

QUALITY MANUAL

for

New England Regional Laboratory (NERL)
Office of Environmental Measurement and Evaluation (OEME)


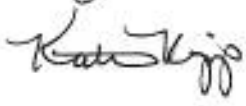

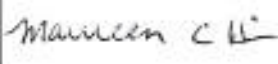

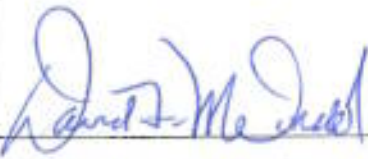


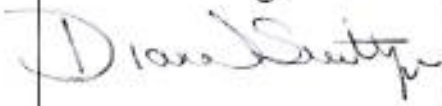
Including the
Ecosystems Assessment Unit (ECA)
Biology Laboratory
EMT Field Team
&
Investigations and Analysis Unit (EIA)
Chemistry Laboratory
EIA Field Team



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REVISION PAGE

Date	Rev#	Summary of Changes	Sections
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08/03/15	2	Updated LOQ acceptance criteria	22.3.2
08/03/15	2	Added detail on control chart development	22.4.1
03/28/16	3	Updated signature page	1
03/28/16	3	Updated ISO/IEC 17025:2005 reference	throughout
03/28/16	3	Updated scope to include reference to field methods	3
03/28/16	3	Updated accreditation reference from L-A-B to PJLA, added water quality monitoring	3.1
03/28/16	3	Updated Acronym List	3.5.2
03/28/16	3	Update OEME QAO role description	5.2.2
03/28/16	3	Update Technical Director responsibilities to ensure compliance with ISO/IEC 17025:2005	5.2.3 & 5.2.4
03/28/16	3	Update Table 5-1: Key Personnel & Back-up Personnel	5
03/28/16	3	Inclusion of confidentiality statement on electronic release of data	10.1
03/28/16	3	Added detail on who can initiate Corrective Actions	14.1
03/28/16	3	Updated use of control charts	22.4.1
03/28/16	3	Updated frequency of thermometer calibration verification	24.1.4
03/28/16	3	Replaced Sample Receipt form with correct version	Figure 26-2
03/28/16	3	Corrected field data reporting	28.1.3
03/28/16	3	Updated Organizational Charts	Appendix B
03/28/16	3	Updated L-A-B Certification to PJLA Certification	Appendix D

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SECTION 3

INTRODUCTION AND SCOPE (ISO/IEC 17025:2005(E), Clause 2)

The purpose of this *Quality Manual* (QM) is to outline the management system for US EPA New England Regional Laboratory (NERL), managed as part of the Office of Environmental Measurement and Evaluation (OEME) within EPA Region 1. NERL includes the Ecosystem Assessment Unit (ECA) with the Ecology Monitoring Team (EMT) and Biology Laboratory, and the Investigations and Analysis Section (EIA) with the Chemistry Laboratory and Investigations Team. For the Biology Laboratory, the *Quality Manual* encompasses all facets of laboratory activity performed by the Toxicity Testing, Microbiology, PCR, Chlorophyll and Milestone laboratories as well as the field methods included in the ISO/IEC 17025:2005 scope of accreditation.. For the Chemistry Laboratory, the *Quality Manual* encompasses all facets of the Chemistry laboratory as well as the field methods included in the ISO/IEC 17025:2005 scope of accreditation, but not including the All Hazard Receipt Facility (AHRF). The objective of the *Quality Manual* is to provide consistent documented objectives and policies that are applicable to and used by laboratory and field operations. The laboratory management shall ensure that these policies and objectives are understood and implemented by all laboratory personnel concerned. The documentation within this manual is intended to identify the necessary activities that are to be implemented to assure the appropriate level of quality to satisfy laboratory and project specific data quality objectives (DQOs) in testing and studies conducted by NERL.

The *Quality Manual* sets the standard under which all laboratory operations are performed, including OEME/NERL's organization, objectives, and operating philosophy. As a government facility, OEME/NERL is a non-profit organization and therefore, the *Quality Manual* has been prepared to assure conformance as applicable with ISO/IEC 17025:2005 requirements that are relevant to the scope of environmental testing services.

This *Quality Manual* is a sub-component of the *EPA New England Quality Management Plan* (QMP) <http://www.epa.gov/region1/lab/qa/qmp/index.html>. The QMP is prepared and maintained by the QA Unit for all EPA New England environmental data operations. The regional memorandum *EPA New England's Commitment to Implementing the Regional Quality System and Upcoming Mandatory QA Training*, 9/20/2011, issued by senior management, reaffirms EPA New England's commitment to implement a regional Quality System.

3.1 Scope of Testing

All testing conducted by NERL falls under this *Quality Manual*. In August 2015 the laboratory was ISO/IEC 17025:2005 certified by the Perry Johnson Laboratory Accreditation, Inc. (PJLA) for a series of methods. Refer to Appendix

D for the PJLA Scope of Accreditation for U.S. EPA Region 1 New England Regional Laboratory.

The laboratory provides chemistry, biological, physical and microbiological analyses. The majority of testing is done for soil and water samples for Superfund sites, NPDES and RCRA investigations (enforcement or non-enforcement), ambient water quality monitoring and air analyses (PAMS and air toxics). Emergency and enforcement samples are the highest priority for the laboratory; they are always accepted and prioritized. If necessary, routine work is then rescheduled or contracted out.

3.2 Components of the Quality System

The quality system for the laboratory comprises many components which serve to accomplish the following:

- Implementation of a comprehensive QA program which relies on documented procedures, a well trained staff, easy to understand reports, prompt laboratory results, and strong management support;
- Availability of the quality documentation for use by the laboratory personnel;
- Audits, reviews, and corrective actions;
- Implementation of essential quality control and data verification procedures;
- Continuous efforts toward improvement into every activity of the laboratory; and
- Development and implementation of procedures that will result in scientifically sound and legally defensible data.

This *Quality Manual* and the Standard Operating Procedures (SOPs) referred to in the document address components of NERL's Quality System including:

- Ethics Policy
- Personnel Qualifications
- Sample Management
- Training
- Analytical Procedures
- Analytical Standards Requirements
- Laboratory Documentation
- QC Procedures
- Data Reduction, Reporting and Internal Verification
- Performance And Systems Audits
- Corrective Action Policy and Procedures
- QA Reports to Management

3.3 Management of the *Quality Manual*

This *Quality Manual* is maintained current and distributed under the responsibility of the laboratory Quality Assurance Officers (QAOs), and undergoes annual review by the QAOs, EIA and ECA Technical Directors and Unit Chiefs, all of whom must, when significant revisions are made, approve the document prior to release.

The *Quality Manual* is a controlled document (Refer to Section 6) and is maintained and distributed through the OEME/NERL Lotus Notes Lab SOP Database (a.k.a. Lab SOP Database) under "Plans & Policies". Superseded electronic versions of the *Quality Manual* are archived in the database; superseded original signed hardcopy versions are maintained in ECA and EIA central files. The QM is reviewed annually at the Quality System Management Review. At that time, or at any time during the year, if significant changes are identified, the QM is revised, increasing the revision number by one. The specific areas of revision are identified the Revision Page. The signature page of the revised *Quality Manual* (Section 1) is re-signed. Minor changes are tracked using a correction page. Personnel are required to read and attest to the most current version of the *Quality Manual*.

3.4 References

References used by the NERL *Quality Manual* include but are not limited to:

1. ISO/IEC 17025:2005 *General Requirements for the Competence of Testing and Calibration Laboratories*.
2. *National Environmental Laboratory Accreditation Conference (NELAC) 2003 Standards*, effective July 1, 2005.

3.5 Glossary and Acronyms Used

The laboratory conforms to ISO 9000 for general definitions related to quality and to ISO/IEC 17000 definitions specifically related to certification and laboratory accreditation. In addition, the laboratory defines commonly used terms in Section 3.5.1.

3.5.1 Glossary

Aliquot - A measured portion of a sample, or solution, taken for sample preparation and/or analysis.

Analysis date/time - The date and time of the injection of the sample, standard, or blank into an analytical instrument.

Batch - A group of samples, extracts or digestates that are analyzed at the same time and, where applicable, within the same calibration sequence. An analytical batch, excluding quality control samples, typically should not to exceed 20 samples.

Holding time - The period of time during which a sample can be stored after collection and preservation without significantly affecting the accuracy of the analysis. For extracts the period of time after extraction during which an extract can be stored without affecting the accuracy of the analysis.

Insufficient quantity - When there is not enough volume or weight to perform any of the required operations: sample analysis for extraction, percent moisture, MS/MSD, etc.

Laboratory Control Sample (LCS) - However named, such as Laboratory Fortified Blank (LFB), spiked blank or another QC check sample (QCS). A sample matrix, free from the analytes of interest, spiked with 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.

Laboratory Fortified Blank (LFB) - An aliquot of reagent water or other blank matrix to which known quantities of the method analytes and all preservation compounds are added in the laboratory- this can be a secondary source standard.

Matrix - The substrate of a Test Sample.

Field of Accreditation Matrix

Drinking Water
Non-Potable Water
Solid and Chemical Materials
Biological Tissue
Air and Emissions

Quality System Matrix - used for purposes of batch and QC requirements

Aqueous
Drinking Water
Saline/Estuarine
Non-aqueous Liquid
Biological Tissue
Solids

Chemical Waste
Air and Emissions

Quality Assurance (QA) - A system of activities whose purpose is to provide to the producer or user of a product or a service the assurance that meets defined standards or quality with a stated level of confidence (Ref. J. Taylor, *Quality Assurance of Chemical Measurements*, 1987). This is the total integrated program for assuring the reliability of the data generated in the laboratory.

Quality Assurance Project (or Program) Plan (QAPP) - A document describing in comprehensive detail the necessary QA, QC and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

Quality Control (QC) - The system of activities whose purpose is to control the quality of a product or service so that it meets the needs of the users (Ref. J Taylor, *Quality Assurance of Chemical Measurements*, 1987). This is the routine application of specific, well-documented procedures.

Quality Control Sample (QCS) - A Quality Control Sample obtained from a second source (different from the source of calibration standards).

Quality Manual (QM) - A document describing management policies, objectives, principles, and general procedures outlining the techniques by which the laboratory produces data of known and accepted quality.

Sample - A portion of material to be analyzed that is contained in single or multiple containers and identified by a unique sample number.

Sample Delivery Acceptance - The point in time at which the laboratory determines that it can proceed with the analytical work. Sample delivery acceptance follows receipt and inspection of the samples and complete definition of analyses required.

Standard Operating Procedure (SOP) - A detailed, written description of a procedure designed to systematize and standardize the performance of the procedure. An "x" after the SOP title indicates most recent version.

Target Analyte List (TAL) - A list of inorganics that are identified and quantified as outlined in the applicable SOPs.

Target Compound List (TCL) - A list of compounds that are identified and quantified as outlined in the applicable SOPs.

Work Cell – A well-defined group of analysts that together perform the method analysis. The members of the group and their specific functions within the work cell must be fully documented.

3.5.2 Acronyms

A list of acronyms used in this document and incorporated references are:

AB	–	Accrediting Body
ANSI	–	American National Standards Institute
ASQC	–	American Society for Quality Control
ASTM	–	American Society for Testing and Materials
Blk	–	Blank
°C	–	degrees Celsius
cal	–	Calibration
CAS	–	Chemical Abstract Service
CCV	–	Continuing Calibration Verification
CHP	–	Chemical Hygiene Plan
CID	–	Criminal Investigation Division
CIS	–	Chemical Inventory System
CO	–	Contracting Officer
COC	–	Chain of Custody
CV	–	Coefficient of Variation
DO	–	Dissolved Oxygen
DOC	–	Demonstration of Capability
EPA	–	Environmental Protection Agency
ECA	–	Ecosystems Assessment Unit
EIA	–	Environmental Investigation and Analysis Unit
EMT	–	Ecology Monitoring Team
EQA	–	Environmental Quality Assurance Unit
ESAT	–	Environmental Services and Analysis Team
g/L	–	Grams per Liter
GC/MS	–	gas chromatography/mass spectrometry
ICP-MS	–	inductively coupled plasma-mass spectrometry
ICV	–	Initial calibration verification
IDC	–	Initial Demonstration of Capability
ISO/IEC	–	International Organization for Standardization/International Electrochemical Commission
lb/in ²	–	Pound per Square Inch
LCS	–	Laboratory control sample
LFB	–	Laboratory fortified blank
LIMS	–	Laboratory Information Management System
LOD	–	Limit of Detection
LOEC	–	Lowest Observed Effect Concentration
LOQ	–	Limit of Quantitation
MDL	–	Method Detection Limit

mg/Kg	–	Milligrams per Kilogram
mg/L	–	Milligrams per Liter
MPN/100ml	–	Most Probable Number per 100 milliliters of sample
MS	–	Matrix Spike
MSD	–	Matrix Spike Duplicate
NELAC	–	National Environmental Laboratory Accreditation Conference
NELAP	–	National Environmental Laboratory Accreditation Program
NERL	–	New England Regional Laboratory
NOEC	–	No Observed Effect Concentration
NIST	–	National Institute of Standards and Technology
OEME	–	Office of Environmental Measurement and Evaluation
OEP	–	Office of Ecosystem Protection
OES	–	Office of Environmental Stewardship
OSC	–	On-Scene Coordinator
OSRR	–	Office of Site Remediation and Restoration
PAMS	–	Photochemical Assessment Monitoring Stations
PT	–	Proficiency Test(ing)
PTP	–	Proficiency Testing Provider
PTPA	–	Proficiency Testing Provider Accreditor
QA	–	Quality Assurance
QAP	–	Quality Assurance Plan
QAPP	–	Quality Assurance Project Plan
QC	–	Quality Control
QM	–	<i>Quality Manual</i>
QMP	–	Quality Management Plan
RL	–	Reporting level
RPD	–	Relative percent difference
RPM	–	Remedial Project Manager
RSD	–	Relative standard deviation
SOPs	–	Standard operating procedures
SRM	–	Standard Reference Material
spk	–	Spike
std	–	Standard
TDF	–	Technical Direction Form (for work assigned to ESAT)
TNI	–	The NELAC Institute
TO	–	Task Order
TOCOR	–	Task Order Contract Officer Representative
ug/L	–	Micrograms per Liter
ug/Kg	–	Micrograms per Kilogram
UV	–	Ultraviolet
VOC	–	Volatile Organic Compound
WET	–	Whole Effluent Toxicity
WIP	–	Work in Progress

SECTION 4

ORGANIZATION (ISO/IEC 17025:2005(E), Clause 4.1)

OEME/NERL is a legally identifiable government organization (Federal Employee Number: 31-1575142). It is responsible for carrying out testing activities that meet the requirements of the ISO/EIC 17025:2005 Standard, state and federal regulations, and that meet the needs of clients. Through application of the policies and procedures outlined in this Section and throughout the *Quality Manual*,

- OEME assures that it is impartial and that personnel are free from undue commercial, financial, or other undue pressures that might influence their technical judgment.
- Management and technical personnel have the authority and resources to carry out their duties and have procedures to identify and correct departures from the laboratory's management system.
- Personnel understand the relevance and importance of their duties as related to the maintenance of the laboratory's management system.
- Ethics and data integrity procedures (Refer to Appendix A and Sections 5 and 19) ensure personnel do not engage in activities that diminish confidence in the laboratory's capabilities.
- Confidentiality is maintained.
- OEME ensures the continuity of quality management practices when faced with organizational or funding changes.

4.1 Organization

EPA New England has responsibility for federal matters relating to the protection of the environment within the six New England states. EPA New England is composed of 6 major offices, 5 of which are located at 5 Post Office Square in Boston, these include: the Office of the Regional Administrator (ORA), the Office of Ecosystem Protection (OEP), the Office of Environmental Stewardship (OES), the Office of Site Remediation and Restoration (OSRR), and the Office of Administration and Resource Management (OARM). Refer to Appendix B-4 for the EPA New England Region organizational chart which is also available at: http://www.epa.gov/aboutepa/orgchart_rl.html.

The sixth office, the Office of Environmental Measurement and Evaluation (OEME), is located at and encompasses the New England Regional Laboratory (NERL) at 11 Technology Drive in North Chelmsford, Massachusetts. OEME is the scientific support organization for the Region and consists of three operational units, the Quality Assurance Unit (EQA), the Ecosystems Assessment Unit (ECA) and the Investigations and Analysis Unit (EIA). Refer to Appendix B-3 for the OEME organizational chart which is also available at:

<http://www.epa.gov/region1/about/pdfs/orgcharts/OEME.pdf>.

The EIA and ECA Unit Chiefs (a.k.a. Managers) report to the Director of OEME. Both the EIA Chemistry Laboratory and ECA Biology Laboratory rely on support functions provided through the Director's office including such functions as waste management, health and safety, purchasing, and environmental management.

The quality management system described in this *Quality Manual* applies to data activities conducted by NERL personnel within the NERL facility, at sites outside of NERL, and in temporary or mobile laboratory units.

Additional information regarding responsibilities, authority and interrelationship of personnel who manage, perform or verify testing is included in Sections 5 and Section 20. These Sections also include information on supervision, training, technical management, job descriptions, quality personnel, and appointment of deputies for key managerial personnel.

NERL has the resources and authority to operate a quality management system that is capable of identifying departures from that system during testing, initiating actions to minimize or prevent departures, and promoting continuous improvement.

4.1.1 Biology Laboratory Organization

The Ecosystems Assessment Unit, which includes the Biology Laboratory, organization chart is provided in Appendix B-1 and as it is currently constructed includes:

- Microbiology Laboratory
- PCR Laboratory
- Toxicity Testing Laboratory
- Milestone Laboratory
- Chlorophyll Laboratory

Each laboratory is supervised by a Laboratory Lead who oversees routine individual laboratory activities. Individuals perform multiple functions within the Biology Laboratory. The Biology Laboratory QAO is responsible for data quality of laboratory products. The Biology Laboratory is under the ECA and its manager. On-site ESAT contractors perform laboratory functions within all of the laboratories.

4.1.2 Chemistry Laboratory Organization

The Investigations and Analysis Unit, which includes the Chemistry Laboratory, organization chart is provided in Appendix B-2. Analytical work within the Chemistry Laboratory is organized by department. There are currently seven technical teams:

- Field Chemistry
- GC and HPLC
- Air Toxics
- Volatile Organics
- Metals
- Wet Chemistry
- BNA Organics

The technical teams are flexible, interdisciplinary groups of laboratory staff who perform the testing procedures from start to finish, including scheduling, sample preparation, sample analysis and data reduction, report preparation and data review. Requests for analytical work that do not fall within these groups is performed by the best qualified team or contracted out to an outside laboratory.

The laboratory structure provides a means for communication from the bench level up to the Unit Chief (Chemistry Laboratory Manager). On-site ESAT contractors perform laboratory functions within all of the laboratories.

4.2 Conflict of Interest and Undue Pressure

The organizational structure indicated above minimizes the potential for conflicting or undue interests that might influence the technical judgment of analytical personnel. NERL applies its Laboratory Ethics Policy and the Principles of Scientific Integrity (Appendices A-1 and A-2, respectively). Personnel attest to these policies annually through the required Laboratory Annual Ethics and Data Integrity Refresher Training. In addition, procedures are in place to prevent outside pressures or involvement in activities that may affect competence, impartiality, judgment, operational integrity, or the quality of the work performed at the laboratory. NERL conforms to the EPA Scientific Integrity Policy, 2/16/2012

http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf, which promotes a culture of scientific integrity and protects scientists from undue coercion or influence regarding the scientific integrity of their work.

As federal employees, all NERL scientists must conform to Standards of Ethical Conduct for Employees of the Executive Branch (5 C.F.R. 2635), EPA Supplemental Standards of Ethical Conduct (5 C.F.R. 6401), and the criminal

conflict of interest statutes (18 U.S.C. 201-209). When applicable, personnel file Confidential Financial Disclosure Reports (OGE Form 450).

In the case where a Technical Director also assumes responsibility as the QAO (e.g., Biology Team Leader), procedures are in place to ensure independent review of their work. Currently, toxicity testing data is reviewed by the Team Leader and/or the ECA Unit Chief. Also, during internal audits, the Toxicity Testing Laboratory is audited by another Laboratory Lead.

Specific sample receipt procedures are in place to address issues of potential conflicts of interest when considering requests for analytical support.

Provisions including policies and procedures to prevent political, commercial, financial or other influences that may negatively affect the quality of the work or negatively reflect on the competence, impartiality, judgment or operational integrity are described in the EPA Scientific Integrity Policy and Standards of Ethical Conduct as described above.

SECTION 5

MANAGEMENT (ISO/IEC 17025:2005(E), Clause 4.2)

NERL maintains a management system that is appropriate to the scope of its activities.

5.1 Management Requirements

EPA New England Senior Management reaffirmed its commitment to quality management in the regional memo EPA New England's Commitment to Implementing the Regional Quality System and Upcoming Mandatory QA Training, 9/20/2011. The OEME Officer Director is part of the Senior Management structure.

The OEME Management Team includes the Office Director and Deputy Office Director, and ECA, EIA and EQA Unit Chiefs. The NERL Laboratory Management Team also includes the ECA and EIA Laboratory Technical Directors. OEME documents its commitment to good professional practice and to the quality of its products in its Quality Policy statement in Section 5.3.

OEME management has overall responsibility for the technical operations and the authority needed to generate the required quality of laboratory operations. Management ensures communication within the organization to maintain an effective management system and to communicate the importance of meeting customer, statutory, and regulatory requirements. Management assures that the system documentation is known and available so that appropriate personnel can implement their part. When changes to the management system occur or are planned, managers ensure that the integrity of the system is maintained. Managers implement, maintain, and improve the management system, identify noncompliance with the management system of procedures, and ensure this *Quality Manual* is current and accurate. Managers initiate actions to prevent or minimize noncompliance.

Management is responsible for carrying out testing activities that comply with the requirements of the ISO/IEC 17025:2005 Standard, conform to state and federal regulations and meet the needs of the client. Management ensures technical competence of personnel operating equipment, performing tests, evaluating results, or signing reports, and limits authority to perform laboratory functions to those appropriately trained and/or supervised. Refer to Section 20 for a description of Personnel requirements. Management is responsible for defining the minimal level of education, qualifications, experience, and skills necessary for all positions in the laboratory and assuring that technical staff have demonstrated capabilities in their tasks. Management works with the EPA Human Resources

Shared Service Center to hire personnel who meet knowledge, skills and experience requirements specified for the job position. Training is kept up to date as described in Section 20 through employee performance review.

Management bears specific responsibility for maintenance of the quality management system. This includes defining roles and responsibilities of personnel, approving documents, providing required training, providing a procedure for confidential reporting of data integrity issues, and periodically reviewing data, procedures, and documentation. Management ensures that audit findings and corrective actions are completed within required time frames.

It is the policy of OEME that each manager designates backup staff to maintain continuity of operation during absences (Table 5-1). For emergencies, EPA New England has documented its continuity plan in a formal document entitled Continuity of Operations for EPA-New England: <http://rl-gis-web.ri.epa.gov:9876/coop/coop.htm>. This document includes plans for maintaining vital services, including laboratory operations, in the event of an emergency.

5.2 Management Roles and Responsibilities

The roles and responsibilities specific to the following positions are further defined in individual Performance Agreements.

5.2.1 OEME Office Director

The OEME Office Director (Director) is responsible for the overall quality, safety, financial, technical, human resource and service performance of NERL. The Director, in conjunction with EPA New England senior management, provides the resources necessary to implement and maintain an effective quality and data integrity program.

In addition, the Director ensures that personnel are free from any commercial, financial and other undue pressures that might adversely affect the quality of their work. The Director also ensures that all personnel have the appropriate education and training to properly carry out the duties assigned to them and ensures that this training has been documented.

5.2.2 OEME Quality Assurance Officer

The QAO position serves as a focal point for QA/QC and is responsible for the oversight and review of quality control data. (Refer to organizational Chart Appendix B-3) The QAO's training, including QA/QC training, and proof of experience in QA/QC procedures, knowledge of analytical methods, and the laboratory's management system are available in EPA personnel files.

Responsibilities:

- Managing Quality System of Chemistry Laboratory, Biology Laboratory and Field Sampling QA program;
- Ensure the chemistry and biology laboratories as well as the applicable field sampling methods are in compliance with ISO/IEC 17025:2005;
- Organizing, scheduling, conducting and documenting internal performance; audits and reviews (PT samples and QC check samples);
- Organizing, scheduling, conducting and documenting internal systems; audits and reviews without outside (managerial) influence;
- Initiating and monitoring corrective actions;
- Periodic verification of the preparation and verification of analytical standards;
- Monitoring general QA practices;
- Maintaining records and archives of PT results, audit comments, MDL and DOC studies, and customer inquiries about data quality;
- Reviewing SOPs, and approving SOPs in concurrence with the Unit Chief;
- Monitoring laboratory performance in the areas of holding times, turnaround times, etc.;
- Routine reports to management;
- Reviewing the NERL *Quality Manual* for needed changes;
- Advising the Director and/or Unit Chiefs on QA issues;
- Maintaining knowledge of analytical test methods for which data review is performed and of quality system as defined under ISO/IEC 17025:2005 ; and
- Monitoring and maintaining laboratory certifications.

Authority:

The QA Officer has authority within the laboratory on all issues dealing with data quality and can require that procedures be amended or discontinued, or analyses suspended or repeated.

5.2.3 OEME ECA Unit

The QA activities of the ECA Unit are directed by the Unit Chief. The implementation of the QA program within the Biology Laboratory is the responsibility of the Biology Laboratory Manager and the Biology Laboratory QA Officer. In addition, all analysts within the laboratory play a vital role in assuring the quality of their work. Responsibilities and levels of authority within the ECA Unit are described below.

5.2.3.1 ECA Unit Chief (Manager)**Responsibilities:**

- Ultimate responsibility for the quality of data produced by ECA;
- Responsible for the unit following the EPA Region 1 QMP and the NERL *Quality Manual*;
- Conducts annual planning process with OEP, OSRR, and states and tribes to identify and prioritize assistance needs and projects, and agree on field and lab projects for the field season;
- Works with the OEME management to discuss the various ECA projects and coordinate OEME support as needed from EIA and EQA;
- Reports to OEP and OSRR management and other customers on status of projects and requested assistance at end of year;
- Reviews, edits, and approves ECA QAPPs, SOPs, policies and final reports;
- Responsible for ECA data management, both electronically on the SA/ECA subdirectory and the printed filing system (project folders);
- Implements applicable Region 1 Field Operations Group (FOG) standards;
- Defines staff qualifications; verifies that staff has appropriate training and experience to perform their assigned responsibilities. An individual training folder is maintained for health and safety, sampling, analytical, and other required specialized training related to the individual duties; and
- Annual review of the Quality System of the Biology Laboratory to ensure the suitability and effectiveness of its program, and ensure corrective actions are carried out in a timely manner.

Authority:

The Unit Chief is the final authority within the Biology Laboratory on all issues dealing with data quality. The Unit Chief has the authority to accept or reject data based on compliance with the well-defined QC criteria, or based on technical reasons. These circumstances must be well documented and any need for corrective action must be defined and initiated.

5.2.3.2 Ecology Monitoring Team - Field Team Leader (ECA Field Technical Director)

Responsibilities:

- Responsible (or designee) for communication between the Boston office and the ECA sampling team;
- Assigns a Project Manager (PM) to each accepted project;
- Reports to the Unit Chief on projects progress, activities, assessment, problems, and deficiencies;
- Maintains and reviews QAPPs, site specific SAPs, and SOPs for projects within the team. The team leader is responsible for maintaining QA of the team members as QAO of the Field team;

- Reviews and updates the EMT Generic and existing Site Specific QAPPs and SOPs annually to ensure the QAPPs and SOPs are current and accurate;
- Convenes team meetings on an as needed basis; and
- Responsible for secondary review of field activities and data.
- Ensure the ECA field methods included within the scope of accreditation under ISO/IEC 17025:2005 are in compliance with ISO/IEC 17025:2005

5.2.3.3 Biology Laboratory Manager/Leader (Technical Director for Biology)

The Biology Laboratory Leader is a full-time laboratory staff member who manages the Biology Laboratory operations, provides technical support and oversees data reporting. If the Biology Team Leader is absent for (fifteen (15) calendar days or more), a deputy (see Table 5-1 below) with appropriate qualifications will perform the Leader's duties. Beyond a thirty-five (35) calendar day absence, management will notify the primary accreditation body in writing of the absence of the Biology Team Leader and the appointment of the deputy.

Responsibilities:

- Reports to the Unit Chief on projects progress, activities, assessment, problems, and deficiencies;
- Reviews all data products prior to release coming out of the Biology Laboratory;
- Provides overall oversight of the following Biology Laboratories:
 - Microbiology
 - PCR
 - Milestone
 - Chlorophyll
 - Toxicity testing, and
- Interacts with customers on laboratory requests to assure the laboratory can meet client requirements and proper planning documentation in place.
- Ensure the Biology laboratories are in compliance with ISO/IEC 17025:2005;

5.2.3.4 Technical Directors for Toxicity Testing and Microbiology and Individual Lab Leads

The Technical Directors for the Toxicity Testing and Microbiology Laboratories are full-time laboratory staff members who respectively manage the Toxicity Testing and Microbiology Laboratory operations, provide technical support and report data. If a Laboratory Technical Director is absent a period of time exceeding 15 consecutive calendar days, the ECA Unit Chief will appoint a deputy with appropriate qualifications to perform the Laboratory Technical

Director duties. In anticipation of extended absences, management will notify the primary accrediting authority in writing.

Responsibilities:

- Ensure the Microbiology and Toxicity Testing laboratories are in compliance with ISO/IEC 17025:2005;
- Monitoring performance data and the validity of the analyses for the laboratory;
- Schedule and oversee, through the ESAT TOCOR, work performed by ESAT contractors as well as the EPA toxicity lab team; and
- Maintaining current SOPs for analytical procedures.

5.2.3.5 Biology Laboratory Quality Assurance Officer (QAO)

The QAO serves as a focal point for QA/QC and is responsible for the oversight and review of quality control data. (Refer to organizational Chart Appendix B-1) The QAO's training, including QA/QC training, and proof of experience in QA/QC procedures, knowledge of analytical methods, and the laboratory's management system are available in EPA personnel files.

Responsibilities:

- Managing Biology Laboratory QA program;
- Organizing, scheduling, conducting and documenting internal performance; audits and reviews (PT samples and QC check samples);
- Organizing, scheduling, conducting and documenting internal systems; audits and reviews without outside (managerial) influence;
- Initiating and monitoring corrective actions;
- Periodic verification of the preparation and verification of analytical standards;
- Monitoring general QA practices;
- Maintaining records and archives of PT results, audit comments, MDL and DOC studies, and customer inquiries about data quality;
- Reviewing SOPs, and approving SOPs in concurrence with the Unit Chief;
- Monitoring laboratory performance in the areas of holding times, turnaround times, etc.;
- Routine reports to management;
- Reviewing the NERL *Quality Manual* for needed updates;
- Advising the Unit Chief on QA issues;
- Maintaining knowledge of analytical test methods for which data review is performed and of quality system as defined under ISO/IEC 17025:2005 ; and
- Monitoring and maintaining laboratory certifications.

Authority:

The QA Officer has authority within the laboratory on all issues dealing with data quality and can require that procedures be amended or discontinued, or analyses suspended or repeated.

5.2.3.6 Biology Laboratory Personnel

Responsibilities:

- Having a working knowledge of the QA program as documented in this *Quality Manual*;
- Reading and attesting to SOPs, plans and other documents as required by management;
- Ensuring that all work is generated in compliance with the QM and applicable written SOPs;
- Maintaining current SOPs for analytical procedures;
- Ensuring that all documentation related to their work is complete and accurate;
- Providing management with immediate notification of quality problems; and,
- Providing secondary review of data and QC for selected analyses in accordance with Biology Laboratory product review requirements.

5.2.4 OEME EIA Unit

The QA activities of the EIA Unit are directed by the Unit Chief. The implementation of the QA program within the Chemistry Laboratory is the responsibility of the Chemistry Laboratory Manager and the QA Officer. In addition, all analysts within the laboratory play a vital role in assuring the quality of their work. Responsibilities and levels of authority within the EIA Unit are described below.

5.2.4.1 EIA Unit Chief (Manager)

Responsibilities:

- Ultimate responsibility for the quality of data produced by EIA;
- Responsible for the unit following the EPA Region 1 QMP and the NERL *Quality Manual*;
- Conducts annual planning process with OES, OSRR, and other customers to identify and prioritize assistance needs and projects, and agree on field and lab projects for the field season;
- Works with the OEME management to discuss the various EIA projects and coordinate OEME support as needed from ECA and EQA;
- Reports to OES and OSRR management and other customers on status of projects and requested assistance at end of year;
- Reviews and approves EIA QAPPs, SOPs, policies and final reports.

- Responsible for EIA data management, both electronically and the printed filing system (project folders);
- Implements applicable Region 1 Field Operations Group (FOG) standards;
- Defines staff qualifications; verifies that staff has appropriate training and experience to perform their assigned responsibilities. An individual training folder is maintained for health and safety, sampling, analytical, and other required specialized training related to the individual duties; and
- Annual review of the Quality System of the Chemistry Laboratory to ensure the suitability and effectiveness of its program, and ensure corrective actions are carried out in a timely manner.

Authority:

The Unit Chief is the final authority within the Chemistry Laboratory on all issues dealing with data quality. The Unit Chief has the authority to accept or reject data based on compliance with the well-defined QC criteria, or based on technical reasons. These circumstances must be well documented and any need for corrective action must be defined and initiated.

5.2.4.2 Chemistry Laboratory Leader (Technical Director for Chemistry)

The Chemistry Laboratory Leader is a full-time laboratory staff member who manages the Chemistry Laboratory operations, provides technical support and oversees data reporting. If the Chemistry Team Leader is absent for (fifteen (15) calendar days or more), a deputy (see Table 5-1 below) with appropriate qualifications will perform the Leader's duties. Beyond a thirty-five (35) calendar day absence, management will notify the primary accreditation body in writing of the absence of the Chemistry Team Leader and the appointment of the deputy.

Responsibilities:

- Ensure the Chemistry Laboratory is in compliance with ISO/IEC 17025:2005;
- Primary interface with laboratory customers;
- Pre-Log surveys/projects;
- Work with customers to properly identify needs, provide QAPP input for testing activities setup and attend scoping meetings;
- Manage Log-in activity;
- Review and approve data reports; and
- Manage subcontracted testing services.

Authority:

The Chemistry Laboratory Leader provides the third level review of all customer reports to ensure that the laboratory is meeting customer expectations, and is complying with the requirements of this *Quality Manual* and with the Quality

Assurance Project Plan (QAPP) and project Data Quality Objectives (DQO) if available. The Team Leader has the authority to accept or reject data based on compliance with the well-defined QC criteria, or based on technical reasons.

5.2.4.3 Investigations Team – Field Team Leader (EIA Field Technical Director)

- Ensure the EIA field methods included within the scope of accreditation under ISO/IEC 17025:2005 are in compliance with ISO/IEC 17025:2005
- Refer to the EIA Field Quality Management Plan, EIAPLN-EIAFQMP.

5.2.4.4 Chemistry Laboratory Quality Assurance Officer (QAO)

The QAO position serves as a focal point for QA/QC and is responsible for the oversight and review of quality control data. (Refer to organizational Chart Appendix B-2) The QAO's training, including QA/QC training, and proof of experience in QA/QC procedures, knowledge of analytical methods, and the laboratory's management system are available in EPA personnel files.

Responsibilities:

- Managing Chemistry Laboratory QA program;
- Organizing, scheduling, conducting and documenting internal performance; audits and reviews (PT samples and QC check samples);
- Organizing, scheduling, conducting and documenting internal systems; audits and reviews without outside (managerial) influence;
- Initiating and monitoring corrective actions;
- Periodic verification of the preparation and verification of analytical standards;
- Monitoring general QA practices;
- Maintaining records and archives of PT results, audit comments, MDL and DOC studies, and customer inquiries about data quality;
- Reviewing SOPs, and approving SOPs in concurrence with the Unit Chief;
- Monitoring laboratory performance in the areas of holding times, turnaround times, etc.;
- Routine reports to management;
- Reviewing the NERL *Quality Manual* for needed changes;
- Advising the Unit Chief on QA issues;
- Maintaining knowledge of analytical test methods for which data review is performed and of quality system as defined under ISO/IEC 17025:2005 ; and
- Monitoring and maintaining laboratory certifications.

Authority:

The QA Officer has authority within the laboratory on all issues dealing with data quality and can require that procedures be amended or discontinued, or analyses suspended or repeated.

5.2.4.5 Chemistry Laboratory Personnel

Responsibilities:

- Having a working knowledge of the QA program as documented in this *Quality Manual*;
- Reading and attesting to SOPs, plans and other documents as required by management;
- Ensuring that all work is generated in compliance with the *Quality Manual* and applicable written SOPs;
- Maintaining current SOPs for analytical procedures;
- Ensuring that all documentation related to their work is complete and accurate;
- Providing management with immediate notification of quality problems; and
- Providing secondary review of data and QC for selected analyses in accordance with Quality Assurance method requirements.

5.2.5 Regional Quality Assurance Manager

The EPA New England Regional Quality Assurance Manager (RQAM) is responsible for developing maintaining and implementing the Regional Quality System in accordance with the approved Quality Management Plan (QMP). The RQAM is also the OEME QA Unit (EQA) Chief. Specific roles and responsibilities assigned to the RQAM and QA Unit are detailed in Section 1.3.2 of the QMP and include the following:

- The EPA NE QA Unit is responsible for reviewing and approving all intramural and extramural QAPPs, except in the case where the review and approval authority has been delegated by the EPA NE Regional Quality Assurance Manager (RQAM).
- Members of the QA Unit are available to provide technical assistance and QA/QC guidance during the planning and implementation of environmental projects. In addition, they perform technical system audits and regional data review activities.
- The QA Unit is also responsible for identifying the QA/QC training needs for the region, including project planning and QAPP training, and for conducting assessments of environmental programs.

5.2.6 Resumes and Staff Qualifications

Resumes and position descriptions are maintained throughout an employee's career in the "Electronic Official Personnel Folders (eOPFs) in accordance with the US OPMs Guide to Personnel Recordkeeping. Resumes are also maintained on file in the personnel office.

5.2.7 Laboratory Key Personnel and Back Up Personnel

The following table defines who assumes the responsibilities of key personnel in their absence:

Table 5-1 Key Personnel and Back Up Personnel		
Key Personnel	Back Up to Key Personnel	Key Personnel/ Back Up Personnel
OEME/NERL Office Director	Deputy Office Director	A. Johnson/Vacant
EIA Unit Chief/Manager	EIA Technical Director - Chemistry Team Leader	E. Waterman/D. Boudreau
ECA Unit Chief/Manager	ECA - EMT Field Team Leader	K. Kipp/D. Switzer
EIA Laboratory Technical Director - Chemistry Team Leader	Senior Analyst	D. Boudreau/P. Philbrook
ECA/EMT Laboratory Technical Director - Biology Laboratory Manager	Microbiology Laboratory Lead	D. McDonald/J. Paar
OEME QAO	Deputy Office Director	M. Hilton/Vacant
ECA/EMT Biology Laboratory QAO	OEME QAO	D. McDonald/M. Hilton
EIA Chemistry Laboratory QAO	EIA Unit Chief/Manager	M. Hilton/E. Waterman
EIA Field Technical Director	EIA Unit Chief/Manager	J. Keefe/E. Waterman
ECA/EMT Field Technical Director	ECA/EMT Laboratory Technical Director	D. Switzer/D. McDonald
ECA/AMT Technical Director	Senior Engineer	R. Judge/P. Kahn

5.3 Quality Policy

NERL conforms to the regional Quality Policy documented in the EPA New England Quality Management Plan (QMP):

<http://www.epa.gov/region1/lab/qa/qmp/index.html>.

As such, the NERL Quality Policy states:

The U.S. EPA New England Regional Laboratory shall produce scientifically sound, legally defensible data of known and documented quality. Management actively promotes good laboratory practices, continuous improvement and ethical conduct to ensure data quality.

Management directs the documentation and implementation of policies and procedures described in the NERL Quality Manual to ensure defensible science; to meet the confidentiality, scientific and usability needs of its customers; and, to conform to all applicable standards, including ISO/IEC 17025:2005, and Federal and State regulations. Management is committed to maintaining the qualifications of its staff and requires and provides training and on policies and standard operating procedures. In addition, all employees are trained annually on ethical principles and procedures surrounding the integrity of data that are generated.

5.4 Ethics and Data Integrity System

The laboratory has an Ethics and Data Integrity policy that is included in Appendix A-1. The laboratory's Ethics and Data Integrity program, training and investigations are further discussed in Section 19.

5.5 Documentation of Management Quality System

The quality management system is defined through the policies and procedures provided in this *Quality Manual*, and written laboratory Standard Operating Procedures (SOPs), Quality Assurance planning documentation and regional policies. The *Quality Manual* and SOPs are controlled documents and as such are maintained on the Lab SOP Database accessible to all NERL and regional personnel.

5.5.1 Standard Operating Procedures (SOPs)

Refer to Section 6.1.2 and 6.1.3 for discussion of written SOPs. SOPs represent all phases of current laboratory operations. SOPs used in the laboratory include: 1) test method SOPs, which have specific requirements as outlined below, 2) general use SOPs which document general procedures, and 3) administrative SOPs. A complete list of the most current SOPs is available on the Lab SOP Database, accessible to all OEME staff through the Lotus Notes system. Throughout this *Quality Manual*, an "x" after the SOP title indicates most recent version. SOPs include an effective date, revision number, and signature of approval and are available to all personnel through the Lab SOP Database. Current copies of the lab SOPs are also available in each lab room. Each

accredited analyte or method has an SOP. SOPs are also available for methods and other activities for which accreditation does not apply.

5.5.2 Quality Assurance Planning Documentation

In accordance with Agency policy, approved QA Project Plans (QAPPs) are required for all environmental data operations. The EPA NE QMP adopts a graded approach for the type of QA planning documentation required for sampling events including project-specific QAPPs and SAPs and Generic Program QAPPs. NERL Generic Program QAPPs are maintained as controlled documents in the Lab SOP Database.

5.5.3 Order of Precedence

In the event of a conflict or discrepancy between policies, the order of precedence is as follows unless otherwise noted:

- Agency and Regional Ethics and Quality Policies
- Region 1 Quality Management Plan
- NERL *Quality Manual*
- QAPPs, SAPs and SOPs
- Written technical direction

SECTION 6

DOCUMENTATION and DOCUMENT CONTROL (ISO/IEC 17025:2005(E), Clause 4.3)

NERL establishes and maintains processes for document management to preclude the use of invalid and/or obsolete documents. Procedures for document management include controlling, distributing, reviewing, and accepting modifications. Documents generated by NERL include but are not limited to SOPs, policy statements, plans, specifications, calibration tables, charts, memoranda, and laboratory records. These may be on various media (hard copy or electronic) and they may be digital, analog, photographic or written.

The management of laboratory records that specifically include data, including raw and reported data, bench sheets, notebooks, control charts, instrument run logs and maintenance logs, and project files is described in Section 16.

The laboratory manages three types of documents: 1) controlled, 2) approved, and 3) archived/obsolete. Controlled documents are uniquely identified, approved, tracked, and kept current as part of the management system. Controlled documents include but are not limited to SOPs, plans, and policies. Controlled documents are maintained as electronic documents at a minimum in the Lab SOP Database. Approved documents are reviewed, signed and dated by the issuing authority(s). Archived/ obsolete documents are documents that have been superseded by more recent versions or are no longer needed. Obsolete documents are archived or disposed of in accordance NERL procedures.

6.1 Controlled Documents

Documents are developed, uniquely identified, reviewed, revised, approved and archived in accordance with document control procedures prescribed under the Office of Environmental Measurement and Evaluation, Document Control Standard Operating Procedure, EQASOP DocContrlSOPx, and laboratory-specific procedures as described below.

A master list of controlled documents is maintained on the Lab SOP Database that includes the unique document number (that includes version number), Code, Title, Revision number, Effective date, Last Reviewed Date, and Status. The controlled document list is kept current and maintained in the Lab SOPs database and updated automatically whenever 1) a new documented is entered by the document "custodian" 2) a controlled document is revised, or 3) a controlled document is archived. The custodian may be the authorized originator of the new document, authorized editor of the revised document, or the person authorized to archive the document. Controlled documents for each custodian may be viewed under document views within the database.

6.1.1 Quality Manual

This *Quality Manual* is maintained as a controlled document in accordance with NERL procedures (Refer to Section 3.4).

6.1.2 Quality Assurance Project Plans (QAPPs) and Sampling and Analysis Plans (SAPs)

In accordance with EPA quality requirements, NERL environmental data operations, including sampling and analytical activities, are conducted under approved Quality Assurance Project Plans (QAPPs), including Sampling and Analysis Plans (SAPs), that are current and accurate. This requirement applies to all data operations performed by EPA or directly for EPA through EPA-funded extramural agreements, such as grants, contracts, and inter-agency agreements. EIA and ECA conduct work under generic program QAPPs and project-specific QAPPs. Refer to EPA New England QMP Section 7.0 for additional information regarding generic and project-specific QAPPs.

6.1.2.1 Generic QAPPs

EIA and ECA develop and maintain Generic Program QAPPs as controlled documents in the Lab SOPs database.

6.1.2.2 Project-Specific QAPPs

Project-specific QAPPs are developed and maintained as approved documents by the EPA project officer.

6.1.3 Laboratory Standard Operating Procedures (SOPs)

SOPs are developed and maintained as controlled documents in electronic format for all routine activities performed in the laboratory. All SOPs contain the following caveats:

The controlled version of this document is the electronic version viewed on-line only. If this is a printed copy of the document, it is an uncontrolled version and may or may not be the version currently in use.

This document contains direction developed solely to provide internal guidance to U.S. Environmental Protection Agency (EPA) personnel. EPA retains the discretion to adopt approaches that differ from these procedures on a case-by-case basis. The procedures set forth do not create any rights, substantive or procedural, enforceable at law by a party to litigation with EPA or the United States.

SOPs are developed and maintained as controlled documents for all routine activities performed in the laboratory in accordance with the SOP for Management of SOPs (ECASOP-SOP Management SOPx) for the Biology Lab and the SOP Document Control (ADMGUIDx) for the Chemistry Lab. All current versions of approved SOPs are assigned a document control and revision number. All SOPs are maintained in the Lab SOP Database.

Procedural changes no matter how small will be considered for incorporation into standard laboratory practices. If the revision is thought to be significant, the SOP will be revised and it will be implemented immediately. If minor, it will be noted by the particular Laboratory Lead and changes made during the annual SOP review process. All SOP development or revision and implementation will follow the review process stated above. Once the revision has been accepted, it will replace the previous version both in the electronic and hard copy file, and all laboratory personnel will be alerted of the need to review the revision.

SECTION 7

REVIEW OF WORK REQUESTS (ISO/IEC 17025:2005(E), Clause 4.4)

NERL reviews clients' requests to ensure they are clearly defined, documented and understood, ensures that it has adequate resources and capabilities, and verifies that test methods are applicable to the customers' needs. NERL requires that requests for new work be supported by appropriate QA planning documentation (i.e., QAPP or SAP). Refer also to Section 25. Requests may be received verbally or electronically. Requests typically include target analyte lists, project-specific reporting limits, project-specific quality control requirements, turnaround time, and requirements for data deliverables. The review includes discussion of Region 1 priorities and current and expected workloads.

7.1 Review of Work Requests

NERL personnel participate in annual and ongoing planning meetings within NERL and with the EPA Region 1 Office of Site Remediation and Restoration (OSRR), Office of Ecosystem Protection (OEP), and Office of Environmental Stewardship (OES) to discuss the level of laboratory support needed by the Region to meet annual commitments, provide data needed for programs and meet emergency response needs, and to ensure laboratory resources and capacity are adequate. Project schedules, analytical requests and methods, personnel resources, equipment, and deliverables are discussed during project scoping when requested, documented in QAPPs (or SAPs), and reviewed and approved prior to sample receipt. Potential conflicts are addressed during scoping or QAPP review.

During the review or development of work requests, NERL is responsible for ensuring:

- The methods to be used are adequately defined, documented and understood;
- The laboratory has the capability and resources to meet all accepted laboratory request requirements;
- The requesting parties are notified of any and all current laboratory accreditation standing(s), as applicable; and
- The laboratory notifies the client of any potential conflict, deficiency, lack of appropriate accreditation status or inability on the laboratory's part to complete the client's work.

7.1.1 ECA/EMT Preplanning and Review Procedures

Projects routinely undertaken by ECA's Ecology Monitoring Team (EMT) are requested by states, tribes, other EPA programs, other federal agencies and local environmental organizations. Once requested, the various projects are prioritized

according to program priorities by ECA's management. Following initial prioritization, the projects to be undertaken are discussed by the EMT as a group. This discussion involves the required laboratory activities to be performed by the group. Ultimately a list of projects is developed that defines the field and laboratory work efforts for the group for the coming year.

Once projects are selected, EMT Project Managers are assigned to ensure a schedule is developed and identify, when projects are proposed to be undertaken, personnel availability and responsibility. The Project Manager is responsible for the scheduling of a scoping meeting, involving all parties including but not limited to, field sampling personnel, laboratory personnel, QA personnel and data users. In addition, the Project Manager is directly responsible for the development and approval of a project specific QAPP and/or SAP. EMT project planning spreadsheets are used to schedule work requests for the year. Refer to Section 25 for additional information on project planning including determination and review of work requests.

7.1.2 Analysis Request Preplanning and Review Procedures

Requests for analyses are submitted to the Chemistry or Biology Laboratory Leader or Unit Manager. Requests are usually received over the phone or email. Preplanning of samples is done after approval of the work by the Unit Manager or the Laboratory Leader. This can be done months or days before the planned arrival of the samples, depending on the nature of the analyses, DQOs, and laboratory capacity. Preplanned project information is used by management to review laboratory capacity. The Biology and Chemistry Laboratory Leader confirms sample request acceptance in a Sample Planning Memorandum (Figure 7-1).

All samples are accepted as capacity and capability allow. Samples the lab cannot analyze are contracted out. If neither the laboratory nor contracted services are available, the requestor is notified by the Unit Manager or the Laboratory Leader that the project cannot be accepted.

7.2 Modifications to Work Requests

In the event that any portion of the scheduled testing is to be performed by another party, the clients will be notified in writing by the NERL Project Lead that the samples will be contracted to another laboratory for analysis. The laboratories performing the tests will be identified in the QAPP. Requests for changes to test methods specified and/or number of samples are documented in a revised Sample Planning Memorandum.

Figure 7-1: Sample Planning Memorandum

SAMPLE PLANNING MEMORANDUM

TO:

FROM:

SUBJECT:

DATE:

CC:

Greetings,

You recently submitted a request for sample analysis assistance to NERL for the following:

Project Name:

SF:

Approved QAPP/SAP:

Date of Request:

Proposed Due Date:

Date Samples Due:

Services Requested:

All samples must meet sample acceptance criteria including:

Appropriate sample temperature

Proper sample labeling (unique identification, durable label, indelible ink)

Proper, full, and complete chain-of-custody documentation

Holding times not exceeded

Proper container integrity

Correct containers used

Adequate sample quantity

If any of the criteria are not met, the Sample Custodian will notify the appropriate NERL contact. The impact to the integrity of the samples on the analysis will be determined; and, as necessary, the client will be contacted. In all cases, the sample acceptance issue will be documented and reported to the client.

SECTION 8

REGIONAL and NATIONAL CONTRACT SERVICES (ISO/IEC 17025:2005(E), Clause 4.6)

NERL is a government laboratory and contracts directly for analytical services. The EPA *Contracts Management Manual* Section 44.2.4 defines a subcontractor as “any supplier, distributor, vendor, or firm that furnishes supplies or services to or for a prime contractor or another subcontractor.” NERL does not use subcontractors. Both regional and national contracts are used for laboratory support. See also Section 9.

8.1 Regional Contracts – Commercial Laboratories

Sample analyses are contracted to other laboratories when NERL does not have the capacity or capability to analyze the samples. The client will be notified of this decision and given the opportunity to approve or seek alternative options. In the event that any portion of the scheduled testing is to be performed by another party, the clients will be notified in writing by the Laboratory Lead that the samples will be contracted to another laboratory for analysis. The laboratories performing the tests will be identified in the QAPP as well as analytical reports.

NERL will ensure that the laboratory capabilities and personnel qualifications of the contract laboratory meet the clients’ requirements, including certification/accreditation requirements, either by a prior on-site visit or a review of the contract laboratory’s QA Plan and/or other documentation. To the extent practicable, contract laboratories are periodically visited by NERL personnel to review the operational procedures and accreditation status.

8.1.1 Procedures for Procuring Contracted Laboratories

The EPA Contract Officer and Invoice Approving Official maintain a list of contracted laboratories. Copies of certificates and analyte lists from contractor laboratories are maintained as evidence of compliance. This information is provided pre-award and maintained by the EPA Contract Officer in the Boston Office Contract Office files. Laboratory Quality Assurance Plans, Certification/Accreditation documentation, list of SOPs, analyses and turnaround times, technical approach for sample pick up/receipt, and electronic reporting – on-line report access are evaluated during pre-award award to ensure that the potential contractor has the appropriate qualifications.

The NERL Project Manager notifies the client of the intent to contract the work during project scoping and obtains concurrence. The laboratory performing the contracted work is identified in the final report. NERL assumes responsibility to the client for the contractor’s work.

8.1.2 Procedures for Sample Receipt by NERL and Transfer to Contract Laboratory

Refer to Section 26.1.7 for sample login, custody, and transfer procedures.

8.1.3 Contract Laboratory Deliverables

For analytical work performed by an outside contract lab, the original report from the contractor is kept with the customer file in the chemistry laboratory. A ".pdf" file is generated and posted on the EPA intranet "Report Website" (Refer also to Section 28). Results for the samples are entered in LIMS (QC results are not entered in LIMS). An EDD is generated and also posted on the "Report Website".

The final laboratory report from the contract laboratory will be reviewed by either the EMT Project Manager, Chemistry Leader or QAO for completeness and adherence to QA guidelines. In addition, project specific requirements will be communicated to the contract lab and the report will be reviewed to ensure the requirements are met. The *Project Review Form Contractor Data* (EIAFRM-CHKLSTCONTDATx) documents the review. The contract laboratory will be notified of any deficiencies, and revised reports and/or corrective action may be requested at that time.

8.2 National Contracts - Environmental Services Assistance Team (ESAT)

Headquarters (Non-Routine Analytical (NRAS) Team) is responsible for placing and managing the Environmental Services Assistance (ESAT) contracts that support the ten EPA Regional laboratories for non-routine sample analyses, as well as contracts or orders for asbestos and dioxin testing or furan analysis. The Regional ESAT Contract Officer Representative (COR) resides at NERL and manages regional tasks assigned to the contract. All ESAT personnel are required to take the Annual NERL Laboratory Ethics and Data Integrity training.

8.2.1 ESAT Contract Procedures

There are contracted activities that take place both in the laboratory and in the field through the ESAT contract that provides technical support on-site for NERL. This contract is enabled through a bidding process which rates both cost and technical capabilities. The contractor develops a workplan and contract QAPP. EPA reviews the plans to ensure that the requested support is identified in accordance with EPA's statement of work (SOW). ESAT staff adheres to all Regional technical requirements and policies, and follow guidelines from the *ESAT QAPP*. In the case of more specific activities (e.g., field efforts) project specific QAPPs and field sampling plans (FSP) are written by the contractor,

reviewed by the QA branch and ultimately approved by EPA prior to the performance of said activity.

Specific work assignments to ESAT are assigned by a Task Order Contract Officer Representative (TOCOR) through the issuance of Technical Direction Forms (TDFs). General laboratory activities are identified as to function and method in the work assignment and therefore do not generally require a specific TDF request. All task products are reviewed by the appropriate TOCOR to ensure that what was requested is obtained and that the quality of the product reflects the use objective of the information.

SECTION 9

PURCHASING SERVICES AND SUPPLIES *(ISO/IEC 17025:2005(E), Clause 4.6)*

Regional procurement functions are conducted in accordance with Federal Acquisition Regulations (FAR) and related Agency policies, directives, and guidance. Contractors, suppliers, and financial assistance recipients are responsible for the quality of work performed directly for EPA and for items and services provided by their subcontractors/sub-awardees and suppliers. For additional information, refer to the Region 1 *Quality Management Plan*: <http://www.epa.gov/region1/lab/qa/qmp/qmp.html#sect4>.

NERL ensures that purchased supplies and services that affect the quality of environmental tests are of the required or specified quality, by using approved suppliers and products. Laboratory personnel work with the NERL Facilities Office Support Services Specialist to procure services and supplies using appropriate procurement forms. The Support Services Specialist coordinates with the Boston OARM and tracks procurements over \$3000 through the EPA Acquisition System (EAS). Procedures for purchasing, receiving, and storage of supplies that affect the quality of environmental tests are described below. Refer also to Section 8.

9.1 Approval of Suppliers of Products and Services under \$3000

NERL Facilities Office maintains a list of pre-approved Blanket Purchasing Agreement (BPA) Agency suppliers for routine supplies under \$3000. Agency contracting officers evaluate vendors and award contracts. All supplies are inspected at the loading dock for package integrity when received. The Facilities Office notifies the originator of the receipt. Original packing slips are maintained in the Facilities Office. A copy is provided to the originator to cross-check accurate delivery. All chemicals and culturing supplies are transferred to Room 190 and the Chemical Inventory System (CIS) manager is notified by facilities that items have been placed there for barcoding into the CIS.

Deliveries are inspected in more detail when delivered to the laboratory or storage area. If supplies are considered to be un-useable due to damage or wrong item, the Facilities Office is notified and the item is returned for refund or replacement. The supplies received are stored according to manufacturer's recommendations, laboratory SOPs and test method specifications. The purchased supplies and reagents that affect the quality of the tests are not used until they are inspected or otherwise verified as complying with requirements defined in the test method.

9.2 Laboratory Consumable Materials Traceability

For all chemical laboratory supplies received, including reagents, standards, media, etc., the manufacturer's lot number along with the associated laboratory

barcode number is recorded in the CIS. An expiration date will also be recorded in the database. If the expiration date is not provided by the manufacturer, a date of five years from entry of the chemical in the database will be logged. At the end of the five year period, the expiration date can be extended if the consumable remains usable for its intended purpose. Materials in current use, including barcode numbers, will be referenced on secondary containers in daily use, and in associated laboratory logbooks, so that at any time the source of a material can be identified.

9.3 Laboratory Supplies

Chemical reagents, solvents, gases, glassware, repair parts, and laboratory supplies are ordered as needed to maintain sufficient quantities of materials on hand. Procurement requests are completed by Laboratory Leads or analysts and approved by the Unit Manager and Deputy Office Director. Purchase orders are maintained by NERL facilities staff to compare against incoming orders. Chemicals are processed into the CIS as they are received prior to storage in the dry chemical storage room, bulk chemical storage areas or the laboratories. The grade or purity of reagents varies depending on the analytical requirements specified in individual SOPs.

9.4 Capital Equipment

Capital equipment is controlled through an EPA inventory management system. All capital equipment is inventoried annually to ensure proper control. From time to time equipment will be removed from the inventory through a formal process to ensure proper disposition of government owned assets.

On an annual basis, laboratory staff members are asked to review capital equipment needs and consider upgrades, replacements and new additions. These needs are then prioritized by evaluating needs against anticipated changes in demand on the laboratory as well as funding availability and considered for purchase by management. Proposed purchases are then formally justified and submitted for laboratory and office management approval on procurement requests. Depending on the value of the equipment and other factors, the government may be obligated to go through a formal bid process for high dollar items. This process, if required, is conducted outside NERL by regional purchasing agents in OARM. Procurement requests are maintained by NERL facilities staff to compare against incoming orders. Upon receipt new equipment will often require professional installation by the manufacturer. The responsible analyst will work with the Unit Manager, NERL facilities staff and the procurement office in Boston to ensure that the equipment is properly installed and meets manufacturer specifications before government acceptance of the equipment.

SECTION 10

SERVICE TO THE CLIENT (ISO/IEC 17025:2005(E), Clause 4.7)

NERL collaborates with clients to clarify their requests and monitors laboratory performance related to their work. Each request is reviewed to determine the nature of the request and the laboratory's ability to comply with the request within the confines of prevailing statutes and/or regulations without risk to the confidentiality of other clients.

10.1 Client Confidentiality

It is laboratory policy that data only be released to the client who submitted the samples. This release includes electronic deliverables and preliminary data. Data may be released to others only with the permission of the customer except where legal requirements may demand otherwise.

To ensure the integrity and confidentiality of data released electronically by the laboratory to a client either through email or fax, the correspondence will include the following confidentiality statement:

Confidentiality Notice: This e-mail message, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential, privileged or non-public information. If you are not the intended recipient, or an authorized agent of the intended recipient, please immediately contact the sender by reply e-mail and destroy/delete all copies of the original message. Any unauthorized review, use, copying, forwarding, disclosure, or distribution by other than the intended recipient or authorized agent is prohibited.

10.2 Client Support

Customer support begins with responding to requests for assistance and as these requests are accepted the planning process begins (see Section 25). Communication with customers is maintained and encouraged to provide proper clarification of laboratory requests and to assist in preplanning projects. Technical staff is available to discuss technical questions, concerns or complaints. Delays or major deviations to the testing are communicated to the client immediately by the Technical Director, or designee.

If any of the sample acceptance criteria are not met, the Sample Custodian will notify the laboratory leads who will determine the impact to the integrity of the samples and on the analysis, and, as necessary, contact the client. In all cases, the condition of these samples shall be noted on the laboratory receipt checklist, and

reported to the client by e-mail. The analysis data of these samples shall be appropriately "qualified" on the final report.

10.3 Client Feedback

NERL seeks both negative and positive feedback following the completion of projects and periodically for ongoing projects. Feedback provides acknowledgement, corrective actions where necessary, and opportunities for continuous improvement. Negative customer feedback is documented as a customer complaint (Refer to Section 11). Annual review of the quality system by management includes a review of the feedback received by the laboratory.

SECTION 11

COMPLAINTS

(ISO/IEC 17025:2005(E), Clause 4.8)

All complaints from clients received by the laboratory are documented and investigated. Any circumstances which raise doubt about the quality of the laboratory's data or its compliance with stated policies are considered to be complaints. In cases where the complaint relates to data quality or the quality system, a prompt follow-up will be conducted by the laboratory QAO and the appropriate Technical Director. Complaints are documented by the applicable Technical Director. If complaints require corrective action, the corrective action procedure outlined in Section 14 of this *Quality Manual* will be followed. If a revision of a report is necessary, the policy and procedures outlined in Section 28 of this *Quality Manual* apply.

11.1 Annual Review of Complaints

Annual documented review of the quality system by management includes a review of the complaints received by the laboratory. Emphasis is on preventive action particularly if recurring complaints are received.

SECTION 12

CONTROL OF NON-CONFORMING ENVIRONMENTAL TESTING WORK (ISO/IEC 17025:2005(E), Clause 4.9)

NERL monitors work that does not meet acceptance criteria or requirements. Non-conformances include departures from standard operating procedures or test methods or unacceptable quality control results (Refer to Section 27). NERL identifies non-conforming work through customer complaints, quality control, instrument calibration, evaluating consumable materials, staff observation, final report review, management reviews and internal and external audits.

12.1 Departures from Documented Policies and Procedures

Planned departures from procedures or policies as documented in approved QAPPs do not require audits or investigations. Unplanned departures from procedures or policies are addressed below.

All work associated with laboratory activities and the generation of data will be performed as prescribed in the relevant SOP(s). In the case of deviation from a laboratory standard procedure, the Laboratory Lead and/or QAO will be notified immediately of the need for the deviation. If the deviation may impact the intended use of the data it is discussed with the client. At this time a decision will be made to proceed, incorporating the deviation, wait for the issue causing the need for the deviation to be rectified or not perform the intended analysis. Full documentation of the cause, the deviation, the decision on proceeding and impact on usability will be documented in the report to the client as well as in the laboratory final project report. The deviation and follow-up activity performed by the laboratory will be documented and incorporated into the laboratory report file.

12.2 Policy for Non-Conforming Work

The lab policy for control of non-conforming work is to identify the non-conformance, determine if it will be permitted, and take appropriate action. All employees have the authority to stop work on samples when any aspect of the process does not conform to laboratory requirements.

The responsibilities and authorities for the management of non-conforming work are detailed in this *Quality Manual* and/or method SOPs. The procedure for investigating and taking appropriate corrective actions of non-conforming work are described in Section 14 – “Corrective Actions”. Formal corrective action procedures are followed for non-conforming work that could reoccur (beyond expected random QC failures) or where there is doubt about NERL’s compliance to its own policies and procedures.

The investigation and associated corrective actions of non-conforming work involving alleged violations of NERL's Ethics and Data Integrity policy follow the procedures outlined in Section 19.

NERL evaluates the significance of the non-conforming work, and takes corrective action immediately. The discovery of a nonconformance for results that have already been reported to the customer is immediately evaluated for significance of the nonconformance, its acceptability to the customer, and determination of the appropriate corrective action. The customer is notified and a corrected report with appropriate documentation of the non-conformance is issued. Non-conforming data are clearly identified in the final report (Refer to Section 28).

SECTION 13

IMPROVEMENT

(ISO/IEC 17025:2005(E), Clause 4.10)

NERL is committed to continuous quality improvement and promotes this concept as part of its annual Ethics and Data Integrity Refresher Training. Improvement in the overall effectiveness of the laboratory management system is a result of the implementation of the various aspects of the laboratory's management system including:

- Quality policy and objectives (Section 5 – “Management”);
- External and Internal auditing practices (Section 17 – “Audits”);
- Review and analysis of data (Section 27 – “Quality Assurance for Environmental Testing”);
- Control charts and PT performance (Section 27 – “QA for Environmental Testing”);
- Corrective action (Section 14 – “Corrective Action”) and preventive action (Section 15 – “Preventive Action”) process;
- Training (Section 20 – “Personnel”);
- Client feedback and complaints (Section 10 – “Service to Client”); and
- Annual management review of the quality management system (Section 18 – “Management Reviews”) where the various aspects of the management/quality system are summarized and evaluated and plans for improvement are developed.

SECTION 14

CORRECTIVE ACTION *(ISO/IEC 17025:2005(E), Clause 4.11)*

NERL implements corrective action (CA) procedures to eliminate the causes of an existing non-conformity, error, or an out-of control situation in order to prevent recurrence.

14.1 Initiation of Corrective Action Process

The corrective action process must be initiated as soon as a quality system finding is made. Corrective action can be initiated by the OEME QAO, Biology Laboratory QAO, Chemistry Laboratory QAO, Laboratory Lead, Technical Director, or Unit Manager by assigning responsibility to appropriate staff.

14.2 Cause Analysis

The first step of the corrective action process starts with the initial investigation and determination of root cause(s) of the problem. Records are maintained in the NERL Project Tracker database of non-conformances requiring corrective action to show that the root cause(s) was investigated, and includes the results of that root cause investigation.

14.3 Selection and Implementation of Corrective Actions

The assigned personnel as described in Subsection 14.1 above, will recommend corrective action that is appropriate to the determined root cause and that will most likely eliminate the problem and prevent recurrence. The proposed corrective action is then reviewed by the appropriate laboratory QAO and Technical Director. In accordance with the planned corrective action, the applicable QAO and, as necessary, the Technical Director will ensure that corrective actions are implemented within the agreed upon time frame.

14.4 Tracking Corrective Actions

Corrective actions at a minimum are tracked in NERL Project Tracker. Use of the NERL Project Tracker ensures the nonconformity was addressed and houses all documentation supporting the CA. Corrective action reports must be filed as soon as possible after a finding occurs. For unacceptable PT results, the laboratory analyst or lead who is responsible for the analysis should review the results, and supporting laboratory activities associated with the deficient result(s), and propose a corrective action to the appropriate laboratory QAO within two weeks after notification of the unacceptable result.

Minor, non-systemic laboratory problems and the corresponding corrective action(s) are documented on a standard Corrective Action Form (Figure 14-1).

14.5 Corrective Action Verification

The Laboratory Leads, Technical Directors and QAOs will monitor implementation and documentation of the corrective action to assure that the corrective actions were effective. The effectiveness of corrective actions is determined through enhanced monitoring of the operation, internal audits or routine data review.

Figure 14-1: Corrective Action Form

Room Number: _____ Date: _____

Originator: _____

PROBLEM IDENTIFICATION (nature and suspected cause):

Originator Signature: _____

Date: _____

Person Contacted: _____

Date: _____

CORRECTIVE ACTION PLANNED:

Laboratory Lead Signature: _____

Date: _____

FOLLOW UP:

Laboratory Lead Signature: _____ Date: _____

SECTION 15

PREVENTIVE ACTION (ISO/IEC 17025:2005(E), Clause 4.12)

NERL incorporates preventive action as a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

Preventive action includes, but is not limited to:

- Regularly scheduled preventive maintenance on equipment and instrument;
- Review of QC data to identify quality trends;
- Technical systems audits and data package reviews;
- Review of client feedback to look for improvement opportunities;
- Review of proficiency testing data;
- Annual review of the quality system by management including a review of the complaints received by the laboratory. Emphasis is on preventive action particularly if recurring complaints are received; and,
- Use of electronic databases to track and monitor preventive and correction actions.

When improvement opportunities are identified or if preventive action is required, action plans are discussed and documented in the notes of the Annual Management Review meeting (Refer to Section 18). Procedures for preventive actions include the initiation of such actions and subsequent monitoring to ensure that they are effective. All personnel have the authority to offer suggestions for improvements and to recommend preventive actions, however management is responsible for implementing preventive action.

SECTION 16

CONTROL OF RECORDS (ISO/IEC 17025:2005(E), Clause 4.13)

Records are maintained for all laboratory activities, at minimum in accordance with Federal Regulations. NERL records may be on any form of media, including electronic and hard copy. Records of original observations and derived data are retained to establish an audit trail.

16.1 Records Maintained

NERL keeps records of all procedures to which a sample is subjected while in its possession. NERL retains all original observations, calculations and derived data (with sufficient information to produce an audit trail), calibration records, personnel records and a copy of the test report for a minimum of five years from generation of the last entry in the records. At a minimum, the following records are maintained by NERL to provide the information needed for historical reconstruction:

- 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);
- A written description or reference to the specific method(s) used, which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value (a copy of all pertinent standard operating procedures);
- Laboratory sample id code;
- Date of analysis;
- 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);
- Instrumentation identification and instrument operating conditions/parameters (or reference to such data);
- All manual calculations (including manual integrations);
- Analyst's or operator's initials/signature or electronic identification;
- Sample preparation, including cleanup, separation protocols, incubation periods or subculture, id codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;
- Test results (including a copy of the final report);
- Standard and reagent origin, receipt, preparation, and use;
- Calibration criteria, frequency and acceptance criteria;

- Data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;
- Quality control protocols and assessment;
- Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;
- Method performance criteria including expected quality control requirements;
- Proficiency test results;
- Records of demonstration of capability for each analyst;
- A record of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record;
- Correspondence relating to laboratory activities for a specific project;
- Corrective action reports;
- Preventive action records;
- Copies of internal and external audits including audit responses;
- Copies of all current and historical laboratory SOPs, policies and *Quality Manuals*;
- Sample receiving records (including information on any interlaboratory transfers);
- Sample storage records;
- Data review and verification records;
- Personnel qualification, experience and training records;
- Archive records; and
- Management reviews.

16.2 Records Management and Storage

NERL maintains a record management system on-site. In the event that the laboratory is privatized or is closed, all documents pertaining to records storage at the FRC in Waltham will be forwarded to the Office of Administration and Resource Management (OARM) of EPA in Boston. Any records stored on-site at the NERL Laboratory facilities in Chelmsford will also be forwarded to OARM in Boston.

16.3 Computer Hardware and Software

The critical laboratory software, LABWORKS LIMS, NWA QA analyst (control charting), and Seagate Crystal Reports, reside on a Dell Power Edge server located in the secured computer room 143. Access to this room is limited to authorized personnel only. LIMS is relied on for sample login, tracking, and storage of analytical data. Data analysis software for toxicity testing (CETIS) is used to maintain the data analysis and reports.

16.4 Laboratory Bench Sheets and Logbooks

All manually generated data are recorded directly, promptly and legibly in permanent ink in logbooks or on bench sheets. Analysts must sign (or initial), and date all bench sheets. Reviews and corrections are also signed or initialed and dated, and corrections are crossed out using a single line. Signatures, initials and dates must be clearly indicated in the records. When corrections are due to reasons other than transcription errors, the reason for the corrections shall be documented. The original sheets are placed into the project file. Logbooks are maintained in the lab room and when filled, are filed according to SOP.

16.5 Project Files

Project folders are created for each project. When complete, each folder contains:

- A copy of the chain-of-custody form
- A project form generated from LIMS (with sample and analysis information)
- Applicable bench sheets and copies of instrument logs
- A project review checklist
- All raw data from the analysis
- A copy of the final report
- Any other documents associated with the analysis (such as a copy of corrective action requests and correspondence with the OSC or project manager)

When the analyses for a project are complete and the final report has been released, all projects folders are inventoried and archived.

16.6 Archiving and Document Retention

All laboratory product reports will be saved in hardcopy. The final electronic reports will be archived on the S: / directory. Project files are maintained on site for up to five years at which time they may be archived at the Federal Records Center for ten additional years. All logbooks and bench sheets, and their location in the laboratory, should be referenced in the method SOPs. Procedures for archiving of laboratory documents and reports, raw data and, when available, electronic data, are listed in the SOPs for archiving and document retention.

SECTION 17

AUDITS (ISO/IEC 17025:2005(E), Clause 4.14)

NERL conducts audits to measure laboratory performance and verify compliance with accreditation/certification and project requirements. Audits provide NERL management with an on-going assessment of the management system. They are also instrumental in identifying areas where improvement in the management/quality system will increase the reliability of data. Audits are of four main types: internal, external, performance and system.

17.1 Internal (On-site) Audits

On an annual basis, internal audits are conducted of all elements of the overarching quality system (ISO/IEC 17025:2005 Sections 4 and 5) and one third of our methods (grouped at technology level). To ensure all technologies are audited within a three year period, a three year audit plan is created by the NERL management team. This plan covers all NERL quantitative and semi-quantitative lab and field methods. The plan is reviewed annually and adjusted, as needed, to accommodate target and schedule changes driven by changes in technology or by monitoring of any Corrective Actions (CA) initiated during the previous year. Execution of the audit plan is monitored by the Deputy Office Director.

Audits are conducted by QAOs or staff designated by unit managers. During each audit, the most recent relevant ISO, NELAC and/or EPA Office of Groundwater Drinking Water checklist can be used as a reference.

An audit report is generated within 21 days of audit completion and presented to unit managers. If a deficiency requiring Corrective Action is observed, it is discussed with the appropriate unit managers immediately. The audit report identifies the area audited, describes how the audit was conducted (e.g., what records examined, interviews conducted). Copies of all audit documentation is maintained in the NERL Project Tracker.

17.2 External (On-site) Assessments

Periodic audits are conducted by an external accrediting body to maintain NERL's ISO/IEC 17025:2005 Scope of Accreditation. Other external on-site audits or assessments may periodically be conducted by outside entities.

17.3 Performance Evaluation Testing

17.3.1 Biology Laboratory

Formal proficiency testing (PT) is performed annually to ensure acceptable laboratory performance of all aqueous test methods in the Toxicity Testing and Microbiology Laboratories. In the absence of a formal PT program, the accuracy of instrumental analysis and analyst performance is checked through the analysis of certified reference materials (CRMs) and separate source standards.

The Toxicity Testing Laboratory voluntarily participates in a national program overseen by the US EPA Office of Enforcement and Compliance Assurance known as Discharge Monitoring Report - Quality Assurance (DMR-QA). This is a performance evaluation of chronic freshwater aquatic toxicity testing involving the testing of unknown synthetic materials. The traditional microbiology laboratory participates on an annual basis in the analysis of performance evaluation (PE) samples for fecal and total coliforms, *E. coli*, HPC and Enterococcus for both drinking water and wastewater (i.e., WS and WP) respectively. In the absence of a formal PT program in other testing areas of Biology Laboratory, the accuracy of instrumental analysis is checked through the analysis of, in the case of the Milestone Laboratory, certified reference materials (CRMs) that are similar in nature to samples routinely tested, and in the Chlorophyll Laboratory, a separate source known midrange concentration standard. Analysts include both EPA and ESAT. Those who routinely analyze samples, participate in the analysis of PT samples for those selected methods or, in other cases, subject to meeting the analytical run QA for which they have demonstrated initial and ongoing capability.

The proof of performance analyses are completed, according to all requirements, using known and unknown synthetic samples for each method commonly in use in the Biology Laboratory.

For WP, WS and DMRQA studies, unknowns are tested and acceptable results ranges are established based on compiled results of all participating laboratories. For other testing, materials of a known concentration are analyzed and acceptable results are as prescribed in the reference material documentation.

For WP, WS and DMRQA, testing results are submitted for each endpoint value by the appropriate laboratory Lead, in the format requested, to the PT sample provider identified in the instruction package. Performance testing results are requested to be sent by the PT provider to the laboratory as well as to the accrediting authority.

In the case of microbiology, results are also submitted to EPA's National Exposure Research Laboratory in Cincinnati, OH. As a function of the Biology Laboratory, data review process results from non-PT analysis are checked by the laboratory lead and the lab QAO.

The Biology Laboratory maintains a file in the ECA Laboratory QA File Area in Room 152. This file contains annual PT performance information as well as continuing and annual DOCs. PT performance is also documented and monitored on an Excel spreadsheet on the ECA S drive under Ecology Monitoring Team/ Biology Laboratory/PT Monitoring.

17.3.2 Chemistry Laboratory

Laboratory Performance Audits (External PE Samples; WS, WP and Interlab Soil Studies): These performance audits verify the ability of the laboratory to correctly analyze compounds in blind check samples. Performance Testing samples are purchased from ISO/IEC 17025:2005 accredited providers (if available). The samples are prepared and analyzed using the instructions from the provider and following the procedures outlined in the applicable laboratory SOP(s). PT samples are handled and analyzed in the same manner as real environmental samples, unless the instructions from the provider require a special storage, preparation or analysis technique (such as a dilution).

Bulk Asbestos Proficiency Analytical Testing: The BAPAT program for bulk asbestos is administered by the American Industrial Hygiene Association (AIHA). These are quarterly PT samples.

National Air Toxics Trends Stations (NATTS) Program: PTs for carbonyls and air toxics are run one round per year.

The EPA Superfund Region 1 Performance Testing Program: These samples for data validation purposes are run when arranged by the end user of the data and results reported to the end user. These are usually submitted as just usual samples. The lab is notified when the PE fails and corrective action is taken.

17.4 Review of Operational Procedures of Outside Laboratories

Refer to Section 8.

17.5 Handling Audit Findings

See Section 14.

SECTION 18

MANAGEMENT REVIEWS (ISO/IEC 17025:2005(E), Clause 4.15)

NERL management reviews the quality management system on an annual basis and maintains records of review findings and actions.

18.1 Management Review Topics

The following are reviewed to ensure their suitability and effectiveness:

- The suitability of policies and procedures;
- Reports from managerial and supervisory personnel;
- The outcome of recent internal audits;
- Corrective and preventive actions;
- Assessments by external bodies;
- The results of interlaboratory comparisons or proficiency tests;
- Changes in the volume and type of the work;
- Customer feedback;
- Complaints;
- Recommendations for improvement;
- Quality control activities;
- Resources; and
- Staff training.

18.2 Procedures

The NERL management team shall meet at least annually to conduct a review of the laboratory's quality processes and environmental testing activities to ensure their continuing suitability and effectiveness, conformance with standards, and to identify necessary changes or improvements to the Quality System.

Annual internal audit findings will be documented and submitted for review to the appropriate laboratory personnel. Any necessary corrective actions will be documented and addressed. The results of these audits and other QA issues will be incorporated into a QA Report to management. Management has access to several reports covering activities related to the Quality System. Management reviews these reports, maintains records of their review findings and/or actions, and ensures corrective actions are carried out in a timely manner.

18.2.1 QA Report to Management

A QA report to management is prepared, at least annually, by the laboratory QAOs. The lab QAOs present the Annual QA Report to Management during a regularly scheduled Manager's meeting. This report takes account of:

- a. the outcome of recent internal audits and data package reviews
- b. corrective and preventive actions
- c. assessments by external bodies
- d. the status of the SOPs and QA Plan
- e. the status of MDLs and DOCs
- f. PT scores or results of other interlaboratory comparison tests, and commentaries
- g. feedback from clients (complaints and their resolution)
- h. changes in the volume and type of work
- i. other QA activities, including training
- j. reference to other QA reports, such as the QAARWP
- k. plans and goals
- l. comments and recommendations

The QA Report to Management is reviewed by the Unit Chiefs for evaluation and consideration. After discussion with the QAOs, the Unit Chiefs may request corrective action based upon the findings of the report. This document is also used as a mechanism to review the overall Quality System and request changes to meet deficiencies or changing demands on the laboratory. A review of the *Quality Manual* is conducted and if necessary, revisions will be made. A copy of the QA Report and a summary of any requests for corrective action are then forwarded on to the NERL Office Director for review and concurrence. Discussion, actions plans, and follow-up issues are documented in the meeting notes.

18.2.2 Building Support Systems Records

The building owner representative maintains records of preventive maintenance of the support systems in the laboratory. Records are also maintained of the installation of new support equipment, replacement of support systems, and ongoing problem areas (ANGUS report- Facilities Manager).

SECTION 19

ETHICS AND DATA INTEGRITY INVESTIGATIONS

(ISO/IEC 17025:2005(E), Clause 4.16)

NERL is committed to ensuring the integrity of its data and providing defensible data of known and documented quality to its clients. A keystone of this commitment is the semiannual Ethics and Data Integrity Training (EQASOP-ETHICSTRAINx.docx). The elements in NERL's Ethics and Data Integrity program include:

- NERL's Ethics Policy (Appendix A) is attested to semiannually by all management and staff during the annual Ethics and Data Integrity Refresher Training (EQASOP-ETHICSTRAINx). This policy is signed, dated, and distributed through the semiannual ethics training required by the Office Director;
- Conformance with the *EPA Scientific Integrity Policy*; Principles of Scientific Integrity; and other Ethics policies and regulations;
- Procedures for confidential reporting of alleged data integrity issues; and
- An audit program that monitors data integrity (Refer to Section 17) and procedures for handling data integrity investigations and client notifications.

19.1 Ethics and Data Integrity Procedures

Written procedures and laboratory requirements that are considered part of the Ethics and Data Integrity program include:

- Requirement to follow written technical and QA/QC policies and procedures when performing sample collection, data generation, review, reporting and record-keeping tasks;
- Requirement to electronically attest to the reading and compliance with Laboratory QA manuals and plans, SOPs, Ethics and Data Integrity Training, etc.;
- Requirement that data products undergo standardized internal review processes prior to release to clients;
- Manual Integration Procedures (EIASOP-ADMINTEGx);
- Corrective Action Procedures;
- Required data integrity investigations conducted as part of the routine review process, as well as the internal laboratory auditing program, evidence of inappropriate actions or vulnerabilities related to data integrity is reviewed;
- Requirement that all investigations resulting in a finding of inappropriate and deliberate activity will result in:
 - Complete documentation of issue, allegation or complaint,
 - Disciplinary action being taken,

- Corrective actions,
 - Notifications to clients, and
 - Retention of all associated records, communications, corrective actions and client notifications.
- Data report amendment procedures (Refer to Section 28); and
- Ethics and Data Integrity Training procedures.

Management reviews data integrity procedures yearly and updates these procedures as needed.

19.2 Training and Records

Ethics and data integrity training is provided as a formal part of new employee orientation and a refresher is given semiannually for all employees. Employees are required to understand that any infractions of the laboratory data integrity procedures shall result in a detailed investigation that could lead to very serious consequences including immediate termination or civil/criminal prosecution. This is discussed in the Ethics Policy that every employee is required to attest to annually. Attendance for required training is monitored and tracked automatically through the electronic tracking of Lotus Notes attestations upon completing the e-training.

The following topics and activities are covered:

- Organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting;
- How and when to report data integrity issues;
- In-depth data monitoring and data integrity procedure documentation; and
- Specific examples of breaches of ethical behavior such as improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards.

To view the most current version of the Refresher Training, refer to Lab SOP Database Training File EQATRIN-20XX Lab Ethics & Data Integrity.

When contracted technical or support (ESAT) personnel are used, the ESAT Project Officer is responsible for ensuring that contractors are trained to the laboratory's management system and data integrity procedures, competent to perform the assigned tasks, and appropriately supervised.

19.3 Confidential Reporting of Ethics and Data Integrity Issues

Confidential reporting of data integrity issues is discussed in the annual training which specifically states that “NERL management ensures confidentiality when staff members identify the occurrence of an improper laboratory practice or violation of the NERL ethics policy”.

Personnel may also directly contact the Region 1 Office of Regional Council regarding legal or ethics issues. Alternatively, they may call the Office of Inspector General Hotline 1-888-546-8740 to report suspected fraud or misconduct.

19.4 Investigations

Under EPA Order 3120.5, EPA’s Office of Inspector General (OIG) maintains independent authority to perform misconduct investigations as authorized. As indicated in Section 19.3, management and staff may directly contact the OIG through the Hotline to file a complaint or allegation of fraud, waste or abuse in EPA programs. OIG investigations are conducted in accordance with their written procedures.

NERL personnel may also contact the Region 1 Office of Regional Council (ORC) to consult with an attorney on legal and ethics issues. Follow-up investigative procedures are conducted in accordance with ORC’s procedures.

All investigations resulting from data integrity issues are conducted confidentially. They are documented and notifications are made to clients who received any negatively affected data that did not meet the client’s data quality requirements.

SECTION 20

PERSONNEL (ISO/IEC 17025:2005(E), Clause 5.2)

NERL employs competent personnel based on education, training, experience and demonstrated skills as required. The laboratory's organizational charts are provided in Appendix B. Staff Health and Safety is addressed separately in the SOP for *General Laboratory Safety Procedures*, *NERL Chemical Hygiene Plan* and health and safety training.

20.1 Overview

All personnel are responsible for complying with all quality and data integrity policies and procedures that are relevant to their area of responsibility. All personnel who are involved in activities related to sample analysis, evaluation of results or who sign test reports, must demonstrate competence in their area of responsibility. Appropriate supervision is given to any personnel in training and the trainer is accountable for the quality of the trainees work. Personnel are qualified to perform the tasks they are responsible for based on education, training, experience and demonstrated skills as required for their area of responsibility.

NERL provides requirements with respect to education, training and skills of laboratory staff. These are outlined official documented Agency job positions. Training needs are identified at the time of employment and when personnel are moved to a new position or new responsibilities are added to their job responsibilities. Training needs are reviewed annually with employees during their performance reviews. Contracted personnel, when used, must meet the same competency standards and follow the same policies and procedures that laboratory employees must meet.

20.2 Position Descriptions

Job descriptions include the 1) Major duties and responsibilities, 2) Knowledge Skills required by the Position 3) Level of education required by the position 4) Supervisory controls, and 5) Work environment.

Job descriptions are available for all positions that manage, perform, or verify work affecting data quality, and are located in personnel files maintained within the Unit by the Unit Chief. Agency records include Position Descriptions and resumes are maintained throughout an employee's career in the "Electronic Official Personnel Folders (eOPFs) in accordance with the US OPM's *Guide to Personnel Recordkeeping*.

An overview of top management's responsibilities is included in Section 5.

20.3 Training

Employees are responsible for taking mandatory training when notified by management including annual refresher Ethics and Data Integrity training. Job-specific training may also be required which employees are responsible for attending.

20.3.1 Training Procedures

New analysts are trained in analytical methods and laboratory procedures by NERL senior staff. The process begins with reading the current version of the test specific SOP(s), and observing the procedures as they are performed by an experienced analyst. The current version of the SOP is available in .PDF format from the Lotus Notes Database. Depending on the experience of the new analyst, the next training phase can be to perform the analysis under supervision of the senior analyst, or perform the test independently with secondary review of the final data.

To evaluate the effectiveness of training, all analysts must perform an Initial Demonstration of Capability (IDC) and continuing Demonstration of Capability (DOC) studies and have a documented DOC Certificate Statement. Training for new instrumentation or new methodologies is usually done in cooperation with instrument suppliers (on- or off-site training or courses). In addition to technical training, all employees are made aware of the components of the laboratory quality system, and instructed in the quality control program.

20.3.2 Training Records

Individual training records for each employee are maintained in the training files. The Unit Manager is responsible for maintaining these files. The training file for each employee includes:

- An attestation record showing that the employee has read, understands, and agrees to use the overall quality system procedures as written in the current *Quality Manual* and the procedures of the current version of the SOPs which relate to the employee's job responsibilities. This attestation is done electronically in the Lab SOP Database.
- The most up-to-date record can be obtained and printed in real-time from the Lab SOP Database.
- Records of technical training (certificates or other documentation). Course listing from the START database.
- Records of Demonstration of Capability (Certificates) and records of Continued Demonstration of Proficiency.
- Records of the annual Ethics and Data Integrity Training.

SECTION 21

ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS (ISO/IEC 17025:2005(E), Clause 5.3)

21.1 Environmental Conditions

The NERL facility is designed and organized to facilitate testing of environmental samples. A description of the building may be found in the *OEME Occupant Emergency Plan* ESHSOP-OCCUPANTx in the Lab SOP Lotus Notes database. NERL operates under an Environmental Management System (EMS) as described in the EMS Manual available at: http://www.epa.gov/region1/lab/pdfs/NERL_EMSManual.pdf and maintained in the Lotus Notes database.

21.1.1 NERL Facilities Building

Environmental conditions are monitored to ensure that conditions do not invalidate results or adversely affect the required quality of any measurement. Such environmental conditions include but are not limited to temperature, humidity, voltage, and biological sterility.

Preventive maintenance schedules and service records for supporting systems are maintained by the building owner's representative in a dedicated database. This includes the following support systems:

- DI Water
- Process Water
- Compressed Air
- House Vacuum System
- Environmental Chambers
- Walk-in Sample Refrigerator
- LN2 Vacuum Pump
- Hoods
- Laboratory HVAC Systems
- Chilled Water System
- Back-up Generator
- Wastewater Treatment System
- Autoclaves

If the laboratory environment is required to be controlled by a method or regulation, the adherence is recorded. Procedures for monitoring temperature in freezers and refrigerators are documented in EIASOP-ADMTEMPx. All freezers, refrigerators and environmental chambers are monitored daily for temperature.

All environmental chambers where culturing or toxicity testing takes place are also monitored quarterly for light cycle and light intensity. Incubators and water baths used in microbiological testing are monitored twice per day. Autoclave sterility checks are performed monthly. All monitoring information is recorded in bound logbooks. Environmental tests are stopped when the environmental conditions jeopardize the results.

21.1.2 Laboratory Water Quality

Laboratory reagent grade water (i.e., DI/RO water) is supplied by the house system. This system is operated and maintained by an outside vendor through the building owner. Quarterly routine maintenance is performed on the system, with documentation of that activity stored in the building maintenance office.

The product of that system is monitored at the point of service by both Biology and Chemistry Laboratory personnel. Data from chemistry analysis blanks are stored on the LIMS system. In addition, the Biology Laboratory samples and tests DI/RO water for pH, resistivity and total residual chlorine (TRC) on a monthly basis with results input into the LIMS as well. If DI water problems are suspected, a report entitled Laboratory Reagent H2O Report, which is automatically generated on a monthly basis, can be consulted at any time.

Specific to the Biology Lab, along with the DI System, the Process Water System is utilized to provide waters for testing and culturing. This system is comprised of well and DI water components. This system provides waters at a requested hardness as prescribed by the tests to be undertaken. Each batch of water is tested for alkalinity and hardness to ensure it is in the prescribed range for testing. On an annual basis these waters, as well as DI water are tested for Pests/PCBs, SVOCs, VOCs and metals. The purpose is to ensure the waters meet minimum standards as defined in the EPA WET method guidance. This information is checked by the Toxicity Testing Lab lead and is maintained on file in the ECA central file area in Room 152.

21.1.3 Air and De-ionized Water Cleanliness Check

Procedures for monitoring the microbiology testing laboratory are detailed in the *SOP Microbiology Laboratory Air Cleanliness Check*, ECASOP-AirCheckSOPx.

21.1.4 NERL Mobile Laboratory

The *SOP for the NERL Mobile Laboratory* (EIASOP-FLDMOBLx) describes among other items the unit's power system, water system, HVAC, storage refrigerators, security and maintenance schedule.

21.2 Work Areas

Work areas include access and entryways to the laboratory, sample receipt area, sample storage area, sample process area, testing and instrumental analysis area, chemical and waste storage area and data handling and storage area. Access to, and use of, areas affecting the quality of the environmental tests is controlled by restriction of areas to authorized personnel only. See Section 21.4 below. The laboratory work spaces are adequate for their use, and appropriately clean to support environmental testing and ensure an unencumbered work area. Laboratory space is arranged to minimize cross-contamination between incompatible areas of the laboratory. Individual laboratory areas are separated from each other. Sample storage is conscientiously separated where possible from culturing and test foods sample processing and testing areas.

21.3 Floor Plan

The floor plan is provided in Appendix C.

21.4 Building Security

The *SOP for General Building Security and Access* (ESHSOP-BUILDINGx) describes the procedure, responsibility and level of training necessary to provide the most secure access to NERL as a Level II facility. Among other details, the SOP describes visitor log-in and out, security guard coverage, card-key identification badges, maintenance personnel access, etc. access.

SECTION 22

ENVIRONMENTAL METHODS AND METHOD VALIDATION

(ISO/IEC 17025:2005(E), Clause 5.4)

Standard Operating Procedures (SOPs) are available for all activities associated with the analysis of samples including preparation and testing. The SOP contains detailed instructions about the use and the expected performance of the method as conducted by NERL. The SOP includes references to applicable standard EPA method(s) and to the applicable QA/QC procedures. If appropriate, deviations from published methodology are documented and explained in the SOPs. Refer to the Lotus Notes SOP Database Directory for a current listing of NERL SOPs. Maximum holding times, and sample collection and preservation information is included in the method SOPs or QAPPs and SAPs. This information can also be found in the Lotus Notes SOP Database.

22.1 Method Selection

NERL primarily uses approved reference methods and/or as documented in approved QAPPs (Refer to Section 25). NERL provides technical assistance in selecting methods to meet project data quality objectives. If a method proposed by a customer is considered to be inappropriate or out-of-date, the customer is informed and the issue resolved before proceeding with analysis of any samples (Refer to Section 7).

22.2 Laboratory-Developed Methods

If the laboratory develops a method, the process of designing and validating the method is carefully planned and documented. Typically, new methods are often developed under the EPA Regional Methods Initiative (RMI) program. Under this program, EPA scientists present proposals to develop new methods and are awarded funding for research and method development. Grant recipients involved in the method design, development and implementation are responsible for communicating with their RMI program coordinator and presenting a final report.

22.3 Method Validation

Reference methods are validated by performing an initial demonstration of capability. All methods that are not reference methods are validated before use. The validation is designed so that the laboratory can demonstrate that the method is appropriate for its intended use. All records (e.g., planning, method procedure, raw data and data analysis) are retained while the method is in use.

22.3.1 Laboratory Demonstration of Capability

A laboratory method can be performed by analysts who have completed a Demonstration of Capability (DOC) Certification Statement. Each DOC will identify the pertinent method(s), instrument, personnel and activity specific laboratory function that each is capable of performing. Work conducted by individual analysts is documented on individual analyst DOC (Fig 22-1). Work conducted by a work cell is documented on work cell DOC (Fig 22-2). In work cells, as personnel functions change, the continuing DOCs will document this change. DOCs will be reviewed annually by both the relevant laboratory leads and the QAO and updated annually through performance of continuing demonstrations of capability (CDOCs).

22.3.2 Laboratory Requirements for Analytical Test Method, Detection Limits, and Limits of Quantitation

Each EPA method followed contains specific acceptability criteria. These are evaluated for each test conducted and conformance is verified before the test is considered valid. As part of putting a new or substantially revised method and/or analytical instrument on line and prior to sample analysis, method detection limit (MDL) (40CFR Part 136 App. B) studies are performed. The initial evaluation of the method and/or instrument also requires establishing Limit of Quantitation (LOQ). In our laboratory Reporting Limits (RL) are based on the lowest concentration calibration standard and are set as the LOQs. LOQs are verified at least annually by running samples at 1-5 times the Reporting Limit at the same time the annual Proficiency Testing samples are analyzed. The LOQ acceptance criteria are based on control charts developed from the LFB, SRM, or RL standard data, all of which are associated with QA samples that have been brought through the complete sample preparation and analysis process. If an analysis does not have these limits calculated then the control limits are set at 50% - 100%.

22.4 Estimation of Analytical Uncertainty

As a testing rather than a calibration laboratory our estimation of analytical uncertainty is linked primarily to demonstrating individual test methods are within control as specified within individual SOPs. Some practices that cut across all analyses are described below.

22.4.1 Use of Control Charts

For laboratories in which control charts are generated, control charts are used to provide an estimate of the acceptable uncertainty of reportable measurements. Control charts are not generated for those laboratories in which a minimum number of data points are not available with which to generate control charts. Under normal circumstances control chart ranges of acceptance are

established using a minimum of 20 data points. With chemical analyses unless sufficient data are available (usually 20-30 test results per year on a specific analysis) the laboratory uses the control limits specified in the reference method. When sufficient data becomes available the laboratories develop control charts from the mean and the standard deviation of the percent recovery. These data are used to establish upper and lower out of control limits and are set at the mean recovery plus and minus 3 standard deviations (SD) respectively. Warning limits are set at plus and minus 2 standard deviations. Control charts are updated at least annually. Within the specific context of toxicity testing, the control charts that are developed are based on the cumulative means of either point estimate or hypothesis testing endpoints. For point estimate endpoint control charts warning limits are ± 2 SD. For hypothesis testing endpoint control charts warning limits are established as within \pm one test concentration of the mode. Out of control limits are set at ± 3 SD and ± 2 concentrations around the mode, respectively. Control charts generated are maintained by the relevant labs as prescribed in the applicable methods.

22.4.2 Use of Laboratory Controls

Laboratory controls, both negative and positive, are tested in parallel under the same test conditions as field samples. Meeting method and test type specific acceptability criteria for controls are required in the determination of an acceptable test. In the case of water toxicity testing, percent minimum significant difference (PMSD) is also used to guide the review on data usability.

22.4.3 Use of Known Standards

22.4.3.1 Standard Reference Material (SRM)

A SRM, in the form of an initial calibration verification (ICV) standard, must be analyzed with each batch of sample. The acceptance criteria must be within accepted range of the SRM or ICV is $\pm 20\%$ of the true value. In addition to ICVs, CCVs and continuing calibration verification blanks (CCB) are analyzed at a 10% frequency over the course of the run. Acceptance criteria are $\pm 10\%$ and $<$ reporting limit (RL), respectively.

22.4.3.2 Laboratory Fortified Blank (LFB)

A LFB must be analyzed for each batch of samples or 5 % frequency whichever is less. The acceptance range for %R is 70-130% until user generated limits (e.g. control charts) are applied. If the calculated %R falls outside the acceptable range all associated sample result should be qualified as estimated in the final report.

22.5 Control of Data

To ensure that data are protected from inadvertent changes or unintentional destruction, NERL uses procedures to check calculations and data transfers (both manual and automated).

22.5.1 Computer and Electronic Data Security Requirements

Refer to Sections 16 for procedures ensuring computer and electronic data security.

22.5.2 Data Reduction

The analyst calculates final results from raw data or appropriate computer programs and provides the results in a reportable format in accordance with method SOPs. The test methods provide required concentration units, calculation formulas and any other information required to obtain final analytical results. All raw data is retained and maintained as described in Section 16.

22.5.2.1 Significant Figures

Where appropriate, all digits reported will be of known confidence in the value except for the final digit. Confidence will be based on the robustness of the procedure. In making experimental observations, the analyst should record all primary (raw) analytical data with as fine a degree of discrimination as possible; rounding will likely be necessary when reporting the analytical results, but rounding-off should not be done when recording the experimental data. Rounding-off rules for arithmetic operations are described below.

Guidance from Chapter 7 of the "Handbook for Analytical Quality Control in Water and Wastewater Laboratories", March 79, EPA-600/4-79-019 shall be followed in determining the number of available significant figures and rounding. Specific method requirements supersede these guidelines.

The term "significant figures" is used here to refer to the case where all the digits in analytical results are known definitely, except for the last digit, which may be in doubt.

The number zero may or may not be a significant figure depending on the situation:

- Final zeros after a decimal point are always meant to be significant figures. For example, to the nearest milligram, 9.8 is reported as 9.800g.

- Zeros before a decimal point with nonzero digits preceding them are significant. With no preceding nonzero digit, a zero before the decimal point is not significant.
- If there are no nonzero digits preceding a decimal point, the zeros after the decimal point but preceding other nonzero digits are not significant. These zeros only indicate the position of the decimal point.
- Chapter 7 of the Handbook describes in detail the significance of final zeros in a whole number and of one or more zeros interspersed in a number. Once the number of significant figures obtainable from a type of analysis is established, data resulting from such analyses are reduced according to the following rounding off rules.

22.5.2.1.2 Rounding

Round off by dropping digits that are not significant. If the figure following those to be retained is less than 5, the figure is dropped, and the retained figures are kept unchanged. If the figure following to those retained is greater than 5, the figure is dropped and the last retained figure is raised by one. If the figure following to those to be retained is 5 and there are no figures other than zero beyond the 5, the figure 5 is dropped, and the last-place figure retained is increased by one if it is an odd number or it is kept unchanged if an even number.

22.5.2.1.3 Selection of Proper Statistical Analyses

Manual summation of toxicity test results is conducted by a primary analyst and checked by a second analyst. Data are analyzed when required for homogeneity of variance and normality to determine the proper statistical test for analysis.

EPA toxicity test methods cited above contain flowcharts directing the examination of test datasets and the recommended selection of statistical analysis.

22.5.3 Data Review Procedures

Data review procedures are documented in Section 27.7.

Figure 22-1: Laboratory Individual Analyst Demonstration of Capability Certification Statement

Demonstration of Capability Certification Statement

Page _ of _

Laboratory Name: EPA New England Region 1 Laboratory, EIA, OEME

Laboratory Address: 11 Technology Drive, North Chelmsford, MA 01863-2431

Date of the Study:

Analyst(s) Name(s):

Matrix:

Method Number, SOP #, Rev. #

Analyte or Class of Analytes Measured:

LIMS Parameter(s):

We, the undersigned, CERTIFY, that:

1. The analyst(s) certified above, using the cited test method(s), which is in use at this facility for the analysis of samples under the National Environmental Laboratory Accreditation Program, have met the Demonstration of Capability.
2. The test method(s) was performed by the analyst(s) identified on this certification.
3. A copy of the test method(s) and the laboratory-specific SOPs are available for all personnel on-site.
4. The data associated with the demonstration of capability are true, accurate, complete and self-explanatory (1).
5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized assessors.

Comments:

Analyst(s) Signature

Date

Quality Assurance Officer's Name

Signature

Date

Technical Director's Name and Title

Signature

Date

Figure 22-2: Laboratory Work Cell Demonstration of Capability Certification Statement

Date:

Laboratory Name: EPA Region 1, Regional Laboratory - Biology Laboratory

Laboratory Address: 11 Technology Dr. N. Chelmsford, MA

Analyst(s) Name(s):

Matrix:

Method ID:

SOP(s):

Parameter(s):

We, the undersigned, CERTIFY that:

1. The analysts identified in the attached matrix, using the cited test method(s) and EMT SOPs, which is in use at this facility for the analyses of samples under the National Environmental Laboratory Accreditation Program, have met the Demonstration of Capability.
2. The test method(s) was performed by the analyst(s) identified in the attached certification.
3. A copy of the test method(s) and the laboratory-specific SOPs are available for all personnel on-site.
4. The data associated with the demonstration capability are true, accurate, complete and self-explanatory (1).
5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized assessors.

Technical Director Signature

Date

Quality Assurance Officer Signature

Date

Laboratory Lead Signature

Date

**Figure 22-2: Laboratory Work Cell Demonstration of Capability
Certification Statement, cont.**

Date:	METHOD ID:				
Analyst Name:	FUNCTIONS ID:				

**Figure 22-2: Laboratory Work Cell Demonstration of Capability
Certification Statement, cont.**

DOC Signature Sheet

_____ Analyst	_____ Date
_____ Analyst	_____ Date
_____ Analyst	_____ Date
_____ Analyst	_____ Date
_____ Analyst	_____ Date
_____ Analyst	_____ Date
_____ Analyst	_____ Date

SECTION 23

CALIBRATION REQUIREMENTS: Equipment and Instrumentation (ISO/IEC 17025:2005(E), Clause 5.5)

23.1 General Equipment Requirements

All equipment and software used for testing and sampling are capable of achieving the accuracy required for complying with the specifications of the environmental test methods as described in the laboratory SOPs. Equipment is operated only by authorized and trained personnel (Refer to Section 20). NERL has procedures for the use, maintenance, handling and storage of equipment which are readily available to laboratory personnel. Manuals provided by the manufacturer of the equipment provide information on use, maintenance, handling and storage of the equipment. Inventories of equipment are maintained that include additional information on storage location and planned maintenance. All equipment is uniquely identified.

All equipment is calibrated or verified before being placed in use to ensure that it meets laboratory specifications and relevant standard specifications. Upon receipt, new equipment will often require professional installation by the manufacturer. The responsible analyst will work with the Unit Chief and NERL facilities staff to ensure that the equipment is properly installed and meets manufacturer specifications before government acceptance of the equipment.

Maintenance documentation is kept on record in individual lab rooms. Problem identification and resolution is documented and maintained in the lab. The owners' manuals for equipment used in the Biology Laboratory are located in a labeled file drawer in the ECA central file in Room 152 for easy access by all staff. Manuals used in the chemistry laboratories are in individual lab rooms.

Laboratory instruments and equipment are cleaned during and after use and repaired when necessary by qualified personnel.

NERL is a secure building with limited "card-key" access and a 24/7 security presence. Test equipment, including hardware and software, are safeguarded from adjustments that would invalidate the test result measurements by limiting access to the equipment and using password protection. Refer also to EIASOP-ADMLIMSx for a detailed description of LIMS program administration and security.

23.2 Support Equipment

Support equipment is maintained in proper working order in accordance with laboratory SOPs. Records are kept for all repair and maintenance activities, including service calls.

23.2.1 Support Equipment Maintenance

Preventive maintenance schedules and a service records for the following supporting systems are maintained by the building support contractor in a dedicated database. This includes the following support systems:

- DI Water
- Process Water
- Compressed Air
- House Vacuum System
- Environmental Chambers
- Walk-in Sample Refrigerator
- LN2 Vacuum Pump
- Hoods, including grain size analysis hood
- Laboratory HVAC Systems
- Chilled Water System
- UPS
- Back-up Generator
- Wastewater Treatment System
- Sediment Toxicity Testing System

23.2.2 Support Equipment Calibration

As required by relevant SOPs support equipment is checked at specified intervals (usually daily or on an as used basis) All support equipment is also calibrated or verified annually over the entire range of use using NIST traceable references, where available. If the results of calibration of support equipment is not within specifications equipment is removed from service until repaired. Please refer to the following SOPs for specific details on support equipment operation and calibration:

Mechanical Pipettors: ECASOP-Adjustable Repeat Pipettex

Balances and Weight Sets: EIASOP-ADMCAL1x; ECASOP-Bio Balancesx

Thermometers: EIASOP-ADM CAL1x; EIASOP-ADMTEMPx; EIASOP-QATCSOx

Sediment Tox Testing System (STTS): ECASOP-Static Bulk Sediment Toxicity Testingx

Freezers, Refrigerators Environmental Chambers and Ovens: All are monitored daily for temperature. All environmental chambers where culturing or toxicity testing is taking place are also monitored quarterly for light cycle and light intensity. Incubators and water baths used in microbiological testing are monitored twice per day. Ovens are monitored during use.

23.3 Analytical Equipment

23.3.1 Instrument Maintenance

Analytical equipment is properly maintained, inspected, and cleaned in accordance with laboratory SOPs. Instrument malfunction is documented in Instrument Maintenance Logs or Instrument Folders, which become part of the laboratory's permanent records. A description of what was done to repair the malfunction and proof of return to control are also documented in the log. Copies of repair bills are maintained by the Facilities Office.

23.3.2 Instrument Calibration

Detailed information on instrument calibration may be found in method-specific laboratory SOPs. If QC criteria for initial or continuing calibrations are not acceptable, corrective action as specified in the SOPs must be performed. Refer also to Section 14.

SECTION 24

MEASUREMENT TRACEABILITY (ISO/IEC 17025:2005(E), Clause 5.6.3)

Traceability of measurements is assured through the use of a system of documentation, and calibration and verification of the equipment used in the laboratory. These calibrations are traceable to national standards of measurement where available.

24.1 Laboratory Traceability Procedures

24.1.1 Preparation of Biological Media, Standards and Reagents

All materials are prepared in accordance with NERL Laboratory SOPs referencing approved ASTM and EPA methods. In the Laboratory all chemicals are procured from reputable providers, historically noted for acceptable quality, at the purity specified or higher in the method. In the Biology Lab most materials are purchased at the concentrations required at time of use. In other areas of the lab and in the Biology Lab, those that are not are prepared for use from high purity stock to concentrations necessary for use. All other materials including containers in use in the lab test and culture foods, test organisms and culture stock are purchased from reputable suppliers or otherwise acquired from other labs at a known quality.

24.1.2 Documentation of Traceability

24.1.2.1 Laboratory Consumable Materials Traceability

The NERL Chemical Inventory System (CIS) is used as a central database to document all pertinent information for consumables received for use in the laboratory including but not limited to neat chemicals, solvents, test reagents, culture media and test and culture foods. The information in the CIS includes an item specific barcode, manufacturer, manufacturer's lot number, date received, expiration date and amount. If the expiration date is not provided by the manufacturer, an expiration date of five years from entry of the chemical into the database is assigned.

All purchased materials are delivered directly to the requestor and/or the requestor lab. The source of these materials, as necessary, must be traceable to national or international standards of measurement. Certificates, if provided by the manufacturer, or other forms of material verification are available for purchased chemicals, cultures, test organisms and other reference materials. If the manufacturer provides a recertification of an expired standard, documentation of this recertification is kept in the laboratory.

24.1.2.2 Documentation of the Preparation of Secondary Materials

To maintain traceability all preparations are documented including CIS barcode of materials being used, other source information, e. g. date filled of containers with water tapped from the in-house DI water source if the water is used for elution or for preparation of analytical reagents or standards, date prepared of sterile water and water from the process water system, exactly what is being prepared, by whom, when, and expiration in the appropriate logbooks.

The required labeling information, including nature or concentration of the material, date prepared, by whom and date expired is placed on each secondary containers so that at any time the source of a material can be identified. It is important to note that manufacturers' expiration dates on stock materials equally apply to prepared dilutions. Labeling exceptions apply to small containers such as ampulated or vial materials that are tracked by each department in standards logbooks. Manufacturers' expiration dates are typically carried forward to prepared dilutions. The exception to this rule is the preparation of multi-component mixes. The shelf life specified in the individual SOP governs the expiration date of such prepared mixes. If individual standards used in a multi-component mix expire before that date it does not constrain the expiration date of the mix. Note that no already expired components are ever used in the preparation of a multi-component mix

24.1.3 Storage of Laboratory Materials

To ensure the integrity all prepared and purchased stock materials are stored as per referenced methods and SOPs and in accordance with the nature of the material and H&S considerations. Documented procedures for the storage of chemicals are contained in the current SOP for *Chemical Inventory and MSDS Management*, ESHSOP-MSDSMANAx.

24.1.4 Traceability of Supporting Laboratory Equipment

All equipment used affecting the quality of test results are calibrated prior to being put into service and on a continuing basis. Class "s" weights used for daily analytical and top loading balance checks are verified in-house on an annual basis against ASTM Class 1 weight sets. Thermometers are verified quarterly using NIST traceable reference thermometers. The accuracy and precision of all analytical and top loading balances are verified annually by an ISO certified outside company. Certificates, if provided by the manufacturer, or other forms of material verification are available for purchased chemicals, cultures, test organisms and other reference materials. Containers with water tapped from the in-house DI water source should be labeled with the date filled if the water is used for elution or for preparation of analytical reagents or standards, and if the water is not used the same day.

SECTION 25

PROJECT PLANNING AND SAMPLE COLLECTION (ISO/IEC 17025:2005(E), Clause 5.7)

NERL provides sampling services through EIA investigation and ECA field teams. Sampling procedures are maintained in the Lab SOP Database by the responsible SOP custodians.

25.1 Preplanning and Review Procedures

The NERL may be requested to perform analytical work by outside organizations or individuals in addition to NERL field samplers. Projects routinely undertaken by ECA's Ecology Monitoring Team (EMT) are requested by EPA Boston program offices, states, tribes, other federal agencies and local environmental organizations. Once requested, the various projects are prioritized according to program priorities by ECA's management in consultation with Boston water program management.

At this stage in the process, one option that can be taken is that at his/her discretion, the unit manager unilaterally may accept or reject such work. Once projects are selected, EMT Project Managers are assigned to assist in ensuring a schedule is developed and identifying, when projects are proposed to be undertaken, personnel availability and responsibility. In addition, the Project Lead is directly responsible for the development and approval of a project specific Quality Assurance Project Plan (QAPP) or Sampling and Analysis Plan (SAP).

All requests for analyses are submitted to laboratory management. Requests can be received over the phone, via e-mail or through a laboratory analytical request form. Preplanning of samples is done after approval of the work by the responsible party, e.g., EIA Unit Manager, Chemistry Team Leader or ECA assigned Project Leads. This can be done months or days before the planned arrival of the samples, depending on the nature of the analyses, DQOs, and laboratory capacity. Modifications to sampling design or laboratory analysis scheduling will be coordinated between sampling and laboratory project leads and the client as necessary.

25.2 Quality Assurance Project Plans and Sampling and Analysis Plans

All NERL environmental data operations, including sampling and analytical activities, must be conducted under an approved Quality Assurance Project Plan (QAPP) or Sampling and Analysis Plan (SAP) that is current and accurate. This requirement applies to all data operations performed by EPA or directly for EPA through EPA-funded extramural agreements, such as grants, contracts, and inter-agency agreements. In the event that requesting parties are other than those above

the EPA's quality requirements for the analytical work are covered by the laboratory components of the QAPP plan, the community's EPA approved quality assurance plan, and the applicable EPA field and analytical standard operating procedures. Exceptions to this requirement include samples collected and analyzed under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

Requirements for QAPPs can be found in the EPA quality system document "EPA Requirements for Quality Assurance Project Plans (QA/R-5)", March 2001, (reissued May 2006). The regional program is documented in "EPA New England Quality Assurance Project Plan Program Guidance", Rev. 2, January 9, 2010.

Both EIA and ECA have approved Generic Field QAPPs documenting the procedures to be used for conducting most sampling and analytical activities. Project-specific work is described in SAPs or project specific QAPPs. The current generic QAPPs are located in the Lab SOP Database.

As an aid to QAPP and SAP development, information on sampling containers, preservation requirements, and holding times for analyses conducted by ECA are provided in Table 25-1 and by EIA are provided in Table 25-2, and are also provided in the Lab SOPs Database under "Collection Info".

The Sample Acceptance Criteria is highlighted in the Sample Planning Memorandum and provided to the analysis requestor. There is one general exception: samples hand delivered to the laboratory and analyzed on the day of collection are expected to be iced during transport, however, they would not be expected to necessarily be in the range stipulated in Table 25-1 at the time of receipt. A more specific instance pertains to microbiology samples and the fact that potentially chlorinated samples are tested in the field for residual chlorine and the field results noted on both the Sample Receipt Form and COC, both of which are to be maintained in the project folder.

25.3 Project Meetings

As part of the project planning process, three different meetings may be held. First is the project scoping meeting. The Project Lead is responsible for the scheduling of the scoping meeting, involving all parties including but not limited to, field sampling personnel, laboratory personnel, QA personnel and data users.

With an approved QAPP completed and necessary personnel and equipment assembled, a pre-sampling meeting may be held to review and ensure that everyone understands the project, media to be sampled, and equipment to be used, and have appropriate training for their assigned responsibilities, prior to field

collection. When requested, these meeting will be attended by the appropriate laboratory personnel.

Once the project is completed, a de-briefing meeting may be held to discuss issues and ideas that arose while the activity was being performed. This meeting serves the purpose of identifying problems while they are fresh on people's minds and to improve future efforts.

25.4 Sampling Records

Record keeping is discussed in Section 16. All records required by the QAPP are maintained including sampling procedure used, the date and time of sampling, the identification of the sampler, environmental conditions, the sampling location, and the statistics upon which the sampling procedures are based. Deviations from the QAPP or SAP are documented in the field logbooks and final report.

Figure 25-1: Project Planning Strategy

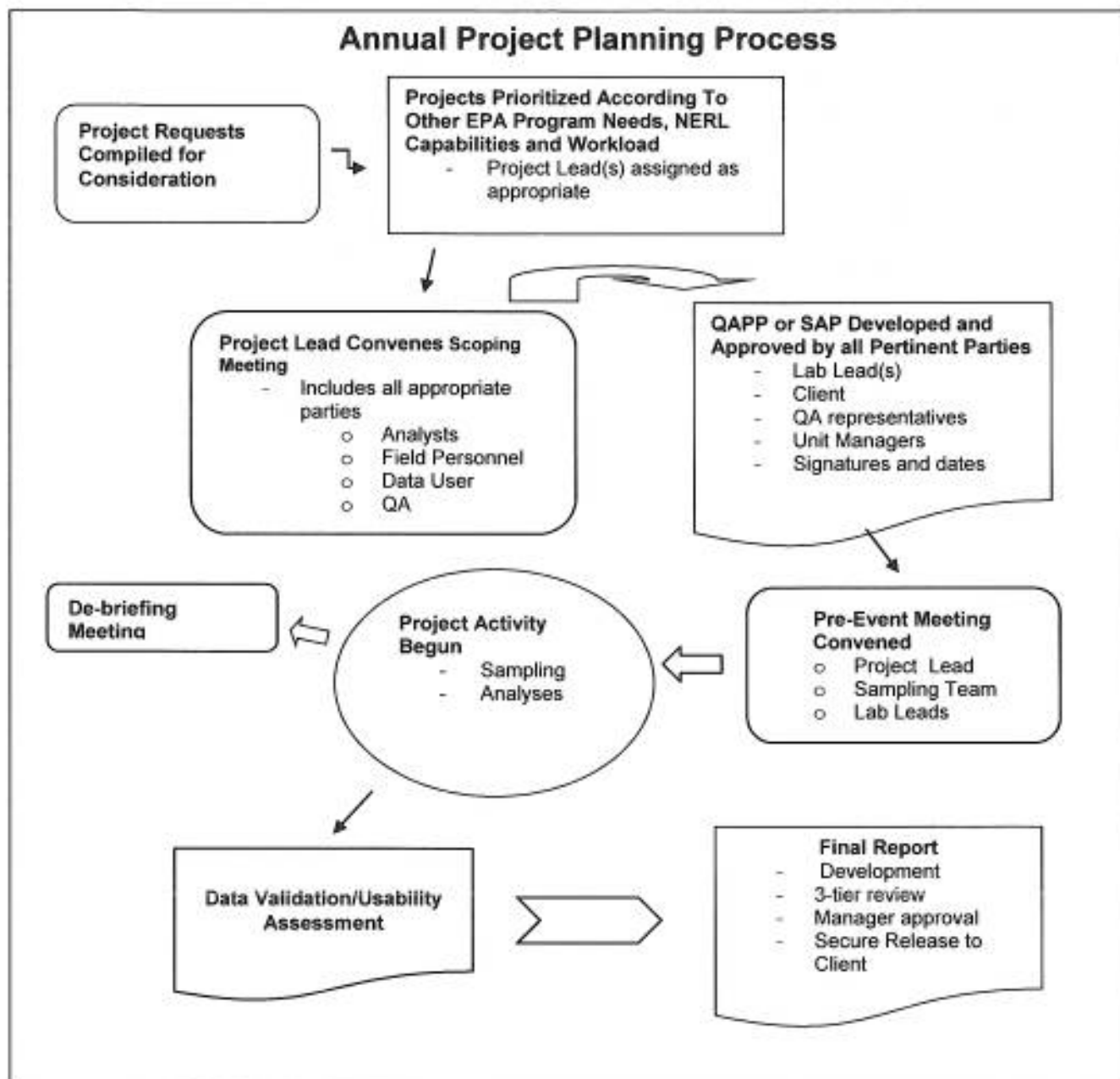


Table 25-1: Biology Laboratory Summary of Sampling Container, Preservation and Holding Time Requirements

PARAMETER	MATRIX	CONTAINERS/Min. VOLUME	PRESERVATIVE	HOLDING TIME
Toxicity test	Aqueous	P, G 3L [§] , 5L/species *	0 - 6 °C	36 hours
Sediment Toxicity	Sediment	P, G 3L	0 - 6 °C	14 days
Microtox	Aqueous	P, G 100 ml	0 - 6 °C	48 hours
	Sediment	P, G 10 grams	0 - 6 °C	48 hours
Tissue Samples	Tissue	as per QAPP	0 - 6 °C or frozen -20°C	as per QAP
Grain Size	Sediment	P 200 grams	NA	NA
Chlorophyll Analysis	Aqueous	Opaque or Amber P 2L	0 - 6 °C	4 hours
Chlorophyll Analysis	Filter	Foil covered Petri dish	Frozen -20 °C	3.5 weeks
Bacteria samples	Aqueous	P 100ml	0 - 10°C for DW 0 - 4°C for WW Na ₂ S ₂ O ₃ , if necessary (TRC = ND)	6 hrs waste/surface water, 24 hrs drinking water

§- for acute tests

*- 3L on the 1st, 3rd and 5th for a chronic standard serial dilution test

Table 25 – 2: Chemistry Laboratory Summary of Sampling Container, Preservation and Holding Time Requirements

Aqueous Sample Reference Guide								
INORGANICS	Analyses ¹	Methods ²	Container Type ³	Recommended Quantity	Preservative	Holding Time ⁴	Reporting Limit ⁵	SOP
Alkalinity	EPA 310.2	Lachat 10-303-31-1-A	Plastic	1 liter	4°C	14 days	20 mg/L	EIASOP-INGTOTALKAO
Chloride	300.0		Plastic or Glass	250 mL	4°C	28 days	0.50 mg/L	EIASOP-INGIC12
Fluoride	300.0		Plastic or Glass	250 mL	4°C	28 days	0.50 mg/L	EIASOP-INGIC12
Nitrate	300.0		Plastic or Glass	250 mL	4°C	48 hours	0.10 mg/L	EIASOP-INGIC12
Nitrite	300.0		Plastic or Glass	250 mL	4°C	48 hours	0.10 mg/L	EIASOP-INGIC12
Nitrate/Nitrite	300.0		Plastic or Glass	250 mL	H ₂ O ₂ , pH = 2	28 days	0.10 mg/L	EIASOP-INGIC12
Sulfate	300.0		Plastic or Glass	250 mL	4°C	28 days	0.10 mg/L	EIASOP-INGIC12
Bromide	300.0		Plastic or Glass	250 mL	4°C	28 days	0.50 mg/L	EIASOP-INGIC12
Magnesium	Based on 300.0		Plastic or Glass	250 mL	4°C	6 weeks	0.20 mg/L	EIASOP-INGIC12
Calcium	Based on 300.0		Plastic or Glass	250 mL	4°C	6 weeks	0.20 mg/L	EIASOP-INGIC12
Sodium	Based on 300.0		Plastic or Glass	250 mL	4°C	6 weeks	0.20 mg/L	EIASOP-INGIC12
Potassium	Based on 300.0		Plastic or Glass	250 mL	4°C	6 weeks	0.20 mg/L	EIASOP-INGIC12
Lithium	Based on 300.0		Plastic or Glass	250 mL	4°C	6 weeks	0.20 mg/L	EIASOP-INGIC12
Ammonium	Based on 300.0		Plastic or Glass	250 mL	4°C	7 days	0.20 mg/L	EIASOP-INGIC12
Cyanide	325.1, SM4500-CN EPA 9012B	Lachat 10-304-00-1-X	Plastic or Glass	250 mL	NaOH, pH=12, 4°C	14 days	5.0 ug/L	EIASOP-INGCNH4
pH	8040B, SM4500-HB		Glass	50 mL	4°C	Immediate, not to exceed 14 days	NA	EIASOP-INGPH6
Total Phosphorus	395.1	Lachat 10-118-01-1-F	Plastic or Glass	1000 mL	H ₂ SO ₄ , pH = 2, 4°C	28 days	5.0 ug/L	EIASOP-INGTP10
ortho-Phosphate	395.1, Lachat 10-115-01-1-F		Plastic or Glass	250 mL	4°C	48 hours	5.0 ug/L	EIASOP-INGTP10
Total Suspended Solids (TSS)	160.2		Plastic	1.0 L	4°C	7 days	5.0 mg/L	INGTSS-TDS-VRE55
Total Dissolved Solids (TDS)	160.1		Plastic	1.0 L	4°C	7 days	5.0 mg/L	INGTSS-TDS-VRE55
Total Volatile Residue (TVRS)	160.4		Plastic	1.0 L	4°C	7 days	2.0 mg/L	INGTSS-TDS-VRE55
Total & Dissolved Metals by ICP-AES	200.7, 6010B, SM2340B		Plastic or Glass	200 mL	HNO ₃ , pH=2, 4°C	180 days	As: 10 ug/L, Arsenic 1.0 ug/L, Barium 20 ug/L, Bismuth 20 ug/L, Cadmium 10 ug/L, Calcium 100 ug/L, Chromium 20 ug/L, Copper 20 ug/L, Iron 40 ug/L, Magnesium 120 ug/L, Manganese 20 ug/L, Nickel 20 ug/L, Lead 20 ug/L, Potassium 20 ug/L, Selenium 20 ug/L, Strontium 20 ug/L, Vanadium 20 ug/L, Zinc 20 ug/L, Zirconium 20 ug/L, Barium 5.0 ug/L, Bismuth 5.0 ug/L, Cadmium 0.25 ug/L, Cobalt 0.25 ug/L, Chromium 0.25 ug/L, Copper 0.25 ug/L, Iron 50 ug/L, Magnesium 180 ug/L, Manganese 5.0 ug/L, Nickel 0.20 ug/L, Lead 0.20 ug/L, Potassium 5.0 ug/L, Selenium 1.0 ug/L, Strontium 0.50 ug/L, Vanadium 0.20 ug/L, Zinc 2.0 ug/L, Zirconium 0.50 ug/L	EIASOP-OPTMA55
Total & Dissolved Metals by ICP-MS	200.8		Plastic	200 mL	HNO ₃ , pH=2, 4°C	180 days	As: 10 ug/L, Arsenic 1.0 ug/L, Barium 20 ug/L, Bismuth 20 ug/L, Cadmium 10 ug/L, Calcium 100 ug/L, Chromium 20 ug/L, Copper 20 ug/L, Iron 40 ug/L, Magnesium 120 ug/L, Manganese 20 ug/L, Nickel 20 ug/L, Lead 20 ug/L, Potassium 20 ug/L, Selenium 20 ug/L, Strontium 20 ug/L, Vanadium 20 ug/L, Zinc 20 ug/L, Zirconium 20 ug/L	EIASOP-INGICPM55
Mercury	245.1, 245.2, 245.3, 7470A, 1311		Plastic or Glass	200 mL	HNO ₃ , pH=2, 4°C	28 days	0.20 ug/L	EIASOP-INGNIPPHHG0
Turbidity	180.1, SM2130B		Plastic or Glass	200 mL	4°C	48 hours	0.2 NTU	EIASOP-INGTURB6
VOLATILE ORGANICS BY GC/MS								
Analyses	Methods	Container Type	Recommended Quantity	Preservative	Holding Time	Reporting Limit	SOP	
Drinking Water	824.2	amber VOA teflon lined cap	4 x 40 mL	Ascorbic acid, HCL, pH 2, 4°C	14 days	0.5 ug/L	EIASOP-VOAGCM59	
Water	824, 8250B	amber VOA teflon lined cap	4 x 40 mL	NaOH/NaHCO ₃ , pH 2, 4°C	14 days	1.0 ug/L	EIASOP-VOAGCM59	
1,4-Dioxane	8250B	amber VOA teflon lined cap	4 x 40 mL	4°C	14 days	2.0 ug/L	EIASOP-VOADOX	
EXTRACTABLE ORGANICS BY GC/MS								
Analyses	Methods	Container Type	Recommended Quantity	Preservative	Holding Time	Reporting Limit	SOP	
Acid/Base Neutral	8270C, 824	Amber glass teflon, lined cap	2 x 1.0 L	4°C, Na ₂ S ₂ O ₅	7 days extraction	varies	EIASOP-BNAW3	
Polynuclear Aromatic Hydrocarbons (PAH)	8270C, 8270C-5/M	Amber glass teflon, lined cap	2 x 1.0 L	4°C, Na ₂ S ₂ O ₅	7 days extraction	varies	EIASOP-BNAW3 EIASOP-PAHWALL6	
EXTRACTABLE ORGANICS BY GC								
Analyses	Methods	Container Type	Recommended Quantity	Preservative	Holding Time	Reporting Limit	SOP	
Pesticides (Organochlorine)	8061A, 806, 3510C, 3655A	Amber glass teflon, lined cap	1 x 1.0 L, 4 liters from 1 location	4°C, Na ₂ S ₂ O ₅	7 days extraction	0.02 ug/L, 0.5 ug/L, isoprene and chlordane	EIASOP-GCPEBWALL6	
PCBs	8062, 806, 3510C, 3655A	Amber glass teflon, lined cap	1 x 1.0 L, 4 liters from 1 location	4°C, Na ₂ S ₂ O ₅	7 days extraction (508), None 8062	0.5 ug/L	EIASOP-GCPEBWALL6	
Oil ID	3840A, 8000B	Amber glass teflon, lined cap	1 x 1.0 L	4°C	7 days extraction	50.0 mg/L	EIASOP-MISCID3	
HPLC/MS/MS								
Analyses	Methods	Container Type	Recommended Quantity	Preservative	Holding Time	Reporting Limit	SOP	
Perchlorate	331.0, 314.0, 8000B	50 mL, sterile HCL	1	Stead, 0.2 M, 4°C	28 days	0.20 ug/L	EIASOP-LCMSCLDW4	

US EPA New England Regional Laboratory Quality Manual

Soil/Solid Sample Reference Guide

INORGANICS							
Analyses	Methods	Container Type	Recommended Quantity	Preservative	Holding Time	Reporting Limit	SOP
Asbestos	EPA-505/5-88-011 335.1, SM4500-CN	Plastic baggie	1	None	None	1%	EIASOP-INGASBSE02
Cyanide	EPA 9012B, Lachat 10-204-00-1-X	4 oz. glass amber jar	1	4°C	14 days	2.5 mg/L	EIASOP-INGCN14
Mercury by CVAA	245.5, 245.5 GLP-M, 7471A, 1311	4 oz. glass or plastic jar	1	4°C	28 days	0.05 mg/Kg	EIASOP-INGNPPONH05
Mercury by DMA	7473	4 oz. glass or plastic jar	1	4°C	28 days		EIASOP-INGDMA1
Metals by ICP-AES	6015B	4 oz. glass or plastic jar	~ 1/2 full	4°C	180 days	Silver 1.0 mg/kg, Aluminum 11 mg/kg, Arsenic 2.5 mg/kg, Barium 2.0 mg/kg, Beryllium 0.5 mg/kg, Cadmium 1.0 mg/kg, Calcium 1.0 mg/kg, Cobalt 2.5 mg/kg, Chromium 2.0 mg/kg, Copper 2.0 mg/kg, Iron 4.0 mg/kg, Magnesium 10 mg/kg, Manganese 2.0 mg/kg, Nickel 2.0 mg/kg, Lead 2.0 mg/kg, Antimony 2.0 mg/kg, Selenium 2.0 mg/kg, Thallium 2.0 mg/kg, Vanadium 2.0 mg/kg, Zinc 2.0 mg/kg	EIASOP-OPTWAS0
pH	9045C	4 oz. glass or plastic jar	1	4°C	Immediate, not to exceed 14 days	NA	EIASOP-INGPH5
Flashpoint	1026A, 3278-89	ASTM D 40 mL VOA	1	4°C	14 days	NA	EIASOP-MSCFLAS10

VOLATILE ORGANICS BY GC/MS

Analyses	Methods	Container Type	Recommended Quantity	Preservative	Holding Time	Reporting Limit	SOP
Volatile Organics	8260, (high level)	5035 40 mL VOA, 10 - 15 grams (1:1 ratio with MeOH)	1 and 1 40-mL VOA with just soil for % solids (2)	MeOH, 4°C	14 days	50.0 ug/Kg	EIASOP-VOAGOW59
Volatile Organics	8260, (low level)	5035 40 mL VOA, 5 g + 5mL water w/str bar	+ (1) sampled for high-level and 1 40 mL VOA with just soil for % solids	NaHSO4, MeOH, 4°C	14 days	50.0 ug/Kg	EIASOP-VOAGOW59

EXTRACTABLE ORGANICS BY GC/MS

Analyses	Methods	Container Type	Recommended Quantity	Preservative	Holding Time	Reporting Limit	SOP
Acid/Base Neutral	8270C, 3640A	8 oz. glass amber jar	1	4°C	14 days	105 ug/Kg - low level, 1.0 mg/Kg mid/high level	EIASOP-BNAN3
Polynuclear Aromatic Hydrocarbons (PAH)	8270C, 8270C-SM	8 oz. glass amber jar	1	4°C	14 days	1.7 ug/Kg	EIASOPBNAN3, EIASOP-PAHWA18
Acid/Base Neutral - product sample non-miscible with water	8270C	40 mL VOA	1	4°C	14 days	250 mg/Kg	EIASOP-BNAP3

EXTRACTABLE ORGANICS BY GC

Analyses	Methods	Container Type	Recommended Quantity	Preservative	Holding Time	Reporting Limit	SOP
Pesticides (Organochlorine)	8000B, 8085A, 3545A, 3665A, 3640A	4 oz. glass amber jar	1	4°C	14 days	5.0 ug/Kg - high level, (100 for toxaphene and chlordane) 0.03 ug/Kg - low level (17 for toxaphene & Chlordane)	EIASOP-PESTS063
PCBs	8000D, 8085A, 3545A, 3665A, 3640A	4 oz. glass amber jar	1	4°C	None	17 ug/Kg low level, 100 ug/Kg high level	EIASOP-PESTS063

Air Sample Reference Guide

Analyses	Methods	Container Type	Recommended Quantity	Preservative	Holding Time	Reporting Limit	SOP
Air Toxics	TO-15	SUMMA	1.5 liter	None	28 days	~ 0.05 ppbv	EIASOP-AIRCAN12
PAHs	EPA/800-R-98/181, Sept., 1998	SUMMA	1.5 liter	None	28 days	Varies	EIASOP-AIRCZ09
Metals	200.9	Glass or plastic	Quartz filter	4°C	180 days	varies	EIASOP-INGCPM55
PAHs	TO-13A	PUFIXAD-2 resin	15 L min ⁻¹ for 4 hours	4°C	7 days	0.05 ng	EIASOP-AIRPAH3
Carbonyls	TO-11	DNPH cartridge	1 x 1 blank	4°C	30 days	varies	EIASOP-AIRCOC5

1. A comprehensive list of our target analytes under each of these analyses is included with the method Standard Operating Procedure (SOP) in our Lotus Notes SOP database. The SOP data base is accessible to EPA staff on our intranet page at <http://r1-gis-web.r1.epa.gov/8670/ocem/>. For many methods we can look for other analytes of interest as Tentatively Identified Compounds (TICs) and can often provide a concentration estimate. Because we do not calibrate for these other compounds we cannot definitively quantify as part of our routine analyses.

2. The Region 1 lab is a Performance Based Method Specific lab which means we operate off of our own SOPs based on EPA drinking water, EPA wastewater, EPA RCRA methods and/or ASTM methods. This column provides the source method(s) our SOP is based on.

3. The Region 1 lab does not provide sample containers to outside contractors.

4. Holding time is the time within which a sample must be analyzed (or an extract of the sample prepared, as noted in table.) It begins at the moment a sample is placed in its container. Any delays in delivery of a sample to the lab compromises our ability to analyze it within its holding time.

5. Reporting limits are the detection limits we can routinely achieve with our methods. Where the table states "varies" you can consult the SOP for the reporting limit for each individual target analyte. A sample matrix likely to interfere with detection of target analytes (e.g. organic rich sediments, landfill leachate) will require additional processing steps and may compromise our ability to achieve reporting limits. These situations require close consultation between programs and OCME.

SECTION 26

SAMPLE HANDLING: Receipt, Custody and Disposition *(ISO/IEC 17025:2005(E), Clause 5.8)*

26.1 General Sample Receipt and Acceptance Procedures

Samples are collected and preserved according to QAPPs, SAPs and method requirements. The Sample Acceptance Policy is made available to sample collection personnel during project planning meetings, or through direct communication with project managers and/or staff responsible for field sample collection via the Sample Planning Memorandum (Figure 7-1). Sample integrity is maintained through adherence with this *Quality Manual* and project-specific QAPPs or SAPs. Appropriate equipment, storage containers, preservation and holding times are used.

Procedures for sample receipt are documented in the SOP for Sample Login, Tracking, Disposition and Disposal, EIASOP-ADMLOGNx and ECASOP-Bio Lab Sample Receiptx. All samples are accompanied by a chain-of-custody (COC) form (Figure 26-1).

During sample receipt, chain-of-custody (COC) is reviewed, sample condition is documented, samples are given unique identifiers, and then logged into the LIMS. This check is performed against the Sample Receipt Checklist (Figure 26-2). If sample acceptance criteria are not met, the Sample Custodian will notify the appropriate ECA/EMT or EIA laboratory personnel who will determine the impact to the integrity of the samples and on the analysis, and as necessary contact the client. In all cases, the condition of these samples shall be noted on the Laboratory Receipt Checklist and reported as necessary to the client by e-mail. The analysis data of these samples shall be appropriately "qualified" on the final report.

The Project Lead will be notified if holding times, sample preservation or sufficient volume have not been met in accordance with Table 25-1 and 25-2 in Section 25 or as per the analysis-specific SOP and/or project QAPP or SAP with the following exception: Samples hand delivered to the laboratory and analyzed on the day of collection are expected to be iced during transport. However, they would not be expected to be in the temperature range stipulated in Table 25-1 prior to test initiation. Data related to such samples meeting this exception would not be qualified for not meeting sample receipt requirements for temperature.

26.1.2 Fixed Laboratory

Samples that are hand delivered to the laboratory custodian are brought into the laboratory through the doors next to the loading dock. Samples that are mailed

(Federal Express, UPS or Postal Service) are accepted by the Facilities Staff and then delivered to the sample custodian in Rm 190. Upon verification of the condition of the samples and the chain-of-custody (COC) form, the sample custodian accepts the samples for the laboratory by signing the COC immediately following relinquishment by the shipper or individual delivering the samples to the laboratory.

Biology Laboratory exceptions to the general sample receipt process are as follows:

- Due to short hold time, bacteria samples for traditional analysis will be received directly into the Microbiology Laboratory. Samples will be checked by the microbiology analyst at that time against the Sample Receipt Checklist. Upon verification, the analyst accepts for the laboratory by signing the COC. Once sample processing is fully initiated the completed COC and Sample Receipt Checklist will be submitted to laboratory login personnel for login into the LIMS.
- For chronic aqueous toxicity testing, the second and third set of samples (1st and 2nd renewals) will be taken and received directly into the Toxicity Testing Laboratory accompanied by a completed COC. Toxicity Lab personnel will write the original sample Project Number on the COC to identify these samples as being associated with the same study as the original samples. Upon receipt, the samples are checked against the Sample Receipt Checklist. The person receiving the sample will enter into the Toxicity Laboratory Sample Receipt logbook any assigned toxicity laboratory ID (including an "A" or "B" denoting first or second renewal sample, respectively), the date of receipt, recipient's initials and designated storage location. On the sample containers, the person receiving the samples will write, as necessary, the toxicity laboratory ID number. Samples will be placed into the storage location. The COCs and Sample Receipt Checklist for renewal samples will be placed in the original project specific folder and a copy of the COC is stapled in the Toxicity Laboratory Sample Receipt logbook.
- Whole biological samples (e.g., fish) submitted for chemical analysis requiring extensive dissection and further processing into multiple parts for individual analysis of each of those parts will initially be received under COC directly into the Biology Laboratory. Upon receipt, the samples are checked against the Sample Receipt Checklist. The person receiving the samples will enter into the Biology Lab Tissue Sample Processing Logbook located in Rm 202, a stapled copy of the COC, the study name, the date of receipt, recipient initials and storage location. Frozen or to be frozen samples will be designated for storage in either the freezer in Rm 205, 181A or the -40°C in Rm 190. The Biology double door refrigerator in Rm 190 will be used for "fresh" samples. The Biology Lab Manager or designee will be emailed that the samples have been received and are located in the designated freezer or refrigerator. These

samples will be processed according to the approved study QAPP to a finished product. The finished samples will be transferred under COC to the NERL sample login for the entrance into the LIMS of sample for analysis at NERL. Whole biological samples submitted for processing only and subsequent shipment will be received under COC directly into the Biology Laboratory. Upon receipt, the samples are checked against the Sample Receipt Checklist. The person receiving the samples will enter into the Biology Lab Tissue Sample Processing Logbook located in Rm 202, a stapled copy of the COC, the study name, the date of receipt, recipient initials and storage location. These samples will be processed according to the approved study QAPP to a finished product. The finished samples will be shipped under COC to the receiving party.

For Criminal Enforcement Division (CID) Samples, EPA analysts are notified and sign the COC form (also see Section 26.2).

The following information is checked on the COC form: project name, sampler's signature, sample numbers (usually pre-assigned by sampling crew), date and time of sample collection, parameters for analysis, number of containers and size, matrix and preservation (if applicable and if documented on the COC), "relinquished by" signature, date and time. If the sample matrix and/or preservation are not listed on the COC, the information is checked on the sample tag or container.

A Sample Receipt Checklist (Figure 26-1) is completed by the sample custodian for each batch of samples that is received. Proper condition of the samples is checked by measuring the temperature of the cooler with a hand held IR thermometer. Actual verification of the pH of preserved samples is done by the laboratory analyst before analyzing samples.

The samples are given a unique laboratory project identification number (NERL project number). This number may have been assigned in the preplanning stage. The samples are then stored in the appropriate storage refrigerator in Room 190, and logged into the applicable sample refrigerator logbooks:

Walk in Unit: Organics, Inorganics, Wet Chem

R-13: VOAs

F2: Air PAMS Carbonyls

R3: Enforcement

Biology Samples: Frozen or to be frozen samples designated for storage in either the freezer in Rm 205, 181A or the -40°C in Rm 190. The Biology double door refrigerators in Rm 190 or Rm 205 will be used for "fresh" samples.

Canisters for air analysis (PAMS and air toxics) are stored on the storage racks in the laboratory hallway.

The original copy of the COC form is stapled in the appropriate Sample Receipt Logbook. Detailed procedures are described in the SOP for Sample Login, Tracking, Disposition and Disposal (ADMLOGNx.SOP x) and ECASOP-Bio Lab Sample Receiptx. . The sample information is then entered in the LABWORKS LIMS database. Designated personnel are notified by email about the receipt of the samples. The sample custodian also prepares project folders and files them according to date received or laboratory location.

26.1.3 Field Analyses

The samples are received by the EPA field analyst in the field. If a COC form accompanies the samples, the EPA analyst verifies the information according to Section 26.1.2. The EPA analyst also checks proper condition of the samples according to guidelines listed in Section 26.1.2. A COC form is required for samples that are brought to the fixed lab for analysis.

26.1.4 Analyses Contracted to ESAT

For samples analyzed by ESAT, sample receipt procedures outlined in section 26.1.2 are used.

26.1.5 Analyses Contracted to Outside Laboratories

For samples that are contracted to an outside analytical laboratory, the following procedures are used:

- A procurement request is completed by EPA. Refer to Section 8.
- When samples arrive at the EPA laboratory, the samples are logged in by the sample custodian according to procedures outlined in section 26.1.2, with the exception that the EPA analysts are not notified, however, a project folder is prepared (not color-coded).
- The samples are then delivered to the independent laboratory (the samples are either delivered by EPA personnel or picked up by a courier of the other laboratory).
- A chain of custody form accompanies all samples that are sent to a contract laboratory.
- Occasionally, arrangements are made with the sampler to deliver the samples directly to the outside laboratory. In this case, storage procedures at the EPA laboratory are not applicable. A copy of the chain of custody is then delivered to EPA for sample login according to the procedures outlined above

26.2 Evidentiary Sample Tracking System – Legal Chain of Custody

If samples are noted as being used for legal/evidentiary purposes, special tracking and storage procedures are applied as described in the Evidentiary Sample Tracking System SOP, EIASOP-ADMEVIDx.

26.3 Sample Custody

All COC forms are reviewed when samples are received. Section 25 describes required sample information. COC forms and any additional records received at the time of sample submission are maintained by the laboratory.

26.3.1 Laboratory Analyses

When preparing to analyze samples, the analyst signs out the samples from the sample storage refrigerator logbook. The analyst also picks up the project folder from the sample check-in or laboratory desk and immediately completes all applicable documentation on the bench sheets in this folder (Section 16). This project folder remains with the samples throughout the analyses. After analysis, the remainder of the sample is returned to the sample storage refrigerators, and signed back into the sample refrigerator logbook. After the sample holding time expires, the sample disposal coordinator arranges for sample disposal, according to the ADMLOGNx.SOP or biology samples are disposed of according to disposal practices described in ECASOP-Bio Lab Sample Receiptx.

Monitoring of the progress of the analytical work is accomplished through the LABWORKS LIMS system. Chemistry analysts must update the STATUS ADVANCE field as soon as the next available status is reached.

Available status fields:

LOGGED IN

IN PROGRESS

DRAFT REPORT

A work in progress report (WIP) can be generated from the LIMS database at any time, showing the status of a particular group of samples. The report includes Project Number, Survey Name, requested analysis, number of samples per matrix, receipt date, due date and LIMS status. Further details on the LIMS system are described in Section 16.

26.3.2 Field Analyses

The EPA field analyst maintains control of the samples in the field. After analysis, the remainder of the sample is sent back to the EPA laboratory and stored awaiting disposal according to the ADMLOGNx.SOP. Occasionally, arrangements are made to dispose of the remainder of the samples at the field site.

Upon notification of the laboratory that the field analyses are completed and preliminary results have been released, the samples are logged into the LIMS system. A unique laboratory identification number is assigned upon login. The final report is then released and the LIMS STATUS ADVANCE field updated.

26.3.3 Analyses Contracted to ESAT

For samples analyzed by ESAT, chain-of-custody procedures outlined in section 26.3.2 are followed by the ESAT chemists. ESAT performs the analyses using instructions from a Technical Direction Form (TDF) issued by the Task Order Contract Officer Representative (TOCOR). ESAT chemists adhere to all the Regional technical requirements and policies, and follow guidelines from the *ESAT Chemistry QA Project Plan*, document QA1-3-96-02, revision 0, 2006.

26.3.4 Analyses Contracted to Outside Laboratories

Chain-of-custody procedures from the individual laboratory are used. If possible, the QA Plan and applicable SOPs from the outside laboratory are reviewed by an EPA analyst before samples are contracted out, and periodic site visits of the contract laboratory are performed by NERL analysts (see also Section 8). At a minimum, NERL determines that laboratories being used have a current ISO or NELAC accreditation, and that analyses being performed are within their scope of accreditation.

26.4 Sample Identification

Samples, including subsamples, extracts and digestates, are uniquely identified in a permanent chronological record in accordance with SOPs:

- LIMS LABWORKS Login Procedure, EIASOP-ADMLABWLOGNx
- Sample Log-in, Tracking and Sample Disposition, ADMADMLOGNx
- Sample Control Procedures for Samples Entering the Biology Laboratory, ECASOP-Bio Lab Sample Receiptx

26.5 Sample Disposal

Sample disposal and waste management are done in accordance with all applicable federal, state, and local regulations. Refer to the *Waste Management Program*, ESHSOP-WASTEMANx and the *SOP for Sample Login, Tracking, Disposition and Disposal*, ADMLOGNx and ECASOP-Bio Lab Sample Receiptx for detailed procedures.

26.6 Sample Transport

Samples that are transported under the responsibility of NERL, where necessary, are done so safely and according to storage conditions. This includes moving bottles within the laboratory.

[illegible]

Figure 26-2: US EPA Region 1 Sample Receipt Checklist

US EPA REGION 1
LABORATORY SAMPLE RECEIPT CHECKLIST

PROJ #:	RECEIPT DATE:
SURVEY NAME:	REC'D BY:
OSC/PO:	
WERE SAMPLES SHIPPED? YES, FEDEX / UPS/ OTHER NO, COURIER PICKUP / HAND DELIVERED	
COOLER TEMPERATURE UPON ARRIVAL _____ °C / NA	
CHAIN OF CUSTODY PRESENT? YES / NO COMPLETE? YES / NO	
CUSTODY SEALS PRESENT ON COOLER? YES / NO SAMPLES? YES / NO	
WERE SAMPLE CONTAINERS INTACT? YES / NO HEADSPACE? YES / NO	
WERE SAMPLES PRESERVED & DOCUMENTED ON COC or LABELS YES / NO	
APPROPRIATE SAMPLE VOLUMES FOR REQUESTED ANALYSIS? YES / NO	
SAMPLES AND COC MATCH? YES / NO	
TRC MEASURED IN FIELD? YES / NO	
RESULT ON COC _____ mg/l	
APPROPRIATE SAMPLE CONTAINERS? YES / NO	
SAMPLES WITHIN HOLDING TIMES? YES / NO	
ALL ANALYSIS SPECIFIED ON COC? YES / NO	
DATE/TIME OF COLLECTION & SAMPLE ID ON COC YES / NO	
IF NECESSARY, SAMPLE PROBLEM ACKNOWLEDGMENT BY SAMPLE DELIVERY PERSON/CLIENT	
_____ (SIGNATURE)	
BIOLOGY LAB MANAGER NOTIFIED? YES / NO	

SECTION 27

QUALITY ASSURANCE FOR ENVIRONMENTAL TESTING (ISO/IEC 17025:2005(E), Clause 5.9)

NERL has procedures for monitoring the validity of the data it generates. Quality control results associated with test results are recorded in such a way that trends are detectable, and where practicable, are statistically evaluated. To evaluate the accuracy and precision, and to ultimately to assess uncertainty, the laboratory uses: certified reference materials, proficiency testing samples calibration check samples, blanks, laboratory control samples (LCS), matrix spikes (MS), duplicates, surrogates and internal standards and control charting.

When quality control data are found to be outside pre-defined criteria, action is taken to correct the problem and to prevent incorrect results from being reported. Data associated with quality control data outside of criteria but still deemed reportable will be qualified so the end user may make a determination of the usability of the data for decision-making.

27.1 Essential Quality Control Procedures

Quality control procedures specified in test method SOPs are followed. The most stringent of control procedures is used in cases where multiple controls are offered. If it is not clear which is the most stringent, that mandated by test method or regulation is followed.

For test methods that do not provide acceptance criteria for an essential quality control element or where no regulatory criteria exist, acceptance criteria are developed and documented in test method SOPs. Also, in accordance with QAPP requirements, project-specific measurement performance criteria are developed to support project quality objectives and DQOs.

All tests methods and main analytical procedures require initial and on-going demonstrations of capability DOC. In the case of the Biology Lab microbiology and toxicity testing DOCs are based on PT and DMRQA studies, respectively. Chlorophyll and Milestone analyses rely on the testing of LFBs followed by measurement of precision and accuracy.

27.2 Internal Quality Control Practices

Detailed QC procedures and QC limits are included in test method SOPs, or where unspecified in the SOPs are detailed in the QAPP.

Analytical data generated with QC samples that fall within all prescribed acceptance limits indicate the test method is deemed to be in control.

QC samples that fall outside QC limits indicate the test method is deemed to be out of control (nonconforming) and that corrective action is required and/or that the data must be qualified (see Sections 12 and 14).

All QC measures are assessed and evaluated on an on-going basis, so that trends are detected.

27.3 Biology Laboratory Quality Control

27.3.1 Toxicity and Microbiology Laboratory Controls

27.3.1.1 Toxicity Testing

In the conduct of toxicity tests, laboratory positive controls are always included to ensure acceptable condition of the test organisms, food and other environmental conditions surrounding the test. Aquatic testing utilizes a dilution water positive control and when sediment toxicity tests are conducted, a prescribed laboratory formulated sediment consisting of sand, silt, clay, calcium carbonate and alpha cellulose (organic component) is tested alongside field samples. Meeting toxicity test specific method defined acceptability criteria for those controls is required in the determination of an acceptable test.

27.3.1.2 Microbiology

Certain microbiological test-specific acceptability measures are required in the determination of an acceptable test. These include positive and negative control samples, dilution water blanks or controls, and laboratory duplicates. Laboratory controls and or blanks are always included to ensure sterility of sample containers, filters, media, and funnels, demonstrate the absence of carry-over during the repetitive use of funnels in membrane filtration procedures and proper bacteria response.

A variety of bacterial reference cultures are maintained as both positive and negative laboratory controls to evaluate and confirm media quality and procedural performance. Laboratory blanks are tested in conjunction with field samples, laboratory replicates, and control culture samples.

27.3.2 Reference Toxicity Testing

Monthly and test concurrent chronic reference aqueous toxicity tests are conducted on *C. dubia* and *P. promelas* and quarterly, 96-hr, water column only, acute tests are performed on *Chironomus tentans* and *Hyaella azteca* for sediments. Reference toxicity testing is performed to monitor the health and consistency of response by test organisms as well as laboratory personnel performance.

Reference toxicant control charts exist for *P. promelas*, *C. dubia*, *H. azteca* and *C. tentans*. Control charts are maintained for both hypothesis and point estimate statistical endpoints. Boundaries are set at \pm one concentration of the hypothesis endpoint mode and \pm 2 SD for point estimate means. Control charts generated for all tests, both chronic and acute are maintained electronically in an EXCEL Spreadsheet file under G:\allshare\ECA\Biology\Laboratory QA\Control Charts. File folders of the results are maintained as hardcopy in the central biology lab files in Rm 152.

27.3.3 Precision and Accuracy

Precision is quantified by a variety of measures which for point estimates at this lab is the coefficient of variation. CV values are maintained as electronic control charts to determine whether test results are within the 75th percentile of previous tests.

27.3.4 Replicates, Duplicates and Dilution

EPA protocols include the use of minimum and/or specific test designs for the proper conduct of statistical analyses and/or results quantification include the following:

For toxicity testing:

- Ten replicates for *C. dubia* chronic and acute testing
- Three and four replicates for the fathead minnow acute and chronic toxicity tests, respectively
- Four replicates for *L. variegatus* bioaccumulation tests
- Eight replicates/species/sample treatment for *C. dilutus* and *H. azteca* sediment toxicity tests

For microbiology analyses:

- A dilution series as a means to a reportable result.
- Each month that a test method which specifies colony counts or the use of plated media is used to analyze samples duplicate counts are to be performed by a different analyst on 10% of the samples duplicate colony counts by different analysts on the same plate will be considered acceptable if the difference in the number of colonies is $\leq 5\%$.
- On a monthly basis each analyst will be checking their own work by analyzing 10% of the samples in duplicate with successful plate counts not to exceed 5% RPD.

27.3.5 Milestone and Chlorophyll Laboratory Controls

Quality Control requirements for each of these analyses including a "QC Requirements Summary Table" which are specified in procedure-specific SOPs.

27.3.6 Laboratory Water and Test Food Supply Quality

Reagent (DI/RO) water quality is monitored for contaminants which could interfere with testing results. On a monthly basis a sample of the water is checked for residual chlorine, specific conductance and pH. Foods and process waters used in the Biology Lab are analyzed in-house annually for metals, mercury, pesticides, PCBs, SVOCs and VOCs by the chemistry laboratory. Results are checked against method specific guidelines. Results are stored in hardcopy in the Biology Laboratory QA/QC central file Rm 152.

27.3.7 Test Method Procedure Assurance

Laboratory requirements for use of all analytical test methods include demonstration of capability (DOCs) and annual continuing demonstrations of capability for each individual analyst or work cell. Additionally, in the case of Milestone and Chlorophyll Lab analyses instrument specific method detection limit studies are performed as a means to identify the particular instrument method reportable limits. Records documenting these activities are located in the Biology Laboratory QA/QC central file Rm 152.

27.3.8 Blanks

27.3.8.1 Milestone and Chlorophyll Method Blank or Laboratory Reagent Blank

The method blank is a sample sized portion of deionized or distilled water. This blank is processed and analyzed like a sample. The results of the blank are used to check for analyte contamination during sample preparation or processing. A method blank is processed with every batch of up to 20 samples processed.

27.3.8.2 Milestone and Chlorophyll Calibration Blanks

The calibration blank is a portion of standard solvent which has not been processed as a sample, but is used to assess instrument run contamination, and establish the "zero" calibration point. It is run at a method specified frequency during the analyses. Refer to the SOPs for further guidance.

27.3.8.3 Milestone and Chlorophyll Instrument Blanks

The results from the instrument blank analysis indicate whether there is contamination associated with the instrumental analysis itself, including from “boats”, carry-over of analytes from standards and/or highly contaminated samples into analysis of environmental samples.

27.3.8.4 Field Blanks

Field blanks (trip blanks and equipment blanks) are check samples that monitor contamination originating from the collection, transport or storage of samples.

27.3.8.5 Milestone and Chlorophyll Blank Acceptability

Criteria for determining blank acceptability are based on consideration of the analytical techniques used, reported analytes, and required reporting limits. Ideally, the concentration of target analytes in the blank should be below the reporting limit for that analyte. The method SOPs address the blank acceptance criteria. The level of contamination of the target analyte must not exceed the reporting limit or, if present above the reporting limit, associated samples results may be qualified.

Samples associated with a contaminated blank must be re-processed and reanalyzed if enough sample is available and can be done within holding time. The project manager is notified and if no resampling is done the sample target analyte results associated with contamination are qualified in the final report (refer to method SOPs). In no instance is blank correction of the final data performed.

27.3.9 Milestone and Chlorophyll Laboratory Sample Duplicates

Laboratory sample duplicates are two equally portioned homogenized field sample which are processed and analyzed simultaneously to assess analytical precision. A Relative Percent Difference (RPD) is calculated to assess the precision of the sample analysis. The RPD QC criteria are referenced in the method SOPs and in the analytical reports released to the client

27.3.10 Milestone and Chlorophyll Matrix Spikes

A matrix spike (MS) is an aliquot of a field sample to which a known amount of analyte has been added. The MS sample is taken through the entire analytical procedure and the recovery of the analyte is calculated. Results are expressed as percent recovery. The MS analysis is used to evaluate the effect of the sample matrix on the accuracy of the analysis. Method SOPs reference the matrix spike frequency, and the criteria for acceptance of the data.

27.3.11 Milestone and Chlorophyll Laboratory Control Samples (LCS)

The LCS or Laboratory Fortified Blank (LFB) is where the target analyte is spiked into a laboratory blank and is analyzed for that analyte for each batch of water samples. Method SOPs reference the LFB frequency, and the criteria for acceptance of the results.

27.3.12 Secondary Source Standards

Standards obtained from a second source (different lot number or different vendor) are analyzed as an initial calibration verification standard (ICV) to verify the acceptability of the initial instrument calibration. Method SOPs reference the use and acceptability criteria of secondary source standard.

27.4 Chemistry Laboratory Quality Control

All SOPs include a "QC Requirements Summary Table. This table summarizes the specific QC requirements for the method, frequency, acceptance criteria and corrective action.

27.4.1 Blanks

27.4.1.1 Method Blank or Laboratory Reagent Blank

The method blank is a sample sized portion of deionized, distilled water or clean artificial sand or soil. This blank is processed and analyzed like a sample. The results of the blank are used to check for target compound contamination during sample preparation, or background interference from reagents. A method blank is processed with every batch of up to 20 samples processed.

27.4.1.2 Calibration Blanks

The calibration blank is a portion of solvent or the instrument specific background matrix which has not been processed as a sample, but is used to assess instrument contamination, and establish the "zero" calibration point. It is run at a method specified frequency during the analyses. Calibration blanks are applicable for inorganics analyses. Refer to the SOPs for further guidance.

27.4.1.3 Instrument Blanks

Instrument blanks are analyzed for all GC methods and for GC/MS methods. The results from the instrument blank analysis indicate whether there is contamination associated with the instrumental analysis itself, particularly with regard to carry-over of analytes from standards or highly contaminated samples into other analyses.

27.4.1.4 Field Blanks

Field blanks (trip blanks and equipment blanks) are check samples that monitor contamination originating from the collection, transport or storage of samples.

A trip blank or field reagent blank is a sample vial of reagent water that accompanies sample containers to the field and shipment.

An equipment blank is a rinsate of a sample collection device.

27.4.1.5 Holding Blanks for VOAs

Holding blanks are blanks that are kept in the sample storage refrigerator for VOAs. The blanks are analyzed quarterly and checked for contamination. Blanks are replaced quarterly.

27.4.1.6 Blank Policy

Criteria for determining blank acceptability are based on consideration of the analytical techniques used, reported analytes, and required reporting limits. Ideally, the concentration of target analytes in the blank should be below the reporting limit for that analyte. In practice, however, some common laboratory solvents and metals are difficult to eliminate to the ppb levels commonly reported in environmental analyses.

The method SOPs address the blank acceptance criteria. For Superfund, RCRA and NPDES methods, the level of contamination of the target analytes must not exceed the reporting limit. For the SDWA methods, contamination must be below the MDL. Exceptions are allowed for common laboratory contaminants as documented in the SOPs. If the blank does not meet acceptance criteria, the source of contamination must be investigated and appropriate corrective action taken and documented.

Samples associated with a contaminated blank must be re-extracted and reanalyzed if enough sample is available and re-extraction can be done within holding time.

Otherwise, the project manager is notified and if no resampling is done, target compounds associated with contamination are flagged in the report (refer to method SOPs).

Blank correction of the final data is not done.

27.4.2 Replicates

27.4.2.1 Laboratory Sample Duplicates

Laboratory sample duplicates are two equal portions of a homogenized field sample which are processed and analyzed simultaneously to assess laboratory precision.

A Relative Percent Difference (RPD) is calculated to assess the precision (Section 27.4). QC criteria are referenced in the method SOPs and in the analytical reports to the client

27.4.2.2 Surrogate Spikes

Surrogates are routinely added to samples for organics analysis by GC and GC/MS. Percent Recoveries are calculated to monitor accuracy and precision (Section 27.4), and the laboratory's day-to-day performance for routine analytical methods. Obvious problems with sample preparation and analysis will result in low surrogate recoveries. Occasionally, matrix effects will also give poor recoveries outside of the recovery limits. QC criteria are referenced in the method SOPs and in the analytical reports to the client.

The results of the surrogate recoveries are compared to well-defined acceptance criteria to determine whether the laboratory system is "in control". Recovery windows and corrective action procedures are documented in the method SOPs.

Trends in surrogate recoveries for blanks and samples are followed using control charts.

27.4.2.3 Matrix Spikes

A matrix spike (MS) and a matrix spike duplicate (MSD) are aliquots of a field sample to which known amounts of method specified analytes have been added. The MS/MSD samples are taken through the entire analytical procedure and the recovery of the analytes is calculated. Results are expressed as percent recovery and RPD.

The MS/MSD analyses are used to evaluate the effect of the sample matrix on the precision and accuracy of the analysis. QC criteria are referenced in the method SOPs and in the analytical reports to the client.

All target compounds are spiked in the matrix spike samples, with the exception for the multi-component pesticides such as technical chlordane, Toxaphene and Aroclors, where spiking simultaneously would interfere with an accurate measurement of the individual isomers. The spiking compounds always include, at a minimum, those specified by the mandated test method. SOPs reference the composition of the matrix spike samples.

A matrix spike is not analyzed for those analytes for which no spiking solutions are available, such as TSS, TDS, pH, color or turbidity.

Method SOPs reference the matrix spike frequency, and the criteria for acceptance of the data. The individual matrix spike recovery is compared to the acceptance criteria as published in the mandated test method. Where there are no established method criteria, the laboratory utilizes internal criteria as listed in the SOP, or can utilize client specified assessment criteria.

If not enough sample is available for an MS/MSD analysis, laboratory blanks spiked with the matrix spike compounds may be used.

27.4.3 Other QC Samples and Checks

27.4.3.1 Laboratory Control Samples (LCS)

The LCS can be a Laboratory Fortified Blank (LFB) or another QC check sample (QCS) obtained from a source independent of the other standards.

All target compounds are spiked, with the exception for the multi-component pesticides such as technical chlordane, Toxaphene and Aroclors, where spiking simultaneously would interfere with an accurate measurement of the individual isomers. The spiking compounds always include, at a minimum, those specified by the mandated test method. SOPs reference the composition of the LCS samples.

For metals analysis by ICP, ICP/MS, GFAAS and CVAA, an aqueous Laboratory Fortified Blank (LFB), spiked with known amounts of all analytes, is analyzed for each batch of soil and water samples.

For organics analysis, LFBs spiked with known amounts of all analytes are analyzed with each batch of samples.

The laboratory routinely analyzes QC check samples from an outside source to monitor the accuracy of the method (at a minimum on a quarterly basis). For inorganics analysis, a solid LCS is always included with each batch of soil samples.

For Wet Chemistry analyses, both an LFB and QCS are analyzed.

An LCS is not analyzed for those analytes for which no spiking solutions are available, such as TSS, TDS, pH, color or turbidity.

Method SOPs reference the LCS (LFB and QCS) frequency, and the criteria for acceptance of the data. The individual LCS is compared to the acceptance criteria as published in the mandated test method. Where there are no established method criteria, the laboratory utilizes internal criteria as listed in the SOP, or can utilize client specified assessment criteria. If the analyst uses acceptance limits based on control charts generated from LIMS, these must fall within the method established criteria.

The matrix spike may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS.

27.4.3.2 Secondary Source Standards

Standards obtained from a second source (different lot number or different vendor) are analyzed to verify the accuracy of the initial calibration standards.

These secondary standards are sometimes also used as spiking material for LFBs or MSD analyses. Method SOPs reference the use of secondary standards if applicable.

27.4.3.3 Reagent Water

Reagent (DI/RO) water quality is monitored for contaminants which could interfere with the chemical analyses by reviewing results from blanks analyzed in the chemistry laboratory. These data are available from the LIMS data base.

27.4.3.4 Solvents and other Blank Media

Solvents and other blank media are checked for method contaminants needed to meet DQOs (for example, if low detection limits are requested, or if a trend of contamination is being observed for common laboratory contaminants).

27.4.3.5 Sample Preservation

Sample preservation is checked by the analyst in the laboratory before analyzing the sample (for Volatiles analyses, a separate vial is used or the pH checked after analysis).

27.4.3.6 Batch Quality Control

When samples are analyzed for a particular customer, and the sample used for batch QC is from another client, reference to the other client's name and sample ID must be deleted from the LIMS report for that particular customer. Whenever possible, duplicate and matrix spike analyses are performed using a sample submitted from the batch submitted by each individual customer. For enforcement work batch QC must be performed on a sample from that individual customer.

27.5 Chemistry Laboratory Requirements for Analytical Test Method Evaluations, Demonstrations of Capability, Continuing Demonstrations of Proficiency, Method Detection Limits, and Limits of Quantitation

See EIASOP-ADMCAPABILITY2, Requirements for Analytical Test Method Evaluations, DOCs, CDOPs, DLs and LOQs.

27.6 Proficiency Test Samples

27.6.1 Biology Laboratory Performance Evaluation

Refer to Section 17.3.

27.6.2 Chemistry Laboratory Performance Audits

Refer to Section 17.4.

27.7 Data Review

It is the policy of NERL to review all data generated in the laboratory for compliance with method, laboratory and client requirements. A three tier review check is incorporated to assure acceptability of control measures, the absence of transcription and calculation errors and accuracy of the final result(s).

The three tiers of review involve initially a review by the primary analyst. A secondary review is then performed by an independent peer analyst or an individual laboratory lead. The final review involves, in the case of the Chemistry Lab, the Chemistry Team Leader and, for the Biology Lab, at least the Biology Lab QAO.

The laboratory uses Project Review Checklists to facilitate and document the internal verification of the data and to help safeguard for protection against common types of data errors. See Figures 27-1 and 27-2 for examples of typical laboratory generic Project Review Checklists. Customized checklists for particular analyses are also generally available in the test method SOP.

Each laboratory generic checklist has a header document control section which includes the file name of the checklist (includes revision number), an abbreviated reference to the analysis and the date.

These checklists which prescribe the particular items necessary in a final report and project folder include the following three areas for review:

- *Requested analysis and data folder completeness:* to ensure that the analyses requested were completed properly including adherence to SOPs, specific holding times and preservation requirements were met, correct sample IDs are presented, final results accurate and all necessary primary and supporting documentation is included in the data package.
- *Data Evaluation:* completed with a review of the raw data package including quality control measures, calculations, absence of transcription errors and the final data reported.
- *Final Report:* completed to ensure the information in the QC project notes are addressed and, if applicable, the qualification of the data (report flags) is made, all necessary information is present and the final report for release is accurate and complete.

Figure 27-1: Biology Laboratory Product Review Form

ECOLOGY MONITORING TEAM LAB PRODUCT REVIEW FORM

Project Title: _____
Project Number(s): _____
Customer: _____

Analyst Review

- ___ are the sample number(s) on the COC and the lab benchsheets the same
- ___ sample receipt information included
 - ___ in project folder
 - ___ in lab logbook
- ___ have the samples been analyzed according to the current SOP(s)
- ___ have holding times been met
- ___ have necessary QC samples been run
- ___ are bench sheets complete
- ___ is all necessary QC information recorded correctly in logs and binders
- ___ has analytical data been entered into LIMS

Analyst Initials _____ Date _____

Lab Lead Review

- ___ all information recorded in LIMS correct
- ___ all benchsheets, COCs and sample receipt information included and correct
- ___ proper QC samples have been used
 - ___ negative controls
 - ___ positive controls
 - ___ duplicates
- ___ benchsheets initialed and dated

Lab Lead Initials _____ Date _____

QAO Review

- ___ product is complete with all the necessary information on the report
 - ___ project number
 - ___ project title
 - ___ analysis times and dates
 - ___ qualification indicators
 - ___ pagination
- ___ is all necessary information included in the project file folder
 - ___ COC
 - ___ sample receipt information
 - ___ statistical analysis
 - ___ copy of pdfed report
- ___ All QC measure have been included and met
- ___ data quality is acceptable and meets the needs of the project

QAO Initials _____ Date _____

Team Lead or Lab Director Initials _____ Date _____

Figure 27-2: Chemistry Project Review Checklist for Miscellaneous Analysis

MISC Review Form

Revision: 4

Date: 4/3/06

EIAFRM-CHKLSTMIS4

QAO Approval:

Date:

Project Review Form

Misc Analysis

Project Number _____ Site _____ LIMS code _____ Matrix _____

Note: Any omissions or problems with the data require resolution before proceeding to the next review step.

REQUESTED ANALYSIS AND DATA FOLDER COMPLETENESS CHECK

- ☐ Does the LIMS information match the COC requests?- Check LIMS Project Form
- ☐ Were all samples analyzed and identified correctly?
- ☐ Have the samples been analyzed according to the current revision of the SOP(s)? Are all deviations of the SOP(s) approved and documented?
- ☐ Have holding times been met?
- ☐ Is sample preservation (if applicable) checked and documented for all samples?
- ☐ Is the raw data folder complete?
 - ☐ Copy of the Chain-of-Custody form and sample receipt checklist
 - ☐ Project notes
 - ☐ % Solids worksheet for soils
 - ☐ Instrument printouts/raw data/calibration data
 - ☐ Does this data require manual integration checks?
 - ☐ Have manual integrations or other manipulations or computer generated data been performed? If Yes, explain here or in Project Notes
 - List file names for manual integrations

Reviewed by:

Date Reviewed:

DATA EVALUATION

- ☐ Have the proper number of QC samples been analyzed?
 - ☐ Blanks
 - ☐ Matrix Spikes
 - ☐ Duplicates
 - ☐ PE Samples (if received with sample delivery)
 - ☐ Laboratory Control Sample/ QC check sample
 - ☐ Laboratory Fortified Blank
 - ☐ Second Source Standard
 - ☐ Calibration standards
 - ☐ Other- specify
- ☐ Is there documentation of standard preparation and traceability?

US EPA New England Regional Laboratory Quality Manual

- ☐ Are blank contaminants within limits? If outside limits, is there documented approval to proceed with analysis?
- ☐ Are surrogate recoveries within limits?
- ☐ Are spike recoveries and other QC check sample results within limits?
- ☐ Are duplicate sample RPDs acceptable?
- ☐ Is the initial calibration acceptable?
- ☐ Are continuing calibration checks (CCV) acceptable?
- ☐ Are manual and computer based calculations correct? Check significant figures and document with a sample calculation from raw data to final concentration (the reviewer initials and dates calculation.)
 - ☐ Dry weight calculations
 - ☐ Report factors
 - ☐ Sample concentrations
 - ☐ Other
- ☐ If manual manipulations of computer generated data were performed, do you concur with the judgment of the primary analyst?
- ☐ Are the concentrations of the analytes found within calibration range?
- ☐ Has the final report been checked for transcription errors?

Reviewed by:

Date Reviewed:

FINAL REPORT

- ☐ Check the following information on the report accuracy.
 - ☐ Sample IDs- laboratory and field
 - ☐ Date sampled (collected)
 - ☐ Date received
 - ☐ Date analyzed
 - ☐ Sample weight, % solids
 - ☐ Reporting Limit (RL), dilution and scaling factor
 - ☐ Qualifiers
 - ☐ pH
- ☐ Is the method summary an accurate reflection of all encountered problems? Are observations about the samples noted? Are method blank contaminants noted?
- ☐ Does the report reflect the current revision of the SOP?
- ☐ Are the reported results consistent with the significant figure policy?
- ☐ Has the final report been checked for transcription errors?

Reviewed by:

Date Reviewed:

Comments:

Y or _ = Yes N/A = Not Applicable
N = No * = See Comments

SECTION 28

REPORTING RESULTS (ISO/IEC 17025:2005(E), Clause 5.10.1)

It is NERL's policy that all data undergo review prior to reporting in accordance with Section 27.7. Laboratory results are reported in a test report that includes all the information requested by the client, necessary for the interpretation of the test results, and required by the method used.

28.1 Data Reporting

28.1.1 Laboratory Data Reporting Format and Procedures

All reports other than toxicity testing are generated through the use of LIMS and Crystal Reports. The toxicity lab data are analyzed and summarized through the Comprehensive Environmental Toxicity Information System (CETIS) statistical program. All our data reports include the information described below and our toxicity test reports may include other information pertinent to environmental toxicity testing and the NPDES program.

Title Page:

The following information is listed on the Title Page:

- The title "Laboratory Report";
- The name and address of the EPA Region 1 Laboratory, OEME;
- The Project Site and Project Number;
- The Client Name and Address;
- The Report date;
- The analyst(s) name;
- Reference to the analytical procedures and SOPs (instrumentation and analytical methodology used for the analysis); and
- The sample receipt date.
- Start of sequential numbering page _of_
- Serial number
- Certification statement

The title page is signed off by the Biology Lab Manager or Chemistry Lab Leader or designee.

Analytical Data Pages:

Data are reported for field samples and blanks, and these pages are numbered.

Pertinent information in each sample data page includes the sample ID (laboratory and client), collection date, extraction (or preparation) and analysis date, weight or volume extracted, % solids, and extract dilution factor (or scaling factor).

For each analyte, concentrations and reporting limits (RL) are listed. Results are reported for concentrations equal to, or exceeding the RL of the compound. Reporting limits may be included in the method specific SOPs, and can also be retrieved from the report templates in the LIMS static database or from the Lotus Notes SOP Database.

If applicable, flags are used to qualify the data (See Figure 28-1.) Reference to these qualifiers is also made in the QC Requirements Summary Table in the applicable method SOPs.

QC Data Pages:

- Laboratory Control Samples (LCS) - can be a Laboratory Fortified Blank (LFB) or another QC check sample (QCS)
- Matrix spikes, Matrix spike duplicates (MS/MSD)
- Duplicate Samples

28.1.2 Fixed Laboratory Analyses

For data generated in the fixed laboratory (this includes data generated by ESAT), sample results are entered in the LIMS data base manually by the analyst, or for some analyses, data are directly uploaded into the LIMS system. Data are then reviewed and reported, and a hard copy report is generated in Crystal Seagate. This report is printed and filed with the raw data folder in the laboratory at: F:\LABWORKS\REPORTS\CRYSTALREPORTS\FINALREPORTS

A .PDF of the Crystal Seagate report for a particular analysis (LIMSCODE) is then generated. A folder is named with the project number and site name, i.e., 07100004 Macera Disposal. After saving the report to this drive the following link is opened: T:\LAB_REPORTS\LAB_REPORTS.exe

This opens an application that allows the .PDF files to be posted to the following "Report Website": <http://r1-gisweb.r1.epa.gov:9876>.

When a .PDF report for a particular analysis is posted, the name of the client is selected from a drop down list, and a notification is sent to the client that a report has been posted. The Chemistry Team Leader and Unit Chief are copied.

When all the analyses for a project have been reported and validated in the LIMS system, an electronic data deliverable, EDD, is generated. This is simply an

EXCEL .csv file. This file is stored in the following directory:
S:\DBOUDREA\Data\EDD\pn. The EDD is also posted on the "Report Website."

28.1.3 Field Analyses

For on-site field work conducted with the mobile lab, analytical results are entered into the Field Logbook. Results are conveyed to the site manager (i.e., OSC, RPM or their designated sampling contractor) as needed during site activities. When all analyses are completed, all sample results are conveyed to the site manager or designee as soon as possible.

A final formal analytical data report will then be prepared at NERL. Field samples are logged into LIMS and results are entered into the LIMS. A final report is generated using LIMS data entries and Seagate Crystal reports. This final report is reviewed for correctness (i.e., transcription errors) by the field analyst. The report and raw data (chromatograms, copies of Field Logbook pages etc.) are then given to the Chemistry Team Leader for final review and distribution. A PDF version of the final report as well as an EDD is posted to the "Report website".

28.2 Release of Preliminary Data

If a circumstance arises where a request for early data release is made it must be approved (verbally) and still requires a review to ensure minimum test procedure QC is met. Data qualifiers will be included as necessary with any data release and the report will be identified as "draft". Subsequently, a full review will be completed and a final report released which will replace any earlier version of the report. Any data results released verbally will require written documentation detailing the results released to be filed in the appropriate project folder.

28.3 Environmental Testing Obtained through Contracts

28.3.1 Analyses Contracted to ESAT

All task products are reviewed by the appropriate Task Order Contracting Officer Representative (TOCOR) to ensure that what was requested is obtained and that the quality of the product reflects the use objective of the information.

Refer to Section 8 for additional ESAT procedures and oversight.

28.3.2 Analyses Contracted to Outside Laboratories

For EIA analytical work performed by an outside contract lab, the original report from the contractor is kept with the customer file in the chemistry laboratory. A

.pdf file is generated and posted on the EPA intranet "Report Website" (Section 28.2.2.1). Results for the samples are entered in LIMS (QC results are not entered in LIMS). An EDD is generated and also posted on the "Report Website".

28.4 Amendments to Reports

Inaccuracies in reports require immediate notification of the Project Manager/Officer by phone and/or e-mail. Reports will then be reissued. Revised reports are clearly identified as "revised". A copy of the original and revised report are retained in the project folder.

Figure 28-1: NERL DATA QUALIFIER FLAGS

- B = Analyte is associated with lab blank or trip blank contamination. This flag is used when the analyte concentration in the sample is less than ten times the concentration in the blank.
- J = Estimated value. This flag is used if quality control limit(s) are exceeded or interferences are observed, or if for some other reason reported values are considered estimated. The reason for estimating the results are explained in the case narrative for the sample. The flag is also used for GC/MS tentatively identified compounds (TIC).
- N = Tentatively Identified Compound (GC/MS).
- A = Suspected aldol condensation product (GC/MS)
- P = This flag is used for a pesticide/Aroclor target analyte when there is greater than 35% difference (but less than 100%) for detected concentrations between the two GC columns. The lower of the two values is then reported.
- C = This flag applies to pesticide results where the identification has been confirmed by GC/MS.
- E = Estimated value, the concentration of the analyte exceeds the calibration range.
- L = Estimated value, the concentration of the analyte is below the calibration range.
- ND = Not Detected. Used when the analyte was analyzed for but not detected.
- NA = Not Applicable. Examples are high sample dilutions or sample interferences. The reason(s) are explained in the case narrative of the sample.
- RL = Reporting limit (Practical Quantitation Limit).

Note: The Microbiology and Milestone Laboratory will signify the data degree of usability through the inclusion of a Region 1 list of data qualifiers as necessary when issuing data reports. In addition, qualifiers will be used that were developed specifically by the Microbiology Laboratory. Each data report issued contains a legend identifying possible qualifiers in use.

APPENDIX A-1

Laboratory Ethics Policy



U.S. Environmental Protection Agency
New England Regional Laboratory
11 Technology Drive
North Chelmsford, MA 01863


ETHICS POLICY

It shall be the policy of the EPA New England Region 1 Laboratory to conduct all business with integrity and in an ethical manner. It is a basic and expected responsibility of each staff member and each manager to hold to the highest ethical standard of professional conduct in the performance of all duties and to adhere to the EPA Principles of Scientific Integrity (1999) and the EPA Scientific Integrity Policy (2012).

Failure to adhere to this policy will result in corrective discipline in accordance with EPA Order 3120.1B, Conduct and Discipline. Section 45 of this EPA Order describes Scientific Misconduct and the following specific offenses:

- § *Fabrication or knowing falsification of data, research procedures, or data analysis.*
- § *Plagiarism or other misrepresentation, in proposing, conducting, reporting, or reviewing research or other scientific activities. This includes the deliberate misstatement or omission of material information.*
- § *Ordering, advising, or suggesting a subordinate engage in scientific misconduct.*

Penalties for violations range from oral admonishment to removal. The specific penalty will be dependent upon a range of factors including those outlined in EPA Order 3120.1 B.2.0.


Robert Maxfield
Director


Date

APPENDIX A-2



EPA's Principles of Scientific Integrity

It is essential that EPA's scientific and technical activities be of the highest quality and credibility if EPA is to carry out its responsibilities to protect human health and the environment. Honesty and integrity in its activities and decision-making processes are vital if the American public is to have trust and confidence in EPA's decisions. EPA adheres to these Principles of Scientific Integrity listed below.

EPA employees, whatever their grade level, job or duties must:

Ensure that their work is of the highest integrity - this means that their work is to be performed objectively, without predetermined outcomes using the most appropriate techniques. Employees are responsible and accountable for the integrity and validity of their own work. Fabrication or falsification of work results are direct assaults on the integrity of EPA and will not be tolerated.

Represent their own work fairly and accurately. When representing the work of others, employees must seek to understand the results and the implication of the work and also represent it fairly and accurately.

Represent and acknowledge the intellectual contributions of others in representing their work to others or in published writings such as journal articles or technical reports. To do otherwise is plagiarism. Employees should also refrain from taking credit for work with which they were not materially involved.

Avoid financial conflicts of interest and ensure impartiality in the performance of their duties by respecting and adhering to the principles of ethical conduct and implementing standards contained in Standards of Ethical Conduct for Employees of the Executive Branch and in supplemental Agency regulations.

Be cognizant of and understand the specific programmatic statutes that guide the employee's work.

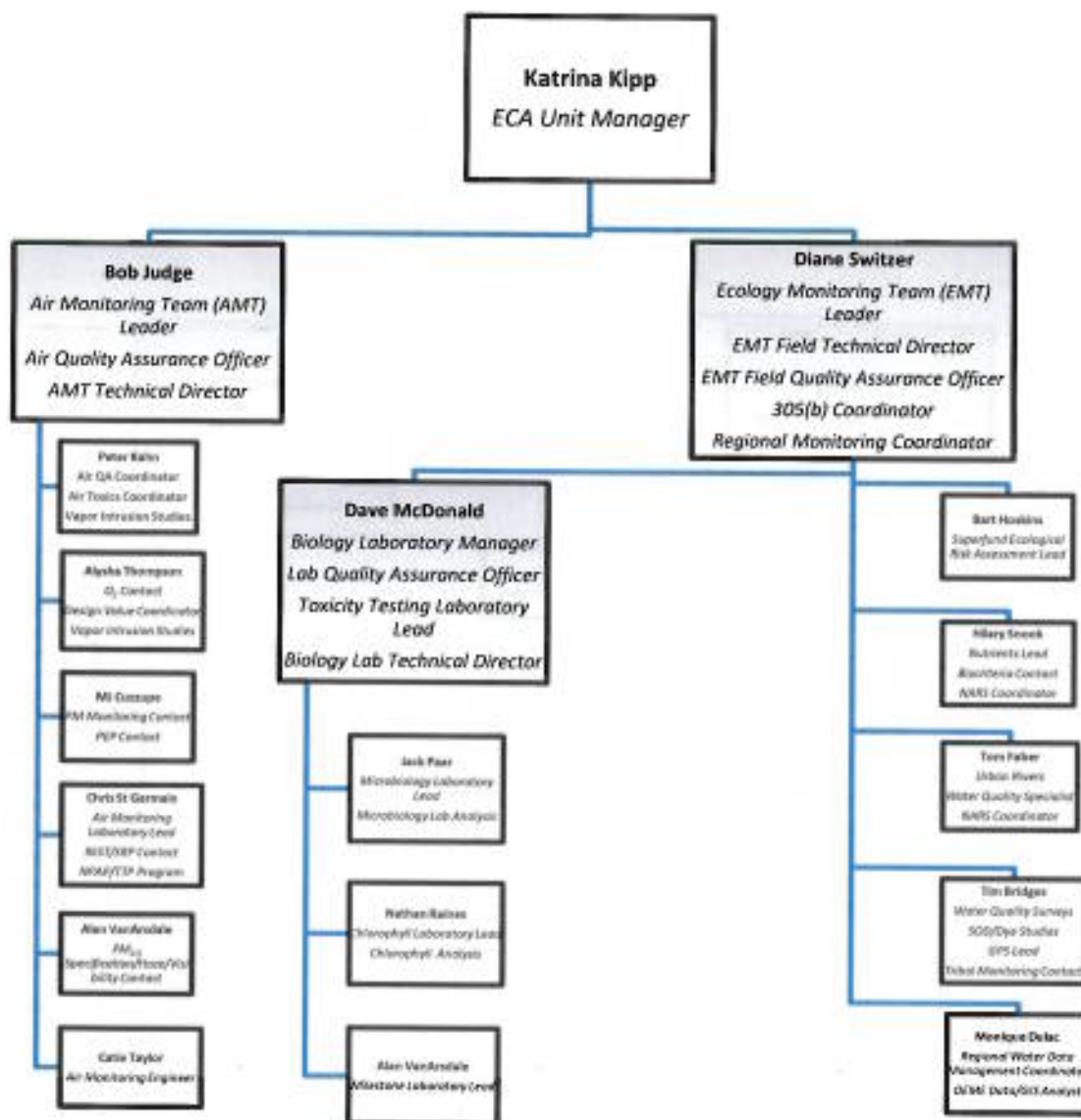
Accept the affirmative responsibility to report any breach of these principles.

Welcome differing views and opinions on scientific and technical matters as a legitimate and necessary part of the process to provide the best possible information to regulatory and policy decision-makers.

APPENDIX B – Laboratory Organization Charts

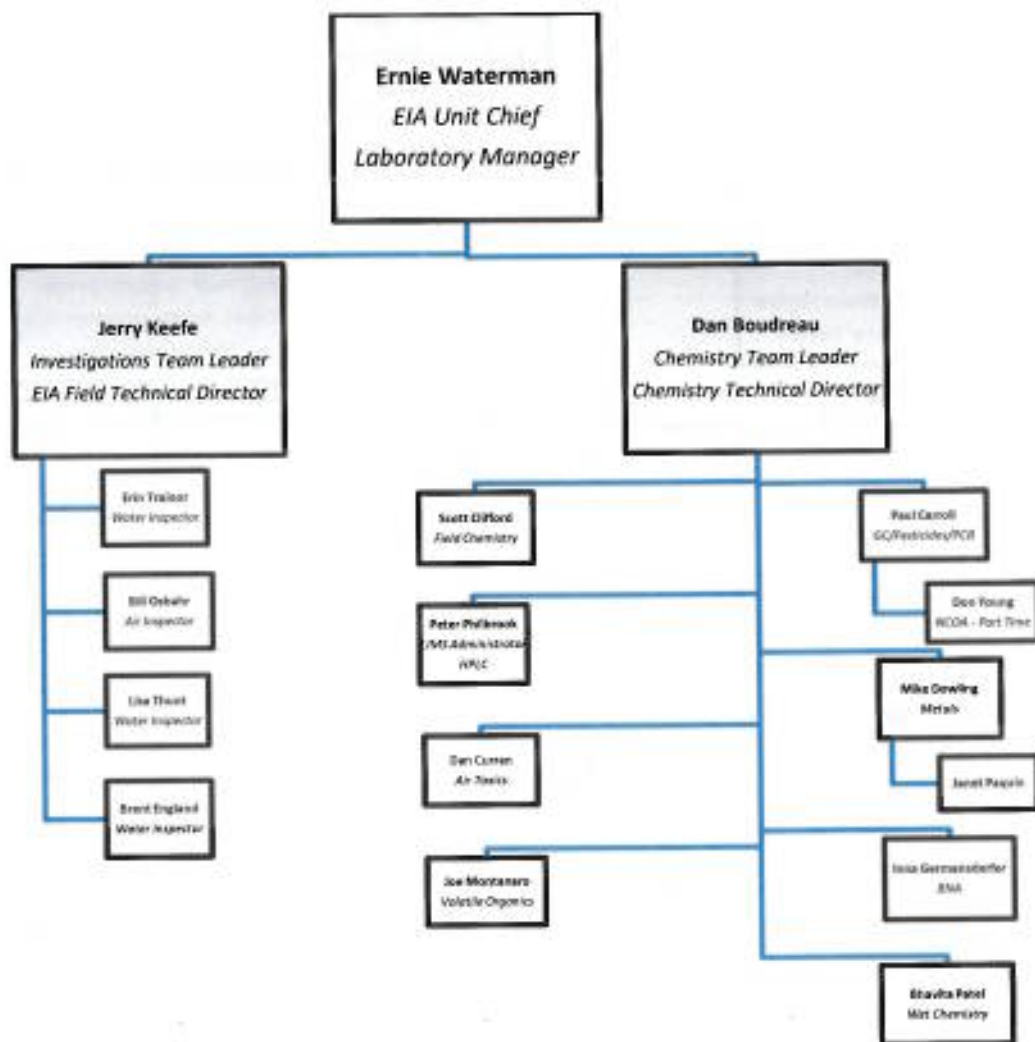
APPENDIX B-1

Ecosystems Assessment Unit



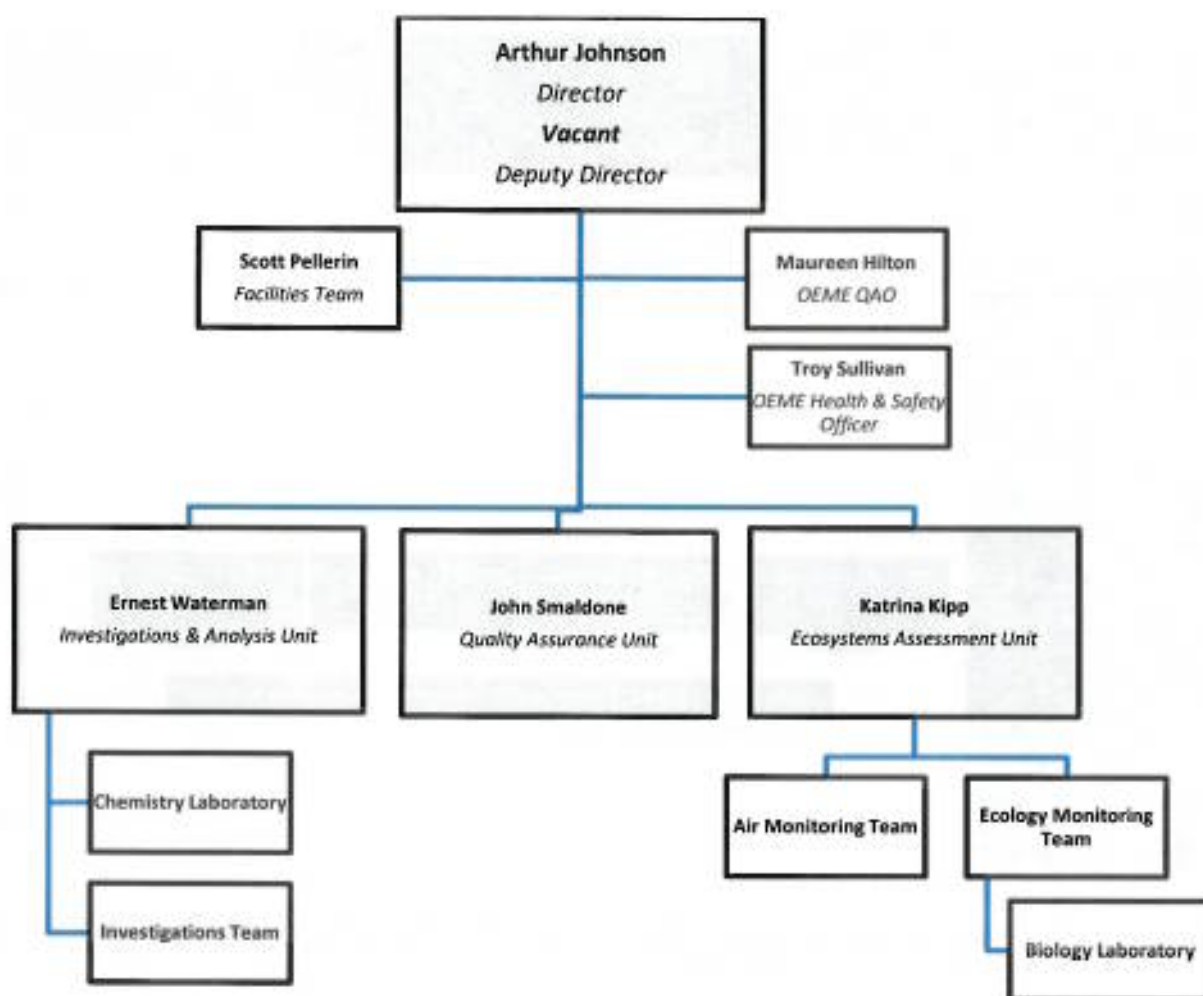
APPENDIX B-2

Investigations and Analysis Unit



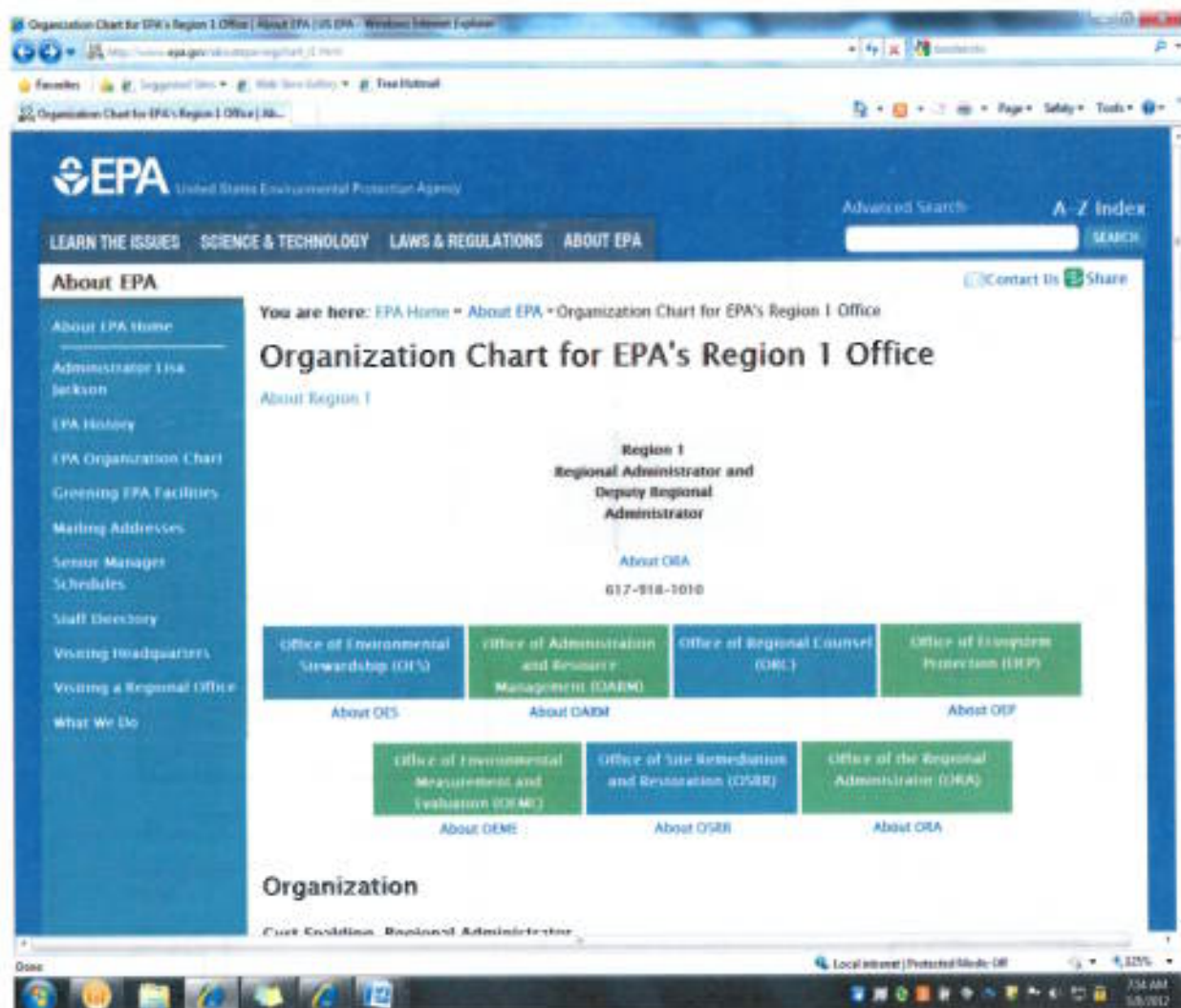
APPENDIX B-3

OEME: Office of Environmental Measurement and Evaluation



APPENDIX B-4

US EPA New England Region 1



APPENDIX D

ISO/IES 17025:2005 Scope of Accreditation for the Laboratory

		PERRY JOHNSON LABORATORY ACCREDITATION, INC.
<h3><i>Certificate of Accreditation</i></h3>		
<p><i>Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:</i></p>		
<p><i>U.S. EPA Region 1 NE Regional Laboratory</i> <i>11 Technology Drive, N. Chelmsford, MA 01863</i></p>		
<p><i>(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:</i></p>		
<p>ISO/IEC 17025:2005</p>		
<p>This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (as outlined by the joint ISO-ILAC-IAP Communique dated January 2009):</p>		
<p><i>Environmental Testing</i> <i>(As detailed in the supplement)</i></p>		
<p>Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby consents with the Accreditation body's duty to observe and comply with the said rules.</p>		
<p>For PJLA:</p>		
	<p>Initial Accreditation Date:</p>	<p>Issue Date:</p>
	<p>August 23, 2015</p>	<p>August 23, 2015</p>
	<p>Expiration Date:</p>	<p>April 23, 2016</p>
	<p>Accreditation No.:</p>	<p>Certificate No.:</p>
	<p>78776</p>	<p>L15-071</p>
<p>Tracy Saenz President/Operations Manager</p>	<p>The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: www.pjla.com</p>	
<p>Perry Johnson Laboratory Accreditation, Inc. (PJLA) 755 W. Big Beaver, Suite 1325 Troy, Michigan 48064</p>		



Certificate of Accreditation: Supplement

U.S. EPA Region 1 NE Regional Laboratory

11 Technology Drive, N. Chelmsford, MA 01863

Ernest Waterman Phone: 617-918-8632

Accreditation is granted to the facility to perform the following testing:

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Environmental	Drinking Water	ELASOP-INGICPMS	EPA 200.2	0.2 ug/L to 50 ug/L
		ELASOP-INGMETALSPREP Metals	EPA 200.8	
		ELASOP-NIPPONHG1 Mercury	ASTM D3223-02	N/A
		ELASOP-HPCMethod Heterotrophic Plate Count	Based on SM 9215 B	
	Wastewater Soil, Sediment	ELASOP-INGDVICP	Based on EPA 200.7 and 6010 B	8.0 ug/L to 110 ug/L
		ELASOP-INGMETALSPREP Metals		0.8 mg/kg to 11 mg/kg
		ELASOP-INGDMA Mercury	Based on EPA 245.1, 7470 A Based on EPA 7471 A	N/A
	Wastewater	ELASOP-VIAGCMS Aqueous Phase Purge & Trap	Based on EPA 5030 B	
		ELASOP-INGMETALSPREP Metals	Based on EPA 200.2	
		ELASOP-INGTP Total Phosphorous	Based on Lachat 10-115-01-1-F	
		ELASOP-GCPESWALL	Based on EPA 3510 C	
		ELASOP-BNAW Separatory Funnel Extraction		
		ELASOP-GCPESWALL PCBs in Aqueous Samples	Based on EPA 8082 A, EPA 608	
		ELASOP-GCPESWALL Chlorinated Organic Compounds in Aqueous Samples	Based on EPA 8081 A, EPA 608	
	Wastewater Soil, Sediments, Sludge TCLP Extracts	ELASOP-INGMETALSPREP Acid Digestion of Water for Total and Dissolved Metals	Based on EPA 3005 A	



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Environmental	Wastewater Liquid Waste	ELASOP-INGMETALSPREP Hot Plate Acid Digestion	Based on EPA 3010 A	N/A
	Soil, Sediments, Sludge	ELASOP-INGMETALSPREP Acid digestion of Solids	Based on EPA 3050 B	
		ELASOP-PESTSOIL ELASOP-BNAs Pressurized Fluid Extraction	Based on EPA 3545A	
		ELASOP-PESTSOIL Chlorinated Organic Compounds in Solids Samples	Based on EPA 8081 A	
	Drinking Water Wastewater	ELASOP-INGDVICP Hardness	Based on SM 2340 B	Calculation based on metals
		ELASOP-INGIC Anions and Cations	Based on EPA 300.0	N/A
		ELASOP-LCMS104W Perchlorate	Based on EPA 331.0	
		ELASOP-INGTURB Turbidity	Based on EPA 180.1 and SM 2310 B	
		ELASOP-INGALKCARB Alkalinity	Based on SM 2320 B	
		ELASOP-INGTP Orthophosphate as P	Based on Lachat 10-115-01-1-B	
		ELASOP-INGTSS-TDS-VRES Total Dissolved Solids Total Suspended Solids	Based on EPA 160.0 and 160.2	
		ELASOP-INGPH pH	Based on EPA 9040 B and SM 4500-H+	1 pH units to 14 pH units
	Soil, Sediment Tissue	ELASOP-INGDMA Mercury	Based on EPA 7473	N/A
	Drinking Water, Wastewater, Soil, Sediment	ELASOP-INGCN Cyanide	Based on EPA 335.4, EPA 9012 B, Lachat 10-204-00-1-α	
	Drinking water, Wastewater, Soil, Sediment, Sludge	ELASOP-VOAGCMS Volatile Organic Compounds	EPA 524.2 Based on EPA 8260 B, EPA 624	



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Environmental	Wastewater, Soil, Sediment, Oil, Sludge	ELASOP-BNAGCMS	Based on EPA 8270C, EPA 625	N/A
		ELASOP-BNAW		
		ELASOP-BNAS Acid, Base/Neutral Organic Compounds		
		ELASOP-PESFLOR	Based on EPA 3630 B	
	Soil, Sediment	Floral Clean-up		Based on EPA 3640 A
		ELASOP-PESGPC Gel Permeation Clean-up		
	Soil, Sediment, Sludge, Oil	ELASOP-VOAGCMS	Based on EPA 5035	Based on EPA 8082
		Solids Phase Purge & Trap		
		ELASOP-PESTSOIL	Based on EPA 8082	
	Liquid Waste	PCBs in Solid Samples		Based on EPA 3665 A
		ELASOP-PESTSOIL		
	Tissue	Sulfuric Acid/Permanganate Clean-up		Based on ASTM D3278 EPA 1020 A
		ELASOP-FLASH		
Environmental	Ambient Surface Water, Drinking Water, Wastewater	Ignitability/Flashpoint	Based on ASTM D3278 EPA 1020 A	Based on EPA 7473
		ECASOP-Milestone		
		SOP Mercury		
		ECASOP-		
	Ambient Surface Water, Wastewater	Fecal Coliform/MF	Based on SM 9222 D	Based on SM 9222 B
		Fecal Coliforms by Membrane filtration		
		ECASOP-		
Environmental	Ambient Surface Water, Wastewater	Total Coliform/MF Total Coliforms by Membrane filtration	Based on SM 9222 B	Based on SM 9221 F + SM 9222 B
		ECASOP-MTF Total Coliform E.coli by Membrane filtration		
		ECASOP-MTF Total Coliform E.coli by Membrane filtration		
		ECASOP-MTF Total Coliform E.coli by Membrane filtration		
Environmental	Ambient Surface Water, Wastewater	Define Substrate	Based on SM 9223 B	Based on SM 9230 D
		ECASOP-ENTERO		
Environmental	Ambient Surface Water, Wastewater	Enterococci by Defined Substrate		Based on SM 9230 D
		ECASOP-ENTERO		



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Ernest Wateman Phone: 617-918-8632

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Environmental ^F	Ambient Surface Water, Wastewater	ECASOP-PHCHRTOX Chronic Toxicity Test Method for Pinnophales Promelas	Based on EPA 1000.0 EPA/821/R-02/013	N/A
		ECASOP-Cd Chronic Tox Test Chronic Toxicity Test Method for Ceriodaphnia Dubia	Based on EPA 1002.0 EPA/821/R-02/013	

1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location. Example: Outside Micrometer^F would mean that the laboratory performs this testing at its fixed location.

