2614A (Tray)	CN80747427	2007		
GC-46	Agilent 7890A Detector(s): FID/FID	CN1080815	2007	LUFT-DRO	XP
	G2913A (Injector)	CN81949036			
	G2614A (Tray)	US83201509			
GC-47	Agilent 7890A Detector(s): FID/FID	CN10819056	2008	LUFT-DRO	XP
	G2913A (Injector)	CN81748778	2008		
	G2614A (Tray)	CN81748307	2008		
GC-48	Agilent 7890A Detector(s): FID/FID	CN10819057	2008	LUFT-DRO	XP

	G2913A (Injector)	CN64837502	2008		
	G2614A (Tray)	CN64541796	2008		
GC-49	Agilent 7890A Detector(s): FID/FID	CN10820151	2008	LUFT-DRO	XP
	G2913A (Injector)	CN71549035	2008		
	G2614A (Tray)	CN82048589	2008		
GC-50	Agilent 7890A Detector(s): FID/FID	CN10820150	2008	LUFT-DRO	XP
	G2913A (Injector)	CN80546905	2008		
	G2614A (Tray)	CN82048581	2008		
GC-51	Agilent 7890A Detector(s): ECD/ECD	CN10822026	2008	Semivolatiles	XP
	G2913A (Injector)	CN82049336	2008		
	G2614A (Tray)	CN82148694	2008		
GC-52	Agilent 7890N Detector(s): FID	CN10824005	2008	Air	XP
GC-53	Agilent 6890N Detector(s): FID	US00002691	2000	Air	XP
GC-54	Agilent 7890A Detector(s): FPD	US10840051	2008	Air	XP
GC-55	Agilent 7890N Detector(s): TCD	CN10844112	2008	Air	XP
GC-56	Agilent 7890N Detector(s): FID	CN10847124	2009	LUFT-GRO	XP
	OI Eclipse	D647466449P			
	Varian Archon	15139	2007		
GC-57	Agilent 7890N Detector(s): ECD/ECD	CN10847113	2009	LUFT-GRO	XP
	OI Eclipse	D81466987P			
	Varian Archon	15140	2007		
GC-58	Agilent 7890N	CN10942196	2009	Semivolatiles	XP
	Agilent 7693 (Tray)	CN64937563	2009		
	Agilent 7693 (Injector)	CN81748311	2009		
GC-59	Agilent 7890N Detector(s): FID	CN10041127	2009	Air	XP
GC-60	Agilent 6890N Detector(s): FID	US10247091	2003	Air	XP
GC-61	Agilent 6890N Detector(s): FID	US00007963	1998	Air	XP
GC-62	Agilent 6890N Detector(s): FID	US00036172	2001	Air	XP
GC-63	Agilent 7890A Detector(s): ECD/ECD	CN12151152	2012	Marine	XP

GC-64	Agilent 6890A Detector(s): FID	US00030941	1999	Air	XP
GC-65	Agilent 7890A Detector(s): TCD	CN12111151	2012	Air	XP
GC-66	Agilent 7890A Detector(s): FID Agilent 7693 (Tray) Agilent 7693 (Injector)	CN12421146 CN12320016 CN12300140	2012	Semivolatiles	XP

Inductively Coupled Plasma Spectrophotometers (ICP)

Designation	Manufacturer/Model	Serial Number	Acquired	Department	OS
ICP-7	PE Optima 7300 DV	077C8120401	2008	Metals	XP
	ESI SC FAST	4DX-F1-TSP	2013		
ICP-8	PE Optima 8300		2014	Metals	Win 7
	ESI SC4 optiFAST Dxi		2014		

Inductively Coupled Plasma/Mass Spectrometers (ICP/MS)

Designation	Manufacturer/Model	Serial Number	Acquired	Department	OS
ICP/MS-3	PE ELAN DRC-e	AH 14610812	2009	Metals	XP
	ESI SC4 DX	X4DX5HSTSP16110413			
ICP/MS-4	PE ELAN DRC-e	AH 13440801	2009	Metals	XP
	ESI SC4 DX	X4DX5HSTSP16110603			
ICP/MS-5	PE NexION 300D	81DN1120502	2011	Metals	XP
	ESI SC4 DX	FST04-TSP-091203	2001		

Flame Atomic Absorption Spectrometers (FAA)

Designation	Manufacturer/Model	Serial Number	Acquired	Department	OS
FAA-3	PE PinAAcle 900F	PFAS11090701	2011	Metals	Win 7

Mercury Analyzers

Designation	Manufacturer/Model	Serial Number	Acquired	Department	OS
HG-4	PE FIMS-400	401S2030103	2005	Metals	XP
HG-5	PE FIMS-400	401S5070901	2005	Metals	XP
HG/AF-1	Teledyne Hydra II	1095	2011	Metals	Win 7

High Performance Liquid Chromatographs (HPLC)

Designation	Manufacturer/Model	Serial Number	Acquired	Department	OS
HPLC-5	Variable Wave. Det.	JP116144U1	2001	Semivolatiles	XP

Agilent 1100 HPLC	Column Compartment	DE11120911	2001		
	Quat. Pump	DE11114727	2001		
	Degasser	JP05029389	2001		
	Autosampler	DE11115637	2001		
HPLC-6	Variable Wave. Det.	JP11414177	2001	Semivolatiles	XP
Agilent 1100 HPLC	Quat. Pump	DE11114712	2001		
	Degasser	JP05029404	2001		
	Autosampler	DE11115492	2001		
HPLC-7	Variable Wave. Det.	DE43602867	2004	Semivolatiles	XP
Agilent 1100 HPLC	Iso Pump	DE409006799	2004		
	Column Compartment	DE111210117	2004		
	Autosampler	DE33225927	2004		
Pickering	Pinnacle PCX	513305	2013		
HPLC-8	Multi. Wave. Det.	DE60555324		Semivolatiles	XP
Agilent 1200 HPLC	Iso Pump	DE62956826			
	Fraction Collector	DE60555134			
	Autosampler	DE63055195			

Liquid Chromatography/Mass Spectrometry (LC/MS/MS)

Designation	Manufacturer/Model	Serial Number	Acquired	Department	OS
LC/TQ-1	Varian 1200L Triple Quad	3060	2005	Inorganics	XP
	Varian Prostar 210	4151	2005		
	Varian Prostar 210	4152	2005		
	Varian 410 Autosampler	50062	2005		
LC/TQ-2	Agilent 6430 LC/MS Triple Quad	SG11077104	2013	Inorganics	7
	Agilent 1260 Quat Pump	DEAB707001	2013		
	Agilent 1260 ALS	DEAAC17936	2013		
TOC-4	OI Soil Module Detector(s): IR	C339776273	2003	Inorganics	XP
TOC-5	OI Soil Module Detector(s): IR	C726776952	2007	Inorganics	XP
TOC-6	OI Aurora 1030	J025730749P	2011	Inorganics	XP
	OI 1088 A/S	J025730749P	2011		
TOC-8	OI Aurora 1030	N248731638P	2012	Inorganics	XP
	OI 1088 A/S	E248788640	2012		
IC-7	Dionex ICS-1000 Detector(s): Conductivity	3100486	2003	Inorganics (Anions)	XP
IC-8	Dionex ICS-2000 Detector(s): Conductivity	4100279	2004	Inorganics (Perchlorate)	XP

IC-9	Dionex ICS-1000 Detector(s): Conductivity	8120823	2008	Inorganics (Anions)	XP
IC-10	Dionex ICS-1000 Detector(s): Conductivity	8120822	2008	Inorganics (Anions)	XP
IC-11 Dionex ICS-3000	Variable Wave. Detector	8120958	2009	Inorganics (Cr(VI))	XP
	Single Pump	9010071	2009		
	Column Comp.	8120362	2009		
	AS-DV Autosampler	10100586	2009		
IC-12 Dionex ICS-3000	Variable Wave. Detector	9060673	2009	Inorganics (Cr(VI))	XP
	Single Pump	9060616	2009		
	Column Comp.	9010928	2009		
IC-13	Dionex ICS-1100 Detector(s): Conductivity	9120764	2009	Inorganics	XP
IC-14 Dionex ICS-5000	Variable Wave. Detector	9100584		Inorganics	XP
	Single Pump	10100152			
	Column Comp.	10100022			
	AS-DV Autosampler	10100586			
IC-15	Dionex ICS-1100 Detector(s): Conductivity	14038039	2014	Inorganics	XP
	AS-DV Autosampler	14037446	2014		
ACA1	OI 3360 Flow Analyzer Detector(s): UV	751893730	2007	Inorganics	XP
UV-4	Thermo Detector(s): UV	3DUK232006	2007	Inorganics	XP
UV-5	Thermo Detector(s): UV	3DUK228001	2007	Inorganics	XP
UV-7	Agilent 8453 Detector(s): Diode Array	CN22807187	2008	Inorganics	XP
UV-8	Agilent 8453 Detector(s): Diode Array	CN22808466	2010	Inorganics	XP
UV-9	Agilent 8453 Detector(s): Diode Array	CN22809400	2013	Inorganics	XP

FT-IR Spectrometer

Designation	Manufacturer/Model	Serial Number	Acquired	Department	OS
IR-2	P.E. Spectrum Two	89327	2011	LUFT-DRO	Win 7

Automated Extractors

Designation	Manufacturer/Model	Serial Number	Acquired	Department
ASE-1	Dionex ASE-200	98120515	1999	Marine Lab
ASE-2	Dionex ASE-200	99090112	1999	Extractions

ASE-3	Dionex ASE-300	1100597	2002	Extractions
ASE-4	Dionex ASE-300	1100598	2002	Extractions
ASE-5	Dionex ASE-200	07040191	2007	Marine Lab
ASE-6	Dionex ASE-200	07010483	2007	Extractions
ASE-7	Dionex ASE-350	08080167	2010	Extractions
ASE-8	Dionex ASE-350	09020620	2010	Extractions
ASE-9	Dionex ASE-350	10090204	2012	Extractions
ASE-10	Dionex ASE-350	10090546	2012	Extractions

Solid Phase Extraction Unit

Designation	Manufacturer/Model	Serial Number	Acquired	Department
SPE-1	Horizon Tech/ 4790	11-1576	2010	Extractions
SPE-2	Horizon Tech/ 4790	11-1577	2010	Extractions
SPE-3	Horizon Tech/ 4790	11-1578	2010	Extractions
SPE-4	Horizon Tech/ 4790	11-1579	2010	Extractions
SPE-5	Horizon Tech/ 4790	11-1580	2010	Extractions
SPE-6	Horizon Tech/ 4790	11-1581	2010	Extractions
SPE-7	Horizon Tech/ 4790	11-1582	2010	Extractions
SPE-8	Horizon Tech/ 4790	11-1583	2010	Extractions

Misc. Shaker/Rotators

Designation	Manufacturer/Model	Serial Number	Acquired	Department
Rotator 7	Associated Design	3740-12BRE-11	?	Extractions
Rotator 9	Heidolf/REAX 20	120702298	?	Extractions
Rotator 3	Associated Design	1897	?	Extractions
Rotator 2	Associated Design	1282	?	Extractions
Rotator 8	Associated Design	2171	?	Extractions
Rotator 1	Associated Design	1697	?	Extractions
	Thermo MAXQ 2508	105253-3	?	Extractions
	Thermo MAXQ 3000	185905-68	?	Extractions
	Thermo MAXQ 3000	1411080905883	?	Extractions
	Southwest Sci. IncuShaker	1411080905883	?	Extractions
	Thermo MAXQ 3000	1411080398252	?	Extractions
	Thermo MAXQ 3000	141071288276	?	Extractions

Extraction Equip.

Designation	Manufacturer/Model	Serial Number	Acquired	Department
DVP001	Horizon DryVap Conc.	1131	?	Extractions
DVP001	Horizon DryVap Conc.	1377	?	Extractions

	Gerhardt SoxTherm	1803	2014	Extractions
	Gerhardt SoxTherm	1849	2014	Extractions
	Gerhardt SoxTherm	1555	2014	Extractions
	Gerhardt SoxTherm	2032	2014	Extractions
	FMS PowerVap Conc.	E-0235	2014	Extractions
	FMS PowerVap Conc.	E-0236	2014	Extractions

Particle Size Analyzer

Designation	Manufacturer/Model	Serial Number	Acquired	Department	OS
PSA-1	B.C. LS13320	AT39390	2011	Marine Lab	XP

Gas Mixer

Designation	Manufacturer/Model	Serial Number	Acquired	Department
Mixer 1	Environics Series 2000	1490	1995	Air
Mixer 2	Environics Series 2000	4618	2009	Air

Wet Chemistry

Designation	Manufacturer/Model	Serial Number	Acquired	Department
PH 1	Fisher Accumet Basic	176	1997	IO
PH 4	Fisher Accumet Basic	AB81210901	2004	IO
ISE1	Thermo Sci. Orion Star	E03578	2011	IO
SC 2	Amber Science 3082	108039	2001	IO
SC 5	Amber Science 2052	1106043	2011	IO
TUR 3	HF Scientific Micro 100	301269	2003	IO
IO 01	Fisher ISOTemp Oven	40300024	2005	IO
IO 07	Fisher ISOTemp 6509 Oven	1580080398315	2012	IO
IO 08	Fisher ISOTemp 6509 Oven	1580080398313	2012	IO
IO 10	Fisher ISOTemp 6509 Oven	613128-624	2013	IO
IO 13	Fisher ISOTemp 6509 Oven	612568-551	2013	IO
Thermo 01	Thermo Sci. FD1535M	152991101110630	2013	IO
BOD 1	Thermo Auto. 10060000	A0067	2003	IO
IC 04	Fisher 11-679-25C Incubator	2018080505659	2012	IO
Balance 13	Fisher A-250	25275	1997	IO
Balance 14	Ohaus E02140	11120030978	1998	IO
Balance 13	Sartorious ME 235P	16503597	2004	IO

	Fisher low temp incubator	2018080505659		IO

Referigerators/Incubators

Designation	Manufacturer/Model	Serial Number	Acquired	Department
	Fisher low temp incubator	2018080505659	?	IO
FG-23	True Manufacturing T-23	7251068	?	Extractions
FG-24	True Manufacturing T-23	1-3453096	?	Extractions
FG-25	True Manufacturing T-23	1-3496118	?	Extractions

Lab Water Systems

Designation	Manufacturer/Model	Serial Number	Acquired	Department
	Barnstead EasyPure RoDi	1332060134165		LUFT
	Barnstead Diamond RO	1266071286485		VOA
	Barnstead NANOpure 7143	491510-421		VOA
	Barnstead E-Pure D4641	1090090114250		IO
	Barnstead E-Pure D4641	229758-32		LUFT D

Glassware Drying Kilns

Designation	Manufacturer/Model	Serial Number	Acquired	Department
Kiln-1	LL Kilns DaVinci	T3427-D-480-3P	2013	
Kiln-2	LL Kilns DaVinci	090111-F-CKG	2012	

Misc. Ovens

Designation	Manufacturer/Model	Serial Number	Acquired	Department
VOA-1	VWR 1325F	4094404		VOA
VOA-2	VWR 1350FM	400503		VOA
VOA-3	VWR 1325F	6109006		VOA
IO-06	VWR 1350FM	1101302		VOA

IT Equip.

Designation	Manufacturer/Model	Serial Number	Acquired	Department
NAS-1	EMC CLARiiON Array	AMP00103500986	2010	Lincoln
NAS-2	EMC CLARiiON Array	AMP00103500987	2010	Lampson
	HP ProCurve switch 5406zl	SG04SU23M		Lampson
	HP ProCurve switch 5406zl	1NO30TI1YZ		Lincoln
	Cisco 3800 router	FTX1143A4GP		Lampson
	Cisco 3800 router	FTX1143A4GQ		Lincoln
Server	Dell PowerEdge R900	FQBFDF1		Lampson

Server	Dell PowerEdge R900	3T8TKH1		Lincoln
Server	Dell PowerEdge 2650	JZR6F61		Lincoln
Server	Dell PowerEdge 2950	8MJWKH1		Lincoln
Server	Dell PowerEdge R720	5JB2TW1		Lincoln
UPS Batt. B/U	APC Symetra LX	ZA0624031279		Lampson
UPS Batt. B/U	Powerware PW9170	660C120AAAAAAAP		Lincoln

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