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QUALITY ASSURANCE MANUAL FOR ENVIRONMENTAL ANALYTICAL SERVICES

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

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1. Introduction

1.1. This *Quality Assurance Manual* is based upon the overall business and management philosophies, mission, and goals of Eurofins Calscience, Inc. ("ECI", "the laboratory"). This manual is written to present the policies employed by the laboratory and the support departments that serve the environmental laboratory and to comply with the requirements of the National Environmental Laboratory Accreditation Program (NELAP), ISO/IEC 17025, and the Department of Defense Environmental Laboratory Accreditation Program (DoD ELAP). These policies define the "what" we do with emphasis on management's responsibilities and commitment to quality. Governing SOPs are in place within the organization, to ensure the proper execution of this policy document and are referenced throughout the document.

1.2. This manual is required reading for laboratory personnel. The appendices are available resources to all personnel but are not required reading for all employees. The most recent and up-to-date *Quality Assurance Manual* and all referenced documents are available to all laboratory personnel who work in or support the laboratory.

2. Normative References

2.1. *Environmental Laboratory Sector, Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis, Modules 1, 2 and 4,* The NELAC Institute, 2009 ("TNI 2009 V1")

2.2. *Department of Defense Quality Systems Manual for Environmental Laboratories,* Version 5.1 (2017). ("QSM")

2.3. *Department of Defense Quality Systems Manual for Environmental Laboratories,* Version 4.2 (2010).

2.4. *ISO/IEC 17025:2005.*

3. Definitions

3.1. Definitions generally applicable to the laboratory are contained in Appendix 1.

3.2. Some specific definitions may appear in SOPs where they are used.

4. Quality Management System

4.1. Organization

4.1.1. Eurofins Calscience, Inc. is a wholly-owned subsidiary of Eurofins Environment Testing US Holdings, Inc. It is a duly licensed business with its main office at 7440 Lincoln Way, Garden Grove, CA 92841-1427.

4.1.2. It is the intention of Eurofins Calscience, Inc. to conform to all requirements of its customers, the National Environmental Laboratory Accreditation Program (NELAP) and the current TNI Standard, the Department of Defense Environmental Laboratory Accreditation Program (DoD ELAP) and the current Quality Systems Manual, the State of California SWRQCB ELAP; and other State and Client Programs as

accredited, certified, licensed or requested.

4.1.3. The laboratory performs its analytical work at its facility on Lincoln Way and at two satellite laboratory spaces in Garden Grove, CA. In addition, the laboratory maintains a Service Center in Concord, CA as well as an internal courier service. All of these facilities and services operate under the management system described in this manual. Full contact information for each is included in Appendix 3.

4.1.4. Eurofins Calscience, Inc. is a stand-alone business entity that operates under the Eurofins organization. Eurofins is an organization of testing laboratories and does not engage in other types of environmental activities in the USA. There are no potential conflicts of interest due to this structure.

4.1.5. The organization, structure and work assignments ensure the following:

4.1.5.1. The laboratory's managerial and technical personnel have the authority and resources needed to carry out their duties.

4.1.5.2. Personnel will not be subjected to undue internal, external, commercial, financial or other pressure that could adversely affect the quality of their work. "Undue pressure" is addressed in the annual Ethics and Data Integrity Training given to all employees of the laboratory. Instructions for managing undue pressure are included in that training. See also the relevant SOP, T065 *Data Integrity*, current revision. Employees may report to the following, as they feel comfortable:

- Their Chain of Command
- Laboratory QA Staff
- The corporate Quality Director
- The corporate ethics hotline through Lighthouse Services (posters are placed throughout the lab)

4.1.5.3. The laboratory protects confidential information and proprietary rights of its customers at all times through rules on data distribution, management of confidentiality during site visits and data security.

4.1.5.4. Management and staff are expected to conduct themselves in an ethical manner at all times. Laboratory employees do not engage in activities that would compromise their ability to generate legally defensible, high quality data. This is also addressed in the Ethics and Data Integrity training given in the laboratory.

4.1.5.5. The laboratory is overseen by the Business Unit Manager (BUMa). Technical operations, Support services, Quality Assurance and Customer services report to the BUMa. Additionally, QA has a "dotted line" relationship with Quality Assurance Director of Eurofins Environment Testing US. Full organizational charts detailing the management structure of Eurofins Calscience, Inc. can be found in Appendix 4. The QA Department keeps the most up to date organizational

chart.

4.1.5.6. This organizational chart shows the responsibility, authority and interrelationships of all personnel who manage, perform, or verify work. Through this organization, management provides adequate supervision of all employees and provides technical management with overall responsibility for the data produced in the laboratory.

4.1.5.7. The laboratory has a designated Quality Assurance (QA) Manager who, along with assigned staff, has responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times. The QA Manager has direct access to the highest level of management in the local company. In addition, the QA Manager has support from the Eurofins Environment Testing Corporate Quality Director.

4.1.5.8. The laboratory appoints deputies for key personnel. These are included in a memo detailing Key Personnel Alternates that is updated regularly by the Laboratory Director and posted, among other places, outside the quality offices. Deputies are assigned for the following:

- Business Unit Manager
- Laboratory Director
- Quality Assurance Manager and other quality personnel
- Operations Manager
- Health and Safety Manager
- IT Manager
- All Project Management Personnel
- All Technical Group Leaders

4.1.5.9. The laboratory ensures that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system. This is mostly accomplished through initial and ongoing training, though additional communications may be used from time to time.

4.1.6. Top management ensures that appropriate communication processes are established with the laboratory and communication takes place regarding the effectiveness of the management system.

4.1.6.1. The laboratory uses a number of formal and informal mechanisms to provide this type of communication.

4.1.6.2. Meetings are held on a daily basis with operations management, quality assurance and project management personnel. While the primary purpose of these meetings is status updates, the venue is used to provide updates on management system issues, projects, technical issues, as well as training on a wide range of topics, including the management system. Group leaders are charged to carry

information from these meetings to personnel in their groups.

4.1.6.3. Training sessions are held as necessary to meet requirements for annual ethics, data integrity and computer security awareness as well as other important topics.

4.1.6.4. Laboratory management holds quarterly meetings with all staff to provide updates on laboratory status, goals, and issues important to personnel, including the management system.

4.1.7. The Quality Assurance Manager and quality staff are empowered and responsible for the following:

4.1.7.1. Serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data;
4.1.7.2. Have functions independent from laboratory operations for which they have quality assurance oversight;
4.1.7.3. Be able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence;
4.1.7.4. Have documented training and/or experience in QA/QC procedures and the laboratory's quality system;
4.1.7.5. Have a general knowledge of the analytical methods for which data review is performed;
4.1.7.6. Maintain the currency of the quality assurance manual and review it at least annually
4.1.7.7. Arrange for or conduct internal audits as per Section 4.14 annually;
4.1.7.8. Notify laboratory management of deficiencies in the quality system;
4.1.7.9. Monitor corrective actions; and
4.1.7.10. Stop work if the system is deemed to be out of control.

4.1.8. The Laboratory Director, Operations Manager, technical Group Leaders and their designees:

4.1.8.1. Are members of the staff who exercise actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results;
4.1.8.2. Are experienced in the fields of accreditation for which the laboratory is accredited;
4.1.8.3. Have duties that include monitoring standards of performance in quality control and quality assurance, and monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data.
4.1.8.4. If absent for a period of time exceeding fifteen (15) consecutive calendar days, must designate another full-time staff member meeting the qualifications of the technical manager(s) to temporarily perform this function. If this absence exceeds thirty-five (35) consecutive calendar days, the primary accreditation body must be notified in writing;
4.1.8.5. Meet the qualification requirements of the standard.

4.1.8.5.1. Have a bachelor's degree in the chemical, environmental, biological sciences, physical

sciences, or engineering, with at least 24 college semester hours of chemistry.

4.1.8.5.2. Have at least two years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory is accredited.

4.1.8.5.3. Other options are available and are fully described in the standard (TNI 2009 V1M2, Section 5.2.6.1)

4.1.8.6. All personnel in these positions are full-time personnel who do not work in other accredited laboratories.

4.2. Management

4.2.1. Beginning with this quality assurance manual, the laboratory has established a management system appropriate to its activities. The system is described in this quality assurance manual, which includes the laboratory policies and includes or references descriptions of its systems and programs and its procedures and instructions.

4.2.1.1. The management system is designed to assure the quality of the laboratory's tests are known and documented. Further, the system describes how these documents are made available to laboratory personnel and requires that personnel understand and implement the requirements contained in them.

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4.2.1.2. The system is designed to support the ECI Mission Statement: **ECI strives to be the leading full-service environmental testing laboratory in the Western United States by having unsurpassed capacity, exceptional customer service, continual quality improvement and consistently superior TAT.**

4.2.2. Management's Quality Policy Statement

4.2.2.1. Eurofins Calscience, Inc. (ECI) is committed to providing its customers with environmental data that is reliable, defensible, and of known and documented quality. We continually strive to meet our customer's requirements and exceed their expectations.

4.2.2.2. This Quality Assurance Manual and related documentation describes the policies and procedures used to meet that commitment. The Manual is designed to meet the Standards used in the NELAP, the DoD ELAP, the State of California ELAP and other government and customer requirements. Laboratory management is committed to the quality improvement processes described in these standards and to providing the resources to ensure laboratory personnel can honor that commitment.

4.2.2.3. Laboratory personnel whose responsibilities include any aspect of testing activities are required to familiarize themselves with all of the quality documentation associated with their job function and to implement the policies and

procedures described in that documentation into all of their work in the laboratory. Laboratory personnel acknowledge this responsibility by signing the Quality Policy contained in the Employee Handbook.

4.2.2.4. Management reviews this Quality Policy and the objectives listed below during the annual Management Review. The signatures of management personnel on this Quality Assurance Manual indicate their concurrence and support of this Policy.

4.2.2.5. Quality Objectives

4.2.2.5.1. Laboratory Management Personnel

- Commit to a quality improvement approach to management that focuses on problem solving through system improvement.
- Provide the resources necessary to allow laboratory personnel to successfully meet customer requirements while maintaining all quality standards.
- Provide a work environment that ensures accessibility to all levels of management and encourages personnel to raise questions, voice concerns, and participate in system development.

4.2.2.5.2. Laboratory Analytical Personnel

- Perform all analyses and related tasks according to documented procedures.
- Record all required and relevant observations completely, accurately, honestly and in “real time”.
- Respond immediately to indications of questionable data, equipment malfunctions, and quality control failures by taking appropriate actions as governed by laboratory procedures and communicating the issues to supervisory personnel.
- Work diligently to meet client needs, including turn-around times, while always keeping quality requirements as the most important objective.

4.2.3. Top management is committed to development and implementation of the management system and to continually improving its effectiveness through consistent internal audits, management reviews, corrective and preventive action and on-going training of personnel. Records of these activities provide evidence of that commitment.

4.2.4. Top management communicates to the organization the importance of meeting customer as well as statutory and regulatory requirements through the quality system as well as on-going meetings and other communications. See 4.1.6 above.

4.2.5. This quality assurance manual includes or references all procedures and outlines the documentation structure of the management system. The Standards under which the laboratory operates include specific

requirements for the quality assurance manual and for technical SOPs, as well as for laboratory operations. The documentation system of the laboratory is designed to capture the requirements contained in these normative documents and provide them to laboratory personnel as applicable.

4.2.5.1. The quality assurance manual is the over-arching, primary document in the system.

4.2.5.2. Standard Operating Procedures are referenced by the quality assurance manual and describe how to perform required procedures.

4.2.5.3. Data is captured using forms that are referenced by the SOPs. Quality Assurance Manager, including compliance with the Standard, are defined in this manual (See Section 4.1), in job descriptions, and where specific responsibilities are required for particular processes, in the SOPs governing those processes.

4.2.6. Top management ensures the integrity when changes are planned and implemented.

4.2.6.1. A “Management of Change” process is used to monitor changes made to computer systems.

4.2.6.2. Method changes require demonstration and governing document updates prior to implementation.

4.2.6.3. Preventive action processes are used to develop and implement changes to the management system.

4.2.7. Additional Requirements

4.2.7.1. Data Integrity-The laboratory maintains a Data Integrity Program as a part of its Ethics requirements. The program is described in Section 4.16 of this quality assurance manual and in the SOP referenced in that section.

4.2.7.2. Approved Signatories-The Business Unit Manager, Laboratory Director and all project managers are authorized to sign reports. Certain Quality Assurance personnel are authorized to sign reports that are for internal use. Additionally, some project manager assistants are authorized to sign preliminary reports and final reports under certain conditions. The Quality Assurance group keeps a current list of approved signatories.

4.2.7.3. The laboratory uses electronic signatures on reports for customers. The IT group collects electronic facsimiles of the authorized user’s actual signature. They are stored securely and attached to the authorized user’s login, where they are made available for use on reports.

4.2.7.4. The laboratory’s lists of approved methods are included on the applicable scopes of accreditation. These are available electronically in the quality department files.

4.3. Document Control

4.3.1. General

The laboratory has established and maintains procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals. The procedures are detailed in Calscience SOPs T002 *Document Control* and T001 *SOP Preparation.* The former document details the overall document control program while the latter provides specific instructions and templates for writing Standard Operating Procedures and related documents.

4.3.2. Document Approval and Issue

4.3.2.1. All documents issued to personnel in the laboratory as part of the management system are reviewed and approved for use by appropriate management and QA personnel prior to issue.

4.3.2.1.1. In general, approval by the group leader and a QA representative is required. Some variations may occur for analyst aids and for higher-level documents such as this Quality Assurance Manual, which must be approved by top management and the QA Manager. The requirements and specifics, including specific responsibilities, are included in T002 *Document Control.*

4.3.2.1.2. Instrument manuals are tacitly approved for use through the purchase of the instrument and are kept in the laboratory near the instrument or in a designated area in the East QA Office.

4.3.2.2. Master lists are used to identify the current revision status and distribution of documents in the management system. A database system is used for all ECI SOPs. Other document types are kept in lists grouped by type of document. These lists are maintained and made readily available to preclude the use of invalid and/or obsolete documents.

4.3.2.3. The procedure(s) adopted ensure the following:

4.3.2.3.1. Authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed.

4.3.2.3.1.1. Hard copies are maintained in binders in laboratory areas

4.3.2.3.1.2. Electronic copies are available to be viewed on the company intranet.

4.3.2.3.2. Documents are periodically reviewed and, where necessary, revised to ensure continuing suitability

and compliance with applicable requirements.

4.3.2.3.2.1. Method SOPs are reviewed as part of the internal audits and at least annually.

4.3.2.3.2.2. This Quality assurance manual will be reviewed at least annually.

4.3.2.3.2.3. Other documents written internally will be reviewed at least every two years.

4.3.2.3.2.4. External documents that may change are verified at least annually.

4.3.2.3.2.5. External documents that do not change, such as manufacturers' instrument manuals, are not reviewed.

4.3.2.3.3. Invalid or obsolete documents are promptly removed from all points of issue or use to prevent unintended use.

4.3.2.3.4. All documents removed from use or replaced are marked as obsolete. Paper documents are shredded with the exception of the master copy, which is marked in permanent ink and placed in an "Obsolete" file. Electronic documents are removed from the active directory and placed into a document archive file.

4.3.2.4. Management system documents generated by the laboratory are uniquely identified. The identification system is detailed in T002 *Document Control.*

4.3.3. Document Changes

4.3.3.1. Changes to documents are reviewed and approved by the same laboratory positions as approved the original document, or their designee. See Section 4.3.2.1 above. The requirements and specifics, including specific responsibilities, are included in T002 *Document Control.*

4.3.3.2. Altered or new text, when practical, is identified in by the use of a bolded font in the finished version of the document. Use of a bolded font is considered not practical when a significant rewrite of a document is performed.

4.3.3.3. Amendment of documents by hand is not allowed.

4.3.3.4. Changes in documents maintained in electronic systems are identical to changes in hard-copy documents, except that the final copy (in .pdf) is placed in the current SOP directory.

4.4. Review of Requests, Tenders and Contracts

4.4.1. The laboratory has established and maintains procedures for the review of requests, tenders and contracts. The policies and procedures adopted for these reviews leading to a contract are intended to ensure the following:

4.4.1.1. The requirements, including the methods to be used, are adequately defined, documented and understood.

4.4.1.2. The laboratory has the capability and resources to meet the requirements.

4.4.1.3. The appropriate test and/or calibration method is selected and is capable of meeting the customers' requirements. Any deviations from the published test method must be communicated to the customer. See Section 5.4.1.5.

4.4.1.4. Any differences between the request or tender and the contract must be resolved before any work commences. Each contract must be acceptable both to the laboratory and to the customer.

4.4.1.5. A contract may be any written or oral agreement to provide a customer with testing services.

4.4.2. Records of reviews, including any significant changes, are maintained. Records are also maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract. A more detailed explanation of the processes used to meet these requirements are contained in the ECI SOP *Project Management and Business Development,* T062, current version.

4.4.2.1. The method of recording the review depends on the type of review required.

4.4.2.2. For large sample contracts, the client usually contacts the laboratory prior to bringing samples to the laboratory. Any telephone conversations will be confirmed by e-mail to the client stating the expected samples, the methods that will be used, etc. These electronic communications are maintained as a record of the review. In addition, checklists are developed for review of RFPs and associated project plans or sampling and analysis plans (SAPs). For ongoing projects, this review only needs to be performed at the outset and if any changes are made.

4.4.2.3. For walk-in clients, a chain of custody is required. If clients do not bring one in with their samples, the laboratory provides one and requests that it be filled out. The laboratory reviews the COC as part of the login process and ensures the specific methods to be used are listed. A laboratory representative signs the COC and provides a copy to the client. This becomes the record of the review.

4.4.2.4. If samples are shipped in without prior notice, the same procedures as for walk-in clients are followed, but the copy of the COC is provided to the client by mail or electronic mail.

4.4.3. The review must also cover any work that is subcontracted by the laboratory. Subcontracting is detailed in the Section 4.5 of this Quality Assurance Manual.

4.4.4. The customer must be informed of any deviation from the contract. Usually, this communication is made by electronic mail. If made by other means, *e.g.,* telephone call, e-mail confirmation will be performed to provide a written record.

4.4.5. If a contract needs to be amended after work has commenced, the same contract review process must be repeated and any amendments are communicated to all affected personnel.

4.5. Subcontracting of Environmental Tests

4.5.1. When the laboratory subcontracts work, whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that holds an appropriate accreditation for the work in question

4.5.1.1. Work requiring NELAP accreditation must be placed with a NELAP-accredited laboratory.
4.5.1.2. Work requiring drinking water certification must be placed with a certified drinking water laboratory.
4.5.1.3. Work requiring DoD accreditation must be placed with a DoD-accredited laboratory. Additionally, the sub-contract must have project-specific approval by the DoD customer before samples are analyzed.

4.5.2. Proper accreditation is confirmed by initial and then by at least annual review of the subcontract laboratory's accreditation certificate(s). Additionally, ECI sends instructions with each subcontracted job requiring the subcontract laboratory to notify ECI of the following:

4.5.2.1. Any changes or loss of accreditation or certification for the applicable analyses,
4.5.2.2. Any analyses for which the laboratory has had unacceptable PT results that are not able to be addressed through corrective action, and
4.5.2.3. Need to further subcontract the sample analyses to a different subcontracting laboratory, including any "in-network" laboratory operating under a different accreditation or certification.

4.5.3. The laboratory advises the customer of the arrangement in writing and, when appropriate, gains the approval of the customer, preferably in writing. Personnel from ECI's Project Management group are tasked with management of subcontracting.

4.5.3.1. In the case of large contract work, notification is done as part of the contracting procedure described in the previous section. (Section 4.4)

4.5.3.2. In the case of walk-in or other individual lot type of work, the need to subcontract will be included on the COC that is copied and given to the customer or in an e-mail to the customer. If by e-mail, it is the project manager's responsibility to maintain the e-mail as a record of notification.

4.5.3.3. In some cases, customers may give a standing order to subcontract their samples. Records of such an order must be maintained by the project manager.

4.5.4. The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

4.5.5. The Project Management group maintains a list of all subcontractors that it uses for tests and a record of having reviewed the appropriate accreditation certificate(s) for the tests that are subcontracted.

4.5.6. The laboratory performing the subcontracted work is indicated in the final report. The laboratory will make a copy of the subcontractor's report available to the client when requested.

4.5.7. Procedure:

4.5.7.1. The ECI project manager generates a separate chain of custody to accompany the subcontracted samples to the designated laboratory.

4.5.7.2. The ECI PM gathers the sample containers to be shipped and places them in a designated area in the sample receiving walk-in cooler. If samples are required to be split, PM personnel ensure that the proper splits are prepared.

4.5.7.3. PM or sample management personnel attach a sheet to the CoC noting the requirements listed in 4.5.2 above.

4.5.7.4. Sample management personnel load the cooler and ship the samples to the subcontract laboratory.

4.6. Purchasing Services and Supplies

4.6.1. The laboratory has a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests. The policy of the laboratory is to purchase items that will be of sufficient quality to complete testing in compliance and to not adversely affect the processes. Procedures exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests as described below.

4.6.2. The laboratory ensures that purchased supplies and reagents and consumable materials that affect the quality of analyses are not used until they have been inspected or otherwise verified as complying with

standard specifications or requirements defined in the methods for the analyses concerned. These services and supplies used are selected to comply with specified requirements. Records of actions taken to check compliance are maintained.

4.6.2.1. In general, supplies, reagents and consumable materials are purchased so that no additional testing is required prior to use. In this case, the initials of the person receiving the material state that the correct material was received, based on the ordering information, and it is, therefore, compliant.

4.6.2.2. In cases where there is no history with a vendor or where a particular supply has been shown to require testing, the testing is performed and records of the results tied to the lot of material tested, are maintained by the Group Leader where the supplies are used.

4.6.2.3. Reagents and standards used in analysis have some more specific requirements for inspection and testing. These requirements are included in the ECI SOP T003, *Standards and Reagents*, current version.

4.6.2.4. Equipment that may affect quality is calibrated or otherwise demonstrated to be suitable prior to use. Requirements and records are maintained as described in the related technical documents; such as method SOPs, support equipment SOPs, etc.

4.6.3. Purchasing documents for items affecting the quality of laboratory output are required to contain data describing the services and supplies ordered. Review and approval for technical content is performed prior to release. The manner in which this is performed depends on the type of supply or service.

4.6.3.1. Many routine consumable supplies are included in a stockroom supply contract. The specific items to be stocked are approved by the Group Leader who prepares the list for their area on an annual basis.

4.6.3.2. Items such as solvents and acids are ordered in bulk after consultation with Group Leaders. Specific grades are specified in the ECI SOP T003, *Standards and Reagents*.

4.6.3.3. Large equipment purchases are approved by laboratory (technical) management or corporate technical areas.

4.6.3.4. Other supplies or services are approved on an individual basis by Group Leaders or designees as part of their sign-off in the routine ordering process.

4.6.4. The laboratory evaluates suppliers of critical consumables, supplies and services that affect the quality of testing and calibration, and maintains records of these evaluations and list those approved.

4.6.4.1. Large supply houses, such as Fisher Scientific and VWR, supplying consumable materials that do not require

traceability are considered to be approved for use unless proven otherwise.

4.6.4.2. Vendors providing calibration services and reference materials used for calibration must be able to provide certificates of accreditation for the specific services or materials provided through an internationally-recognized ISO Accreditation Body and must be able to provide endorsed certificates of calibration under the appropriate ISO or national standard in order to be considered approved. Where accredited reference materials are not available, other requirements apply. See the ECI SOPs T003, *Reagents and Standards*, and T043, *Support Equipment*, current versions, for further information.

4.6.4.3. Consultants are approved based on evaluation of their work history and, if deemed necessary by the Laboratory Director or designee, by reference.

4.6.4.4. The corporate purchasing system does not include technical vendor approval. ECI maintains a list of approved vendors in the Laboratory Operations office. Quality critical items and services must be purchased from vendors that are included on the list maintained locally. Other vendors, though available on the purchasing system, must not be used.

4.7. Service to the Client

4.7.1. The laboratory is willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory can ensure confidentiality to other customers.

4.7.1.1. The laboratory will provide the customer or the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests performed for the customer, provided this can be done while ensuring confidentiality to other customers.

4.7.1.2. Customers wishing to perform on-site audits of the laboratory must commit to maintaining confidentiality. The laboratory maintains an SOP and confidentiality agreement for external audits, ECI SOP *Customer and Regulatory Audits,* T-027, current version. Note: Assessors representing State and Third Party Accreditation Bodies or similar agencies bound by their own confidentiality policies are not included under this clause.

4.7.1.3. If requested, the laboratory will help with preparation, packaging, and dispatch of samples needed by the customer for verification purposes.

4.7.1.4. The laboratory will take other such reasonable actions requested by the customer.

4.7.2. The laboratory seeks feedback, both positive and negative, from its customers. The feedback is used and analyzed to improve the management system, testing and calibration activities and customer service.

4.7.2.1. Feedback is solicited with each electronic report sent to the customer.

4.7.2.2. Feedback is also solicited on an annual survey coordinated through Eurofins corporate office. The project management group provides a list of customers to the corporate office, which sends surveys to selected customers on the list. Results are compiled and returned to the laboratory.

4.7.2.3. Feedback collected is included for review in the annual Management Review.

4.8. Complaints

4.8.1. The laboratory has a policy and procedure for the resolution of complaints received from customers or other parties. Records are maintained of all complaints and of the investigations and corrective actions taken by the laboratory.

4.8.2. All complaints must be recorded and investigated at least sufficiently enough to determine whether they are with or without merit.

4.8.2.1. Complaints are recorded in the eJira system by the person who receives the complaint. The “issue” screen is filled out down through the “Description” section of the screen.

4.8.2.2. That individual either investigates the complaint or assigns the investigation to another individual using the eJira system.

4.8.3. Complaints are initially evaluated as with merit, *e.g.,* complaints about missed turn-around times or results that are found to have been reported erroneously, or as without merit, *e.g.,* complaints about results that, while not desired, are in fact correct or about pricing that was previously accepted.

4.8.3.1. Record the investigation in the “Investigation” field

4.8.3.2. Conclude that that investigation is with merit or without merit.

4.8.4. Complaints that are found to be with merit are placed into the corrective action system for disposition. In eJira, an ICAR is created, the issues are further investigated, root cause is determined, actions are taken and all of these steps are recorded as described in the corrective action procedures.

4.9. Control of Nonconforming Environmental Testing Work

4.9.1. The laboratory has a policy and procedures that must be implemented when any aspect of its testing work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy of the laboratory is that non-conforming work must be addressed as defined below or in pertinent SOPs so that the needs of

the customer are met. Examples of places non-conforming work could occur include customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report checking, management reviews and internal or external audits.

4.9.1.1. The responsibilities and authorities for the management of nonconforming work are as follows.

4.9.1.1.1. All laboratory personnel are responsible for taking appropriate action when non-conforming work is identified, including notification of the Laboratory Director, if needed. In many cases, the appropriate action is defined in the analytical SOPs.

4.9.1.1.2. All personnel may stop work when non-conforming work is identified, but the Group Leader, Operations Manager, Laboratory Director, QA representative or QA manager must be notified of a stoppage as soon as is feasible.

4.9.1.1.3. The Laboratory Director, QA Manager, Operations Manager or their designees, are authorized to recall work or withhold analytical reports, if necessary.

4.9.1.2. An evaluation of the significance of the nonconforming work is made. Exceptions are first evaluated by the analyst or other personnel performing the work and their group leader.

4.9.1.3. Correction is taken immediately, together with any decision about the acceptability of the nonconforming work. “Corrections” are things done to continue working, report the data, and fix the immediate problem. Note that this is different than corrective action, which is described in Section 4.11.

4.9.1.4. Where necessary, the customer is notified and work is recalled. The responsibility for authorizing the resumption of work given to the Laboratory Director, or designee, in consultation with the QA manager and following the review of root cause(s) and corrective action.

4.9.2. Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed.

4.9.3. For projects under DoD ELAP Accreditation, the laboratory shall notify all affected clients of potential data quality issues resulting from nonconforming work within 15 business days, even if corrective action has not been completed. Notification shall be performed according to documented procedures. Documentation of corrective actions taken to resolve the nonconformance shall be submitted to the client(s) in a timely and responsive manner. See ECI SOP T062, *Project Management.*

4.10. Improvement

4.10.1. The laboratory strives to continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

4.10.2. Personnel are encouraged to bring to the attention of management items that may improve the functioning of the laboratory and its management system.

4.10.3. Improvements must be vetted and follow the change control procedures used in the laboratory to ensure continuing compliance with policies, Standards, regulations, methods, etc.

4.11. Corrective Action

4.11.1. General

4.11.1.1. The laboratory policy is to take appropriate corrective action whenever departures from the laboratory's policies and procedures are identified in the management system or the laboratory's technical operations. This is done using the procedures described below. For quality control outliers that do not appear to be systematic, appropriate actions are defined in the analytical SOPs and this formal corrective action process is not required.

4.11.1.2. A non-conformance with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, proficiency test failures, management reviews, and feedback from customers and from staff observations.

4.11.1.3. All personnel in the laboratory are responsible to initiate corrective action when indicated by SOPs, observance of departures from documented systems, or simply good scientific judgment or common sense. When bench analysts believe corrective action is needed, they must notify their group leader as soon as possible so the group leader can review and assign responsibilities.

4.11.1.4. The eJira system is used to record all steps of the corrective action process.

4.11.1.5. The issue must be defined with adequate detail to allow further investigation. Typically, the important elements to include are: what event(s) occurred, in what process did the event(s) occur, who witnessed the event(s) or performed the process, when (date/time) did the event(s) occur, where did the event(s) occur, what other processes were or may be impacted. Record this information in the "Description" section of the eJira system.

4.11.1.6. Once the problem or failure is defined, responsibility for investigation is assigned to one or more laboratory personnel by the Group Leader, Operations Director, Laboratory Director, or Quality Assurance personnel. The eJira system sends an email to those assigned to notify them of the responsibility.

4.11.1.7. If sample data are affected, provide as much information as possible about which data and how it was affected in the "Impact on Sample Data" section of the eJira system.

4.11.2. Cause Analysis

4.11.2.1. For failures that appear to be systematic, the procedure for corrective action starts with an investigation to determine the root cause(s) of the problem. Cause analysis is key to the corrective action procedure.

4.11.2.2. Root cause analysis is the most challenging aspect of the corrective action process. When correctly applied, root cause analysis leads to more effective solutions, continuous improvement, and a reduced likelihood of further deficiencies. In some cases, the root cause is singular and easily discerned. In other cases, determination of the root cause or causes may require more effort to identify. For this reason, there is no single 'recipe' that can be followed. There is no singe procedure that will be applicable to all scenarios, but there are guiding principles, the most important of which is addressing the question: "Why did this deficiency occur?"

4.11.2.3. Root Cause Analysis seeks to identify the origin of a problem. It assumes that systems and events are interrelated. One event leads to another, which leads to another. By tracing back these actions, you can discover the original source of the problem.

4.11.2.4. Adequate data must be collected to allow effective Root Cause Analysis. In addition to the information required in the definition of the problem, investigations must also attempt to determine the duration, frequency, and/or pervasiveness of the problem and identify any other areas where the same or similar problems could occur.

4.11.2.5. Root causes are specific underlying causes that can be reasonably identified, that management has control to fix and for which effective recommendations for preventing recurrences can be generated.

4.11.2.6. Potential causes could include, but are not limited to, issues related to customer requirements, sample matrix, methods and procedures, staff skills and training, consumables, equipment calibration and maintenance, environmental conditions.

4.11.2.7. Record the Root Cause(s) determined in detail in eJira Section "Detailed Explanation of the Root Cause". At the

same time, select the best option in the "Root Cause Category" drop down. This is used for category tracking purposes. If more than one root cause is identified, choose the category that has a greater impact on the laboratory.

4.11.3. Selection and Implementation of Corrective Actions

4.11.3.1. If possible, generate several potential solutions to the root cause(s) of the problem.

4.11.3.2. Rank the potential solutions according to their likelihood of eliminating the problem, preventing its recurrence, the cost vs benefit, and the risk of unintended negative impacts.

4.11.3.3. Select one or more actions appropriate to the magnitude of the problem and the risk of recurrence.

4.11.3.4. List the potential corrective action(s) and note those selected for implementation in the "Corrective Action Plan" section in the eJira

4.11.3.5. Assign personnel responsible for implementation in eJira. The system will email the person(s) assigned to notify them of the responsibility.

4.11.3.6. Assign a completion date for implementation. Standard completion time is targeted at two weeks, but this may not be appropriate and may be changed depending on the nature of the actions and the needs of the laboratory and its customers.

4.11.4. Monitoring of Corrective Actions

4.11.4.1. Routine monitoring of corrective actions is combined with internal auditing. . When ICARs are closed by a member of QA, that person will enter the issue into the "QA Issue Follow Ups" Excel. On the first business day of the month, the Quality Assurance Manager or their designee will query this document for issues that have not been followed-up on. These issues will be checked to ensure activities are proceeding in a timely way and implemented corrective actions appear to be effective.

4.11.4.2. Additionally, during preparation for internal audits, the eJira system is queried for corrective actions related to the area to be audited. Verification of the continued effectiveness of these corrective actions are then included in the scope of the internal audit. Records of the verification are maintained in the audit record.

4.11.5. Additional Audits--Where the review of corrective actions shows clusters of similar root causes, or where monitoring of implementation of corrective actions shows continued or significant non-conformances, the laboratory ensures that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.

4.12. Preventive Action

4.12.1. Needed improvements and potential sources of nonconformities, either technical or concerning the management system, must be identified. When improvement opportunities are identified or if preventive action is required, action plans are developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

4.12.2. As noted in the Standard, preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints. Performing appropriate preventive action requires a mindset of looking at laboratory operations with an eye toward seeing what could go wrong. Often, this will be based on what types of problems have been solved in the past. Preventive actions may come as a result of the management review process or through attempts to improve the efficiency of the laboratory, including LEAN initiatives.

4.12.3. The preventive action process is as follows

- Identify the needed preventive action
- Develop an action plan to implement the action
- Implement the action, with changes as necessary
- Monitor the results of the action to verify that the action taken is achieving the desired results and has not caused unanticipated negative impacts

4.12.4. Preventive actions should be recorded. Unless another mechanism is indicated, such as the Management of Change (MOC) system or LEAN records, use the eJira system. Identification of a root cause is not part of the preventive action system. Fields in the eJira system relating to root cause should be listed as “NA”.

4.13. Control of Records

4.13.1. General

4.13.1.1. The laboratory has established and maintains procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records maintained include reports from internal audits and management reviews as well as records of corrective and preventive actions.

4.13.1.2. All records must be legible and stored in such a way that they are readily retrievable. ECI maintains records in both hard copy and electronic formats. Both types of records must be stored so as to prevent damage and deterioration. All records are maintained for a minimum of five years after last use.

4.13.1.3. All records are held secure and in confidence.

4.13.1.4. The laboratory maintains procedures to protect and back up electronic records and to prevent unauthorized amendments

to these records.

4.13.2. Technical records

4.13.2.1. The laboratory is required to retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each analytical report issued, for the time period defined above or longer, if required by the customer. The records for each test or calibration must contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records must include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.

4.13.2.2. Observations, data and calculations must be recorded at the time they are made and must be identifiable to the specific task. For example, it is not acceptable to record a number without identifying what the number means.

4.13.2.3. When mistakes occur in records, each mistake shall be crossed out with a single line; not erased, made illegible or deleted; and the correct value entered alongside. All such alterations to records shall be dated and signed or initialed by the person making the correction. Additionally, corrections due to reasons other than transcription errors must specify the reason for the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

4.13.3. Additional Requirements

4.13.3.1. The laboratory's record keeping system is designed to allow the history of the sample and associated data to be readily understood through the documentation. This system must produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts.

4.13.3.2. Records are made available to the accreditation body. Records concerning a customer's samples will be made available to that customer if it can be done without compromising the confidentiality of other customer's data.

4.13.3.3. Records that are stored only on electronic media must be supported by the hardware and software necessary for their retrieval for the full retention time required for the record type.

4.13.3.4. Access to archived information must be documented with an access log. Electronic access is tracked through the electronic storage systems. Hard copy archive access is

documented with a log.

4.13.3.5. All information necessary for the historical reconstruction of data shall be maintained by the laboratory, including the items listed below. Instructions for how each item is maintained are found in the SOPs governing those activities and in the technical SOPs for each method.

4.13.3.5.1. All raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts' worksheets and data output records (chromatograms, strip charts, and other instrument response readout records).
4.13.3.5.2. A written description or reference to the specific method used, which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value.
4.13.3.5.3. The laboratory sample ID code.
4.13.3.5.4. The date of analysis.
4.13.3.5.5. The time of analysis is required if the holding time is seventy-two (72) hours or less, or when time critical steps are included in the analysis (e.g., extractions and incubations).
4.13.3.5.6. Instrumentation identification and instrument operating conditions/parameters (or reference to such data).
4.13.3.5.7. All manual calculations.
4.13.3.5.8. Analyst's or operator's initials/signature or electronic identification.
4.13.3.5.9. Sample preparation including cleanup, separation protocols, volumes, weights, instrument printouts, meter readings, calculations, and reagents.
4.13.3.5.10. Test results.
4.13.3.5.11. Standard and reagent origin, receipt, preparation and use.
4.13.3.5.12. Calibration criteria, frequency and acceptance criteria.

4.13.3.6. All generated data, except those that are generated by automated data collection systems, are recorded legibly in permanent ink.

4.13.3.7. If the laboratory transfers ownership or goes out of business, ECI will ensure that the records are maintained or transferred according to customer instruction.

4.13.3.7.1. 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.
4.13.3.7.2. If 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.

4.13.4. Analytical Record-Keeping System Design

4.13.4.1. Analyses in the laboratory are either performed on analytical instrumentation that provides the required records electronically, usually using vendor-supplied software, or there is an analytical "bench sheet" designed for the analysis to capture all required information.

4.13.4.2. Where electronic systems do not capture all of the required information, they may be augmented with a bench sheet or batch sheet to provide information missing from the electronic files.

4.13.4.3. Some of the required analytical information is recorded on the "worksheet", a collection of sample tracking information printed for each sample group at log-in and carried through the laboratory process with the samples.

4.13.4.4. Signature log: The laboratory keeps a log of each employee's name, signature and initials. The laboratory also assigns each employee a numerical "Analyst ID". Technical personnel generally use this number rather than their signature or initials on analytical records. The log is kept on file in the QA offices.

4.14. Internal Audits

4.14.1. The laboratory periodically, and in accordance with a predetermined schedule and procedure, conducts internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and with all applicable Standards. The internal audit program addresses all elements of the management system and laboratory process. Additional detail on auditing requirements and qualification of internal auditors is found in the ECI SOP *Internal Audit Procedures,* T028, current revision.

4.14.1.1. It is the responsibility of the Quality Assurance Manager to plan and organize audits as required by the schedule and requested by management. Auits are performed so that the entire management system is audited annually.

4.14.1.2. Internal audits are performed by trained and qualified personnel who are independent of the activity to be audited.

4.14.1.3. Checklists are used to assist the audit procedure. This ensures that there is documentation of what items were checked and what the results of the checks were.

4.14.2. If audit findings cast doubt on the correctness or validity of calibrations or analytical results, immediate corrective action must be taken. Deficiencies discovered during the auditing process are rectified and documented

using the corrective action process described in Section 4.11 of this manual. Records are maintained in the eJira system.

4.14.3. The area of activity audited, the audit findings and corrective actions that arise from them are recorded in an audit report.

4.14.4. Follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken. Follow up is a part of the corrective action procedure and is documented in the corrective action system.

4.14.5. Additional Items

4.14.5.1. If the laboratory identifies events that cast doubt on the validity of test results, the laboratory is required to notify clients with affected data within seven calendar days of the discovery. Notification must be recorded in the eJira system.

4.14.5.2. The laboratory management must ensure that these actions taken as a result of internal audits are discharged within the agreed time frame.

4.15. Management Review

4.15.1. The Laboratory Management is responsible for performing an annual management review of the laboratory. The focus of the management review is on the sufficiency of the Quality Assurance Manual and system to meet the standards of NELAP.

4.15.1.1. The review is performed in multiple stages. First, the quality department personnel and the BUMa collect information to fill out the Eurofins Environment form “Management Review Meeting Agenda”.

4.15.1.2. Then, a local meeting is held with the BUMa, the quality department staff, the production manager and other parties as decided by the BUMa.

4.15.1.3. The output of the meeting is the completed “Management Review Meeting Agenda” form with proposed action items.

4.15.1.4. The final step is for the BUMa and the quality staff to review the information and proposed action items with the [Insert Paul Wise’s Title here] and the Corporate Quality Director to finalize action items.

4.15.2. The review will include but is not limited to the following items:

4.15.2.1. The suitability of policies and procedures, including data integrity procedures
4.15.2.2. Results of the annual assessment
4.15.2.3. Results of proficiency testing samples
4.15.2.4. Corrective and preventive actions
4.15.2.5. Results of any external assessments, *e.g.*, certification assessments
4.15.2.6. Any changes in the volume or type of work, particularly

anticipated changes

4.15.2.7. Review of client complaints or other client feedback

4.15.2.8. Any other relevant factors, such as quality control activities, resources, and staff training.

4.15.3. A record of the discussions included in the review will be kept on file in the laboratory.

4.15.3.1. The record must include determinations as to whether the management system is meeting the needs of the laboratory and where improvements will be made.

4.15.3.2. Action items resulting from the review will be entered into the eJira system, where they will be assigned to specific personnel and given a timeline for implementation.

4.16. Data Integrity

4.16.1. It is the policy of the laboratory to produce data which are sound, correct and complete. The laboratory maintains a documented data integrity system which is reviewed annually and approved by management. The program in place in the laboratory includes the following elements which are detailed in the ECI SOP T065, *Data Integrity*, current version.

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4.16.1.1. Data Integrity Training

4.16.1.2. Documentation signed by each employee

4.16.1.3. In-depth, periodic monitoring of data integrity

4.16.1.4. Documentation of data integrity procedures.

4.16.2. Laboratory management will uphold the spirit of the laboratory's data integrity program and will work to effectively implement the requirements of these procedures.

4.16.3. Employees undergo Data Integrity training and sign statements that they agree to abide by the requirements of the Data Integrity Program at orientation and annually.

4.16.4. The laboratory maintains a no-fault reporting policy for data integrity issues.

4.16.5. If a report is received of a potential violation of the laboratory's data integrity procedures or if the laboratory's auditing program reveals evidence of inappropriate actions or vulnerabilities related to data integrity, further review is required. All investigations will be handled in a confidential manner until such time as a follow-up evaluation, full investigation, or other appropriate actions have been completed and the issues clarified.

4.16.6. All investigations that result in finding of inappropriate activity must be recorded and the records must include any disciplinary actions involved, corrective actions taken, and all notifications of clients. All records must be kept for at least five years.

5. Technical Requirements

5.1. General

5.1.1. Many factors determine the correctness and reliability of the tests performed by a laboratory including human factors, accommodation and environmental conditions, test and calibration methods and method validation, equipment, measurement traceability, sampling, handling of test items, as well as others.

5.1.2. The extent to which the factors contribute to the total uncertainty of measurement differs considerably between different types of test. The laboratory takes these factors into consideration in developing test methods and procedures, in training and qualifying personnel and in the selection and calibration of the equipment it uses.

5.2. Personnel

5.2.1. The laboratory management must ensure the competence of all who operate specific equipment, perform tests, evaluate results, and sign test reports. When using staff in training, appropriate supervision must be provided. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

5.2.2. The management of the laboratory formulates goals with respect to the education, training and skills of the laboratory personnel. The laboratory policy and procedures for identifying training needs and providing training of personnel are outlined below. The training program is intended to be relevant to the present and anticipated tasks of the laboratory. The overall goals of the training program are to ensure that all personnel have the skills to perform their work in compliance with the management system and the Standard, are trained in the parts of the management system that affect their specific job, and have demonstrated competency to perform the tests, parts of tests or other functions for which they are responsible. Details of the training program, including records requirements, are contained in the ECI SOP *Employee Training*, T010 (current version).

5.2.2.1. Training needs are identified through evaluation of current skills by management. Initially, individuals are trained to perform specific methods or support procedures as defined by their initial job description. After initial training in specific job functions, annual evaluations include identification of other training needs. Training on basic laboratory techniques is performed along with method training that uses those techniques.

5.2.2.2. Initial training is designed to provide a new employee with the information required to perform their job in compliance with the overall management system. Additional training needs are determined during employee evaluations and may include additional method training, training in additional tasks such as sample management, refresher training, or, in some cases, retraining on particular parts of the management system.

5.2.2.3. Training effectiveness is evaluated initially through observation of the employee's performance of tasks and/or through evaluations of Demonstrations of Capability. Continuing evaluations are made through additional observation, through evaluation of quality control data and proficiency testing data as well as review of reports and records generated by the employee in the performance of their duties.

5.2.3. The laboratory routinely uses personnel who are employed by the laboratory. However, new employees are often brought in through a temporary agency and may be converted to full-time company employees after a trial period. Regardless of whether company employees or contracted personnel are used, the laboratory ensures that such personnel are supervised and competent and that they work in accordance with the laboratory's management system.

5.2.4. The laboratory maintains current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations. Minimum job descriptions (as required by the Standard) for key managerial personnel are found in Appendix 2 of this Quality Manual. Job descriptions for analytical ("bench") personnel are maintained by the Operations Manager and/or Group Leaders. Information in job description may include, for example, the following items.

5.2.4.1. Responsibilities with respect to performing tests.
5.2.4.2. Responsibilities with respect to the planning of tests and evaluation of results
5.2.4.3. Responsibilities with respect to method modification and development and validation of new methods
5.2.4.4. Expertise and experience required
5.2.4.5. Qualifications and any required training programs
5.2.4.6. Managerial duties.

5.2.5. Laboratory management authorizes specific personnel to perform particular types of sampling and testing, to issue test reports, and to operate particular types of equipment. The laboratory maintains records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information is maintained by the QA office and kept readily available. It must include the date on which authorization and/or competence is confirmed.

5.2.5.1. Authorization to perform tests is given by the approval of the Initial Demonstration of Capability. Authorization to operate specific types of equipment is included with the method authorization that uses that equipment.

5.2.5.2. Each analyst must demonstrate capability for each test method used in the laboratory initially, prior to reporting samples using the method, and on an annual basis thereafter. Records of these demonstrations must be maintained.

5.2.5.3. For processes that do not include an analytical method, authorization is indicated by one of several methods:

5.2.5.3.1. For processes that require specific LIMS or other electronic permissions, the authorization is indicated by the supervisor's e-mail to QA requesting that the permission be given to the employee.

5.2.5.3.2. For analytical processes that do not lend themselves to a demonstration of capability, authorization is indicated through inclusion by the supervisor of the method on the employee's "Method Proficiency List and Demonstration of Capability Certification Statement" form along with the record of having read and understood the governing SOP(s).

5.2.5.4. This laboratory does not offer opinions or interpretations, so there is no authorization procedure for them.

5.2.5.5. All records of training are included in the employees' training files.

5.2.6. Group Leader responsibilities

5.2.6.1. Group leaders are responsible for ensuring that training requirements are met for assigned personnel, and

5.2.6.2. Ensuring that training records are maintained and up to date for assigned personnel.

5.2.7. Data Integrity Training

5.2.7.1. Data integrity training is required as a part of the initial new employee orientation and annually thereafter.

5.2.7.2. The Data Integrity Program, including training requirements, is described in Section 4.16 above and in the SOP referenced there.

5.3. Accommodation and Environmental Conditions

5.3.1. The laboratory facilities for testing, including but not limited to energy sources, lighting and environmental conditions, must facilitate correct performance of the tests. The laboratory will ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. The technical requirements for accommodation and environmental conditions that can affect the results of test and calibration are required to be documented.

5.3.2. Most of the laboratory is amenable to normal industrial building controls. There are few areas in the laboratory where temperature requirements are prescribed. Where test methods make specific requirements, these are incorporated into the testing areas. The following environmental conditions are considered essential to obtaining accurate results:

5.3.2.1. Leaching tumblers (*e.g.,* TCLP) are kept in a room that is controlled and monitored during tumbling and meets the

requirements of the test methods.

5.3.2.2. Biomonitoring (Whole Effluent Toxicity Testing, "WETT") is performed in a room that is controlled and monitored during testing to meet the requirements of the test methods.

5.3.3. The laboratory maintains an effective separation between areas in which there are incompatible activities. Measures are taken to prevent cross-contamination.

5.3.3.1. Volatile organic analyses and air analyses are performed in a building that is separated from the main building, where organic extractions and semivolatile organic analyses are performed.

5.3.3.2. Other analyses with a potential for cross-contamination from preparation (e.g., metals) are performed in separate rooms.

5.3.4. Laboratory access is controlled. Only authorized individuals are allowed in the laboratory area. Guests may be allowed in the laboratory only with an authorized escort. Detailed protocols for managing customer visits and external audits are included in the ECI SOP *Customer and Regulatory Audits,* T-027, current version.

5.3.4.1. Customer information must be kept confidential when visitors are in the laboratory area. Do not allow visitors, particularly customers, to view worksheets from other customers' samples.

5.3.4.2. Do not leave visitors unescorted in the laboratory areas.

5.3.5. Laboratory personnel are required to practice appropriate good housekeeping.

5.3.5.1. In general, no specific laboratory protocols are required for the types of analyses performed at ECI. Where specific protocols are required for specific tests, they are documented in the applicable test method SOPs.

5.3.5.2. The laboratory LEAN program seeks to minimize clutter while maximizing accessibility of appropriate apparatus, reagents, and standards. Laboratory personnel are required to maintain their work spaces as indicated in the LEAN 5S Standards.

5.3.5.3. The laboratory employs a contractor to provide basic custodial services. The contractor has been instructed to not use cleaning chemicals in the areas where volatile organic analyses are performed.

5.4. Environmental Methods and Method Validation

5.4.1. The laboratory is required to use appropriate methods and procedures for all tests within its scope and all calibrations and verifications of equipment.

5.4.1.1. These include sampling, handling, transport, storage and preparation of samples to be analyzed and, and, where

appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of quality control data.

5.4.1.2. The laboratory has instructions on the use and operation of all relevant equipment, and on the handling and preparation of samples for analysis, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations.

5.4.1.2.1. These instructions are included in the laboratory's SOPs for specific methods and in the instrument manufacturer's manuals.

5.4.1.2.2. Additional instructions may be included in SOPs specific to a particular task or instrument.

5.4.1.3. All instructions, standards, manuals and reference data relevant to the work of the laboratory are required to be kept up to date and made readily available to personnel (see 4.3). Deviation from test and calibration methods may occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

5.4.1.4. The laboratory maintains specific SOPs for each environmental test method used in the laboratory.

5.4.1.5. Deviations from the published method are listed in a specific section in the SOP along with their technical justification. Data supporting the validity of listed deviations, if required, is kept on file in the laboratory. Listed deviations are collated by the QA department and then provided to project management.

5.4.2. The laboratory must ensure it uses test methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes.

5.4.2.1. Methods published in international, regional or national standards are preferably used.

5.4.2.1.1. Sources include methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Specific sources of methods used at ECI include the EPA, *Standard Methods for the Examination of Water and Wastewater*, ASTM, the State of California and local municipalities, and scientific journals.

5.4.2.1.2. The laboratory must use the latest valid edition of a standard unless it is not appropriate or possible to do so. Note: Some accreditations and some contracts held by the laboratory require the use of

earlier editions of methods.

5.4.2.1.3. When necessary, the method is supplemented with additional details to ensure consistent application.

5.4.2.2. When the customer does not specify the method to be used, the laboratory selects what it deems the most appropriate method.

5.4.2.3. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer must be informed as to the method chosen. See clause 5.4.3 below.

5.4.2.4. The laboratory is required to confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, in such a way that the detection system, the chemistry, or the sensitivity of the method may be affected, the confirmation must be repeated. This is accomplished by performing a Demonstration of Capability and, where applicable, a determination of detection limits study.

5.4.2.5. The laboratory must inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.

5.4.2.6. All customer notifications are performed as part of the request, tenders, and contracts procedure. (See Section 4.4)

5.4.3. Laboratory-Developed methods. It is not likely that the laboratory will develop any in-house methods. If the need arises, the laboratory will develop validation plans in line with the requirements of the Standards.

5.4.4. Non-Standard methods, if used, will be validated using the procedures included in the Eurofins Calscience, Inc. SOP *Method Validation and Demonstration of Analytical Capability,* T046, current version.

5.4.5. Validation of the implementation of analytical methods will be performed using the procedures included in the Eurofins Calscience, Inc. SOP *Method Validation and Demonstration of Analytical Capability* T046, current version.

5.4.6. Estimation of Analytical Uncertainty

5.4.6.1. The laboratory maintains procedures for determining the uncertainty associated with analysis. Determination of total uncertainty, including sampling, transport, etc. is beyond the scope of the laboratory and will not be determined.

5.4.6.1.1. The exact nature of some test methods may preclude rigorous, statistically valid estimation of analytical uncertainty. In these cases the laboratory will attempt to identify all components of analytical uncertainty and make a reasonable

estimation and shall ensure that the form of data reporting does not give a wrong impression of the uncertainty. A reasonable estimation is based on knowledge of method performance and previous experience. When estimating the analytical uncertainty, all uncertainty components which are of importance in the given situation must be taken into account.

5.4.6.1.2. In those cases where a well-recognized test method specifies limits to the values of the major source of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied the requirements on analytical uncertainty by following the test method and reporting instructions.

5.4.6.1.3. The laboratory is only responsible for estimating the portion of measurement uncertainty that is under its control. As stated in Section 5.10.3.1.c, test reports will include a statement of the estimated analytical uncertainty only when required by the customer.

5.4.6.2. Analytical uncertainty will not be routinely reported to the customer. Uncertainty will only be reported when requested by the customer or when the uncertainty affects compliance to a specification limit, if known by the laboratory. The laboratory uses no methods where the uncertainty is routinely relevant to the validity or application of the test results.

5.4.6.2.1. If a project requires analytical uncertainty to be reported, the laboratory shall report the estimated uncertainty based on project-specific procedures or, if not available, an internal procedure based on results of Laboratory Control Samples will be used.

5.4.6.2.2. The estimated analytical uncertainty can be expressed as a range (±) around the reported analytical results at a specified confidence level. A laboratory may report the in-house, statistically-derived LCS control limits based on historical LCS recovery data as an estimate of the minimum laboratory contribution to analytical uncertainty at a 99% confidence level.

5.4.6.3. For testing laboratories, the laboratory shall ensure that the equipment used can provide the analytical portion of measurement uncertainty needed by the customer.

5.4.6.4. For further information and procedures for determining analytical uncertainty, see the ECI SOP *Uncertainty in Measurement*, T045, current version.

5.4.7. Control of Data

5.4.7.1. Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

5.4.7.2. When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory ensures that:

5.4.7.2.1. Computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;

5.4.7.2.2. Procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

5.4.7.2.3. Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

5.4.7.2.4. Commercial off-the-shelf software (e.g. word processing, database and statistical programs) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/ modifications should be validated as in 5.4.7.2.1.

5.4.7.2.5. User names and passwords are required for all information system access. Passwords are changed at least every six months.

5.4.7.2.6. Employees are trained at hiring and annually thereafter on computer security awareness. This training is combined with Ethics and Data Integrity Training for ease of implementation.

5.4.7.2.7. The Quality Assurance Manager or designee is responsible for annual inspection of the LIMS. At a minimum, archived reports are compared to re-generated reports to verify data and calculation integrity. Records are kept and laboratory management is notified of any problems identified and any corrective actions taken.

5.4.7.2.8. If the laboratory develops information systems that allow electronic customer interaction, the laboratory must also develop a procedure to

provide prior notification to customers of software or hardware changes that will adversely affect customer electronic data.

5.4.7.3. The validation procedures for computer software vary depending on the source and use.

5.4.7.3.1. Instrument software provided by the instrument vendor or by a recognized third-party vendor is considered to be validated by the vendor under the NELAP standard, but calculation algorithms are required to be validated under the DoD ELAP. Specific configurations installed by the vendor are also considered validated unless changed significantly by the laboratory.

5.4.7.3.2. Office software applications such as Word and Excel are considered to be validated by the vendor, including specific functions included in those applications.

5.4.7.3.3. Any software applications designed in the laboratory must be validated by the laboratory, including spreadsheets used to perform quality-critical calculations. See the next section for specific validation requirements.

5.4.7.3.4. All software, including user-defined software such as spreadsheet applications must be protected from unauthorized changes. Calculation cells in spreadsheets must be locked to prevent alterations of the formulae.

5.4.7.4. Some analyses and processes in the laboratory have spreadsheets that have been designed to perform the calculations necessary to generate the reportable results. All spreadsheets created for the laboratory will be validated for use prior to implementation. Vendor software that requires validation will also be validated using one of these methods.

5.4.7.4.1. One method of validation consists of a manual confirmation of the calculations performed by the spreadsheet. This verification will be kept on file in the laboratory.

5.4.7.4.2. Other methods of validation may include comparison of data generated by the old validated sheet to the data generated by the new sheet, or comparison of a set of new software calculations against calculations of the same data from the old, validated software.

5.4.7.4.3. Validation is only required when changes are made to calculation cells but not when changes are made to cells that look up sample description data (non-numerical) in LIMS, or when the

changes are purely cosmetic (font, column width etc).

5.5. Equipment

5.5.1. The laboratory is furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). The laboratory does not use equipment that is outside its permanent control

5.5.2. Equipment and its software used for testing, calibration and sampling are capable of achieving the accuracy required and procedures ensure that the equipment complies with specifications relevant to the tests and/or calibrations concerned.

5.5.2.1. Calibration programs are established for key quantities or values of the instruments where these properties have a significant effect on the results. General equipment requirements are described in this section. Specific requirements are described in pertinent SOPs.

5.5.2.1.1. Calibration of analytical instrumentation is generally described the ECI SOP *Internal Quality Control Checks*, T020, current version. Specific requirements are contained in the test method SOPs governing the equipment.

5.5.2.1.2. Calibration and verification of support equipment is described ECI SOP *Support Equipment Calibration, Verification, and Monitoring*, T043, current version.

5.5.2.2. Before being placed into service, equipment (including that used for sampling) must be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use as required by the analytical methods or the SOPs.

5.5.3. Equipment is operated only by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) are readily available for use by the appropriate laboratory personnel. See the ECI SOPs *Routine Instrument Maintenance*, T066, current version, *Support Equipment Calibration, Verification, and Monitoring*, T043, current version, instrument manuals or the specific test method SOPs for these instructions.

5.5.4. Each item of equipment and its software used for testing and significant to the result is, when practical, be uniquely identified.

5.5.5. Records are maintained of each item of equipment and its software significant to the tests performed. The records shall include at least the following:

5.5.5.1. the identity of the item of equipment and its software;

5.5.5.2. the manufacturer's name, type identification, and serial number or other unique identification;

5.5.5.3. checks that equipment complies with the specification (see 5.5.2);

5.5.5.4. the current location, where appropriate;

5.5.5.5. the manufacturer's instructions, if available, or reference to their location;

5.5.5.6. dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;

5.5.5.7. the maintenance plan, where appropriate, and maintenance carried out to date;

5.5.5.8. any damage, malfunction, modification or repair to the equipment.

Items 1, 2 and 4 are kept in spreadsheets by the QA Department. Items required in item 5 are kept in the QA Department. Maintenance plans are kept in the ECI SOP *Routine Instrument Maintenance*, T066, current version. Records of calibration/verification of analytical equipment are kept in the analytical data. Records of calibration/verification of support equipment are kept by the QA Department. Records of maintenance are kept in maintenance logs with the equipment.

5.5.6. The laboratory has procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration. Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling. See the ECI SOPs *Routine Instrument Maintenance*, T-066, current version, *Support Equipment Calibration, Verification, and Monitoring*, T043, current version, or the specific test method SOPs for these instructions.

5.5.7. Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, must be taken out of service.

5.5.7.1. The equipment is isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory has “Out of Service” signs available to place on instrumentation and requirements to include the out of service notification in logbooks associated with the equipment.

5.5.7.2. The laboratory must examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and institute the "Control of nonconforming work" procedure (see 4.9). This is particularly important if support equipment is found to be out of tolerance during routine calibration cycles or if analytical equipment or reporting systems are found to have errors that may have been missed when used to generate earlier data.

5.5.8. Whenever possible, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

5.5.8.1. Support equipment is labeled with its calibration status whenever possible.

5.5.8.2. Analytical instrumentation is calibrated according to test method requirements and requires some sort of calibration or calibration verification with every use. Therefore, the calibration status is generally maintained in and inferred from the instrument data.

5.5.9. When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

5.5.9.1. Analytical Instrumentation must pass method calibration requirements prior to return to use. If the instrumentation has been subject to repairs or alterations, new detection limit studies and an IDOC may be required. When in doubt, check with QA personnel.

5.5.9.2. Support equipment must be calibrated or verified as required before use.

5.5.9.3. Calibration Standards, such as Class 2 weights and traceable thermometers require verification upon return from calibration. See the ECI SOP *Support Equipment Calibration, Verification, and Monitoring.* T043, current version, for more information.

5.5.10. When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks are carried out according to the procedures in the governing SOPs.

5.5.11. Where calibrations give rise to a set of correction factors, the laboratory procedures ensure that copies (e.g. in computer software, on calibration records, etc.) are correctly updated.

5.5.11.1. Interelement correction factors used in metals analysis, for example, must be updated through the software and saved appropriately.

5.5.11.2. Correction factors used on thermometers, for example, are listed on the thermometer.

5.5.12. Test and calibration equipment, including both hardware and software, must be safeguarded from adjustments which would invalidate the test and/or calibration results.

5.5.13. Support Equipment

5.5.13.1. In addition to analytical instruments, requirements for calibration 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, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices 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. Detailed requirements and procedures are contained in the ECI SOP *Support Equipment Calibration, Verification, and Monitoring*, T043, current version.

5.5.13.1.1. All support equipment shall be maintained in proper working order. The records of all repair and maintenance activities, including service calls, shall be kept.

5.5.13.1.2. All support equipment must be calibrated or verified at least annually, using references traceable to recognized a National Metrology Institute, such as NIST, when available, and bracketing the range of use.

The results of such calibration or verification are required to be within the specifications required of the application for which this equipment is used or the equipment is removed from service until repaired.

The laboratory must maintain records of established correction factors arising from these calibrations or verifications to correct all measurements.

5.5.13.1.3. Raw data records are retained to document equipment performance.

5.5.13.1.4. On each day the equipment is used, balances, ovens, refrigerators, freezers and water baths shall be checked and the results recorded. The acceptability for use or continued use is set according to the needs of the analysis or application for which the equipment is being used.

5.5.13.1.5. Volumetric dispensing devices (except Class A glassware and glass microliter syringes) used for quality-affecting measurements are checked for accuracy on a quarterly basis.

5.5.14. Instrument Calibration

5.5.14.1. Calibration of analytical instrumentation is addressed in general in the ECI SOP *Internal Quality Control Checks*, T020, current version.

5.5.14.2. Specifics of instrument calibration, including acceptance criteria, are contained in the technical SOP governing the analysis.

5.6. Measurement Traceability

5.6.1. All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory's program and procedures for the calibration of its equipment as well as traceability of standards and reagents is described in this section.

5.6.2. Measuring and test equipment with measuring functions used must be calibrated on at least an annual basis. Whenever possible, calibration is performed using reference standards or reference materials that are traceable to a national standard or other standard acceptable to the NELAP, DoD or customer, as applicable, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory ensures that the equipment used can provide the uncertainty of measurement needed.

5.6.3. Reference Standards and Reference Materials

5.6.3.1. Reference Standards –The laboratory has a program and procedure for the calibration of its reference standards. Reference standards, such as weights used for checking balances and reference thermometers, must be calibrated by a calibration laboratory accredited to ISO 17025 for the particular calibration provided. Reference standards of measurement held by the laboratory are used for calibration or verification only and for no other purpose. The specifics of the calibration program are contained in the ECI SOP *Support Equipment Calibration, Verification, and Monitoring*, T043, current version.

5.6.3.2. Reference Materials – Reference materials, where possible, are traceable to SI units of measurement, to certified reference materials, or to national or international standard reference materials. Internal reference materials are checked as far as is technically and economically practicable.

5.6.3.3. Intermediate Checks – Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials are carried out according to procedures and schedules defined in the appropriate technical SOPs.

5.6.3.4. The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

5.6.4. Documentation and Labeling of Standards, Reagents, and Reference Materials -- Documented procedures are in place for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory.

5.6.4.1. The laboratory retains records for all standards, reagents, reference materials, and media, including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if available), the date of receipt, and recommended storage conditions.

5.6.4.2. For original containers, if an expiration date is provided by the manufacturer or vendor it shall be recorded on the container. If an expiration date is not provided by the manufacturer or vendor it is not required.

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

5.6.4.4. All containers of prepared standards, reference materials, and reagents are labeled with a unique identifier and expiration date.

5.6.4.5. Procedures are in place to ensure prepared reagents meet the requirements of the method.

5.6.4.6. Standards, reference materials, and reagents shall not be used after their expiration dates unless their reliability is verified by the laboratory.

5.7. Sampling

5.7.1. The laboratory performs some sampling for customers, virtually all of it related to wastewater treatment. Additionally, the laboratory performs subsampling of samples provided by customers to provide aliquots for specific analyses.

5.7.1.1. For external sampling, the procedures are described in detail in the ECI SOP *Industrial Wastewater Sampling*, T101, current version. Customers provide sampling plans to the laboratory. The SOP describes the specifics of the processes and factors to be controlled or monitored.

5.7.1.2. Subsampling, as in obtaining a representative sample for analysis from a sample container, is described in technical SOPs that deal with sample preparation.

5.7.2. Where the customer requires deviations, additions or exclusions from the documented sampling procedure, these are recorded in detail with the appropriate sampling data and are included in all documents containing test and/or calibration results, and are communicated to the appropriate personnel.

5.7.3. The laboratory maintains procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.

5.7.4. Sampling records for external sampling include the date and time of sampling and any deviations from the sampling procedures that were requested or required.

5.8. Handling Samples and Test Items

5.8.1. The laboratory has procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. The procedures used to meet the requirements of this section are included in the ECI SOP T100 *Sample Receipt and Log-in Procedures*, current version.

5.8.2. The laboratory has a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system is designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system accommodates a sub-division of groups of items and the transfer of items within and from the laboratory, including all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates.

5.8.2.1. The system generates a laboratory code, which maintains an unequivocal link with the unique field ID code assigned to each sample.

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

5.8.2.3. The laboratory ID code is entered into LIMS and is the link that associates the sample with related laboratory activities such as sample preparation.

5.8.3. Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory consults the customer for further instructions before proceeding and shall record the discussion.

5.8.3.1. The laboratory maintains procedures to be used when samples show signs of damage, contamination, inadequate preservation, or other exceptions to the sample receipt policy.

5.8.3.2. If the sample does not meet the sample receipt acceptance criteria listed, sample receiving personnel notify the

appropriate project manager of the exceptions or questions, who, in turn, confer with the customer. The laboratory shall either:

5.8.3.2.1. Retain correspondence and/or records of conversations concerning the final disposition of rejected samples; or,

5.8.3.2.2. Fully document any decision to proceed with the analysis of samples not meeting acceptance criteria.

5.8.3.2.3. The condition of these samples shall be noted on the chain of custody or transmittal form and in LIMS.

5.8.3.2.4. The analysis data shall be appropriately qualified on the final report.

5.8.4. The laboratory has procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. These procedures are contained in the ECI SOP T100 *Sample Receipt and Log-in Procedures*, current version.

Note: Eurofins Calscience, Inc. does not provide secure, legal chain-of-custody procedures.

5.8.5. Additional Requirements – Sample Receipt Protocols

5.8.5.1. The laboratory has implemented procedures for verifying and documenting preservation.

5.8.5.2. The laboratory uses LIMS to create a permanent chronological record to document receipt of all sample containers. This record contains the following required information:

5.8.5.2.1. Client/project name,
5.8.5.2.2. Date and time of laboratory receipt,
5.8.5.2.3. Unique laboratory ID code, and,
5.8.5.2.4. The identification of the person making the entries.

5.8.5.3. During the login process, the following information shall be unequivocally linked to the log record using the LIMS.

5.8.5.3.1. The field ID code, which identifies each sample, shall be linked to the laboratory ID code in the sample receipt log.

5.8.5.3.2. The date and time of sample collection shall be linked to the sample and to the date and time of receipt in the laboratory.

5.8.5.3.3. The requested analyses (including applicable approved method numbers), linked to the laboratory ID code.

5.8.5.3.4. Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code.

5.8.5.4. All documentation, such as memos, chain of custody, or transmittal forms that are transmitted to the laboratory by the sample transmitter, is retained.

5.8.5.5. A complete chain of custody record form, if utilized, is maintained to document transfer of the sample to the laboratory.

5.8.5.5.1. For most samples, once the sample is inside the laboratory and the receiving process is completed, sample movement within the laboratory is not recorded, but can be inferred from documentation of analytical processes.

5.8.5.5.2. An internal chain-of-custody is available upon customer request.

5.8.6. The laboratory has a written sample acceptance policy, which is available to customers of the laboratory and other sampling personnel. This policy requires the following information be provided with each sample. The policy is included as an appendix in the ECI SOP T100 *Sample Receipt and Log-in Procedures*, current version.

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

5.8.6.2. Proper sample labeling to include 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;

5.8.6.3. Use of appropriate sample containers;

5.8.6.4. Adherence to specified holding times;

5.8.6.5. Sufficient sample volume to perform the necessary tests;

5.8.7. Additional Requirements – Sample Storage and Disposal

5.8.7.1. Samples shall be stored according to the conditions specified by preservation protocols. For most samples, this means that samples are refrigerated.

5.8.7.1.1. Samples that require thermal preservation shall be stored under refrigeration that is +/- 2°C of the specified preservation temperature unless

regulatory or method specific 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 shall be acceptable.

5.8.7.1.2. In practice, most samples are kept in the refrigerators for ease of retrieval.

5.8.7.1.3. Samples must be stored away from all standards, reagents, and food. Samples must be stored in such a manner to prevent cross contamination.

5.8.7.2. Sample fractions, extracts, leachates and other sample preparation products are stored according to specifications in the method and the requirements listed above.

5.8.7.3. The laboratory addresses disposal of samples, digestates, leachates and extracts and other sample preparation products in SOP T005, *Disposal of Laboratory Samples and Wastes*.

5.9. Quality Control for Environmental Testing

5.9.1. The laboratory has implemented quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data are recorded in such a way that trends are detectable and, where possible, statistical techniques are applied to the reviewing of the results. This monitoring is planned and reviewed and includes, but may not be limited to, the following:

5.9.1.1. regular use of certified reference materials and/or internal quality control using secondary reference materials;

5.9.1.2. participation in proficiency-testing programs;

5.9.1.3. replicate testing;

5.9.1.4. retesting or recalibration of retained items;

5.9.1.5. correlation of results for different characteristics of an item.

5.9.2. Quality control data are analyzed as soon as is feasible after analysis and, where they are found to be outside pre-defined criteria, planned action is taken to correct the problem and to prevent incorrect results from being reported.

5.9.3. Essential Quality Control Procedures

5.9.3.1. The laboratory has written protocols in place to monitor the following quality controls. The specific controls and their evaluations are contained in ECI SOP T020, *Internal Quality Control Checks*, current version, and in the appropriate test method SOPs.

5.9.3.1.1. positive and negative controls, as applicable to the test type, to monitor tests such as blanks,

LCSs, and matrix spikes;

5.9.3.1.2. tests to define the variability and/or repeatability of the laboratory results such as replicates, laboratory duplicates, and spiked duplicates;

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

5.9.3.1.4. measures to evaluate method capability, such as limit of detection and limit of quantitation or range of applicability such as linearity;

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

5.9.3.1.6. selection and use of reagents and standards of appropriate quality;

5.9.3.1.7. measures to assure the selectivity of the test for its intended purpose; and

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

5.9.3.2. All quality control measures are assessed and evaluated on an on-going basis and quality control acceptance criteria are used.

5.9.3.3. The laboratory has procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist.

5.9.3.4. The quality control protocols specified by the laboratory's SOP shall be followed. The laboratory ensures that the essential standards outlined in the Technical Module of the Standards (TNI or DOD V1M4, as applicable) or mandated methods or regulations (whichever are more stringent) are incorporated into their test method SOPs. When it is not apparent which is more stringent, the QC in the mandated method or regulations is to be followed.

5.9.4. Instruments are calibrated as described in Section 5.5 of this QAM and detailed in ECI SOP T020, *Internal Quality Control Checks*, current version, and the laboratory method SOPs.

5.9.5. Batch QC samples are prepared with each preparation batch prepared in the laboratory. A preparation batch is a batch of samples of the same quality system matrix not to exceed a total of 20 field samples. QC

samples are not counted as part of the twenty. Unless otherwise specified and justified in the test method SOP, the following QC samples are required. The test method SOP may reduce or increase this requirement.

5.9.5.1. Each batch must contain, where applicable; a Laboratory Control Sample, a Method Blank, a Matrix Spike sample and a Matrix Spike Duplicate or Matrix Duplicate sample. The preparation and specific evaluation criteria for each of these QC sample types are detailed in the laboratory method SOPs.

5.9.5.2. All quality control measures must be assessed and evaluated while analyses are on-going. Laboratory personnel use bench sheets or instrument software to record all raw data. These systems include the recording and evaluating of QC data at the same time as the sample data. QC data is used to determine the usability of sample data as described later in this section.

5.9.5.3. Specific requirements for QC samples and their evaluation are included in the ECI SOP T020, *Internal Quality Control Checks*, current version

5.9.6. Limits of Detection and Limits of Quantitation

The laboratory uses a combination of Limits of Detection and Limits of Quantitation ("Reporting Limits") to convey sensitivity for each analysis performed in the laboratory. Specific requirements and instructions for the determination of these limits are contained in the ECI SOP T006, *Determination of Detection Limits*, current version.

5.10. Reporting of Results

5.10.1. General Considerations

5.10.1.1. The result of each environmental test must be reported accurately, clearly, unambiguously and objectively as well as in accordance with any specific instructions included in the test method.

5.10.1.2. The results shall be reported in a test report and shall include all the information requested by the customer and necessary for the interpretation of the test results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4, below.

5.10.1.3. Instructions for generating test reports are located in the ECI SOP-T063, *LIMS*, current revision. See also SOP-T009, *Significant Figures, Rounding, and Reporting of Results*; SOP-T025, *Reporting of Tentatively Identified Compounds (TICs)*; and T-026, *Reporting of Data Qualifiers*.

5.10.2. Test Reports

Each test report shall include at least the following information. An exception is taken when "Preliminary Results" are provided to meet customer's rush turn-

around time requests. Preliminary reports are labeled as such on the cover and are always followed by the complete final report.

5.10.2.1. A Title. This laboratory titles its reports “Analytical Report”
5.10.2.2. The name and address of the laboratory;
5.10.2.3. The Work Order number is the unique identification of the test report. It is displayed on each page in order to ensure that the page is recognized as a part of the test report. Report pages are numbered as 1 of *n,* where “n” is the total number of pages.
5.10.2.4. The name and address of the customer;
5.10.2.5. identification of the test method used;
5.10.2.6. description of, the condition of, and unambiguous identification of the samples tested;
5.10.2.7. the date of receipt of the samples where this is critical to the validity and application of the results (See 5.10.11 below), and the date(s) of performance of the analysis or different analytical steps, as applicable;
5.10.2.8. reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results (this is rare in this laboratory);
5.10.2.9. the analytical results with the units of measurement;
5.10.2.10. the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;
5.10.2.11. where relevant, a statement to the effect that the results relate only to the samples tested;
5.10.2.12. a statement specifying that the client is specifically prohibited from making material changes to the report and, to the extent that such changes are made, Calscience is not responsible, legally or otherwise.

5.10.3. Test Reports

5.10.3.1. In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:

5.10.3.1.1. Deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;
5.10.3.1.2. Where relevant, a statement of compliance/non-compliance with requirements and/or specifications;
5.10.3.1.3. Where applicable, a statement on the estimated uncertainty of measurement. (Note: estimation of uncertainty in measurement is addressed in Section 5.6 of this document); information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit;
5.10.3.1.4. Wdditional information which may be required by specific methods, customers or groups of

customers.

5.10.3.2. In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:

5.10.3.2.1. The date of sampling
5.10.3.2.2. The customer's reference to the sampling site and other information as noted on the Chain of Custody.

5.10.4. The TNI standard notes that the section in ISO 17025 regarding Calibration Certificates (ISO/IEC 17025:2005(E), Clause 5.10.4) does not apply to environmental testing activities.

5.10.5. Opinions and interpretations

The laboratory does not offer opinions or interpretations of the data reported.

5.10.6. Testing and calibration results obtained from subcontractors

When the analytical report contains results of tests performed by subcontractors, these results are clearly identified. The subcontractor must report the results either in writing or electronically.

5.10.7. Electronic transmission of results

5.10.7.1. In the case of transmission of test or calibration results by telephone, e-mail, facsimile or other electronic or electromagnetic means, the requirements of this section (see also Section 5.4.7).

5.10.7.2. Most reports are submitted by electronic mail to the person requesting the analysis. Results may not be submitted to any other entities without the approval of the original requestor. A record of this approval must be maintained by the laboratory.

5.10.7.3. Electronic mail transmissions are accompanied by statements regarding confidentiality and privacy of information.

5.10.8. Format of reports

The format of the reports is designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse.

5.10.9. Amendments to test reports and calibration certificates,

5.10.9.1. When required, amendments are made by regenerating the entire report. Amended reports are labeled on the cover as "Supplemental Report #" where "#" is a sequential number, starting with 1. The Work Order number is also listed and the electronic file name is incremented with "_s#" to clearly identify the revision.

5.10.9.2. Such amendments are designed to meet all the requirements of this International Standard.

5.10.10. While rare, it is possible that ECI may be requested to produce abbreviated report at some times. If the request arises, ECI will maintain all of the information that would be required for the full report.

5.10.11. Additional Requirements

Reports must also include the following information, when applicable.

5.10.11.1. Time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to seventy-two (72) hours.

5.10.11.2. Results that are reported on a basis other than as received (*e. g.*, dry weight).

5.10.11.3. Any non-accredited tests shall be clearly identified as such to the client when claims of accreditation to this Standard are made in the analytical report or in the supporting electronic or hardcopy deliverables.

5.10.11.4. Clear identification of numerical results with values outside the calibration range.

End of Quality Manual

APPENDIX 1 - Definitions

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 TNI. The source of each definition, unless otherwise identified, is the TNI 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. (TNI)

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)

Analyst: The designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality. (TNI)

Analyte: A substance, organism, physical parameter, property or chemical constituent(s) for which an environmental sample is being analyzed. (TNI)

Analytical Uncertainty: A subset of Uncertainty in Measurement that includes all laboratory activities performed as part of the analysis. (TNI)

Assessment: The evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (*e.g.*, to the standards and requirements of TNI NELAP, DoD ELAP, others as necessary). (TNI)

Audit: A systematic and independent examination of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management, and reporting aspects of a system to determine whether QA/QC and technical activities are being conducted as planned and whether these activities will effectively achieve quality objectives. (TNI)

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 TNI-defined matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An **analytical batch** is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various environmental matrices and can exceed 20 samples. (TNI Quality Systems Committee)

Bias: The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value). (TNI)

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)

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.

Calibration: A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

1) In calibration of support equipment the values realized by standards are established through the use of reference standards that are traceable to the International System of Units (SI).

2) In calibration according to methods, the values realized by standards are typically established through the use of Reference Materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications. (TNI)

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

Calibration 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. (TNI)

Confirmation: Verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to:

- Second column confirmation;
- Alternate wavelength;
- Derivatization;
- Mass spectral interpretation;
- Alternative detectors; or
- Additional cleanup procedures. (TNI)

Conformance: An affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements. (ANSI/ ASQC E4-1994)

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 Integrity: The condition that exists when data are sound, correct and complete, and accurately reflect activities and requirements. (TNI)

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. (TNI)

Detection Limit: The lowest concentration or amount of the target analyte that can be identified, measured, and reported with confidence that the analyte concentration is not a false positive value. See Method Detection Limit. (TNI)

Document Control: The act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed. (ASQC)

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)

In-depth Data Monitoring: When used in the context of data integrity activities, a review and evaluation of documentation related to all aspects of the data generation process that includes items such as preparation, equipment, software, calculations, and quality controls. Such monitoring shall determine if the laboratory uses appropriate data handling, data use and data reduction activities to support the laboratory's data integrity policies and procedures.

Internal Standard: A known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method. (TNI)

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 Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample): A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst-specific precision and bias or to assess the performance of all or a portion of the measurement system. (TNI)

Legal Chain of Custody Protocols: Procedures employed to record the possession of samples from the time of sampling through the retention time specified by the client or program. These procedures are performed at the special request of the client and include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples by the laboratory. In addition, these protocols document all handling of the samples within the laboratory. (TNI)

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%. (TNI)

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

Matrix: The substrate of a test sample. (TNI)

Matrix Duplicate: A replicate matrix prepared in the laboratory and analyzed to obtain a measure of precision. (TNI)

Matrix Spike (spiked sample or fortified sample): A sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency. (QAMS)

Matrix Spike Duplicate (spiked sample or fortified sample duplicate): A second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte. (QAMS)

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. (TNI)

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)

National Environmental Laboratory Accreditation Program (NELAP): A Program of TNI through which recognized State Accreditation Bodies and Non-Governmental Accreditation Bodies accredit laboratories using the TNI Standards. (TNI)

National Institute of Standards and Technology (NIST): A federal agency of the US Department
of Commerce's Technology Administration that is designed as the United States national metrology institute (NMI). (TNI)

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

Positive Control: Measures taken to ensure that a test and/or its components are working properly and producing correct or expected results from positive test subjects. (TNI)

Precision: The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms. (TNI)

Preservation: Refrigeration and/or reagents added at the time of sample collection (or later) to maintain the chemical and/or biological integrity of the sample. (TNI)

Proficiency Testing: A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. (TNI) [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. (TNI)

Proficiency Test Sample (PT): A sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria. (QAMS)

Protocol: A detailed written procedure for field and/or laboratory operation (e.g., sampling, and analysis) which must be strictly followed. (EPA- QAD)

Quality Assurance: An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. (QAMS)

Quality Assurance (Project) Plan (QAPP): A formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EPA-QAD)

Quality Control: The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. (QAMS)

Quality Control Sample: A sample used to assess the performance of all or a portion of the measurement system. One of any number of samples, such as Certified Reference Materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking, intended to demonstrate that a measurement system or activity is in control. (TNI)
Quality Manual: A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users. (TNI)

Quality System: A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC. (ANSI/ ASQC E-41994)

Quality System Matrix: These matrix definitions are to be used for purposes of batch and quality control requirements:
Air and Emissions: Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbant tube, impinger solution, filter, or other device.
Aqueous: Any aqueous sample excluded from the definition of Drinking Water or Saline/Estuarine. Includes surface water, ground water effluents, and TCLP or other extracts.
Biological Tissue: Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.
Chemical Waste: A product or by-product of an industrial process that results in a matrix not previously defined.
Drinking Water: Any aqueous sample that has been designated a potable or potential potable water source.
Non-Aqueous Liquid: Any organic liquid with <15% settleable solids.
Saline/Estuarine: Any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.
Solids: Includes soils, sediments, sludges and other matrices with >15% settleable solids.

Quantitation Limits: Levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported at a specific degree of confidence. (TNI)

Raw Data: The documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, untabulated sample results, QC sample results, printouts of chromatograms, instrument outputs and handwritten records. (TNI)

Reagent Blank (method reagent blank): A sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps. (QAMS)

Reagent Water: Water in which no target analytes or interferences are detected as required by the analytical method. (TNI)

Reference Material: A material or substance with one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. (ISO Guide 30- 2.1)

Reference 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). (TNI)

Replicate Analyses: The measurements of the variable of interest performed identically on two or more sub-samples of the same sample within a short time interval. (TNI)

Sampling: Activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure. (TNI)

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

Selectivity: (Analytical chemistry) The capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances. (EPA-QAD)

Sensitivity: The capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. (TNI)

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. (TNI)

Standard: The document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of TNI and meets the approval requirements of TNI procedures and policies. (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)

Standard Reference Material (SRM): A certified reference material produced by the U.S. National Institute of Standards and Technology or other National Metrology Institute (NMI) and characterized for absolute content, independent of analytical method. (EPA-QAD)

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)

TNI: The NELAC Institute. www.nelac-institute.org

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), or, The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project. (TNI)

Uncertainty of Measurement (Measurement Uncertainty, Uncertainty): Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used. (VIM 2-26) A more colloquial (but less exact) definition could be "The range of values in which the true value would be statistically likely to occur due to variability within the test system." (ECI)

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

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

NOTE: In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

The result of verification leads to a decision either to restore in service, to perform adjustment, to repair, to downgrade, or to declare obsolete. In all cases, it is required that a written trace of the verification performed shall be kept on the measuring instrument's individual record.

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

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 (TNI), July 1998 Standards

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

Appendix 2 – Job Descriptions of Key Personnel

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 Operations Director, QA Manager, and Technical Managers (at ECI known as Group Leaders):

- ⇨ 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.

Quality Assurance Manager:

The Quality Assurance (QA) Manager has full authority through the Business Unit Manager in all matters relating to quality assurance and quality control systems. The QA Manager 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 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:

- ⇨ 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 Specialist:

The Quality Assurance Specialist has full authority through the QA Manager in matters dealing within the laboratory. The Quality Assurance Specialist can make recommendations to the QA Manager and regarding the suspension or termination of employees on the grounds of non-compliance with QA/QC procedures. An alternate Quality Assurance Specialist is always assigned. In the absence of the primary designate, the alternate will act in the Quality Assurance Specialist's capacity with the full authority of the position as allowed by ECI governing documents. In addition, the Quality Assurance Specialist 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 Quality Assurance (QA) Assistant reports to the QA Specialist and performs the following functions:

- ⇨ Assists the Quality Specialists and lab staff with internal audits, corrective action review, test method assessments and overall implementation of the QA program;
- ⇨ Performs daily balance checks and periodic thermometer checks;
- ⇨ Generates and reviews, in conjunction with the Quality Specialists, Control Charts and Method Detection Limit (MDL) studies;
- ⇨ Prepares logbooks for use in the laboratory;
- ⇨ 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 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.

APPENDIX 3 – LIST OF PHYSICAL LOCATIONS

Main Laboratory

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

Satellite Laboratory 1 "Lampson"

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

Satellite Laboratory 2 "Knott"

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

Concord, CA Service Center

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

APPENDIX 4 – ORGANIZATIONAL CHART

The organizational chart included in this manual was correct at the time of publication and shows the structure of the laboratory. The chart is kept current by the administrative office and can be obtained from the QA Department.