

**QUALITY MANUAL**  
for  
New England Regional Laboratory (NERL)  
Laboratory Services and Applied Science Division

Including the  
Laboratory Services Branch (LSB)  
Biology Laboratory  
Chemistry Laboratory  
&  
Field Services 1 Branch (FSB 1)  
AMT Field Team  
Waste Management Team  
&  
Field Services 2 Branch (FSB 2)  
EMT Field Team  
Investigations Team  
&  
Quality Assurance Branch (QAB)



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## REVISION PAGE

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<b>04/11/22</b>	<b>5</b>	<b>Added use of LIMS reports to identify nonconformances</b>	<b>12</b>
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### 3 INTRODUCTION AND SCOPE

The purpose of this *Quality Manual* (QM) is to outline the management system for scope of accreditation under ISO 17025:2017 for the US EPA New England Regional Laboratory (LS), managed as part of the Laboratory Services and Applied Science Division (LSASD) within EPA Region 1. This scope of accreditation includes the two Field Services Branches (FSB 1 and FSB 2) with the Ecology Monitoring Team (EMT), Investigations Team, Waste Management Team, and the Air Monitoring Team (AMT), and the Laboratory Services Branch with the Chemistry Laboratory and Biology Laboratory. For the Biology Laboratory, the Chemistry Laboratory and the Field Services Branches, the *Quality Manual* encompasses all facets of laboratory and field activity performed including in the ISO/IEC 17025:2017 scope of accreditation. 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 LSASD 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 LSASD.

The *Quality Manual* sets the standard under which all laboratory and field operations are performed, including LSASD/LSASD's organization, objectives, and operating philosophy. The *Quality Manual* has been prepared to assure conformance as applicable with ISO/IEC 17025:2017 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) <https://work.epa.gov/sites/default/files/2021-10/epa-region-1-qmp-1.pdf> The QMP is prepared and maintained by the QA Branch for all EPA New England environmental information operations.

#### 3.1 Scope of Testing

The laboratory provides chemical, biological, and physical analyses as well as field measurements. The majority of analyses are done for soil and water samples for Superfund sites, water and RCRA investigations (enforcement or non-enforcement), ambient water quality monitoring and air analyses.

### **3.2 Components of the Quality Program**

The quality program for LSASD comprises many components which serve to accomplish the following:

- Implementation of a comprehensive QA program which relies on documented procedures, well trained staff, easy to understand reports, prompt laboratory results, and strong management support;
- Availability of the quality documentation for use by the laboratory and field personnel;
- Audits, reviews, and corrective actions;
- Implementation of essential quality control and data verification procedures;
- Continuous efforts toward improvement into every activity of LSASD; 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 LSASD's Quality System including:

- Ethics Policy
- Personnel Qualifications
- Sample Management
- Training
- Analytical Procedures
- Analytical Standards Requirements
- Laboratory and field 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 LSASD Quality Assurance Officer (QAO), and undergoes annual review by the QAO, Branch Managers, Director and Deputy Director, 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 Region 1 Document Control System (DCS). Superseded electronic versions of the *Quality Manual* are archived in the DCS. The *Quality Manual*

(QM) is reviewed annually at the Annual 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 on 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 17025:2017 *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 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.

**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
EMT	–	Ecology Monitoring Team

ESAT	–	Environmental Services and Analysis Team
FSB	–	Field Services Branch
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 <sup>2</sup>	–	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
LSASD	–	Laboratory Services and Applied Science Division
LSB	–	Laboratory Services Branch
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
OSC	–	On-Scene Coordinator
PAMS	–	Photochemical Assessment Monitoring Stations
PT	–	Proficiency Test(ing)
PTP	–	Proficiency Testing Provider
PTPA	–	Proficiency Testing Provider Accreditor
QA	–	Quality Assurance
QAB	–	Quality Assurance Branch
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
WIP	–	Work in Progress

## 4 ORGANIZATION

LSASD/NERL is a legally identifiable government organization (Federal Employer Number: 31-1575142). It is responsible for carrying out testing activities that meet the requirements of the ISO/EIC 17025:2017 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*,

- LSASD assures that it is impartial and that personnel are free from 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.
- LSASD ensures the continuity of quality management practices when faced with organizational or funding changes.

### 4.1 Organization

EPA Region 1 has responsibility for federal matters relating to the protection of the environment within the six New England states. Refer to Appendix B-1 for the EPA Region 1 organizational chart which is also available at:

<https://www.epa.gov/aboutepa/organization-epas-region-1-office-boston>

Laboratory Services and Applied Science Division (LSASD) is located at and encompasses the New England Regional Laboratory (NERL) at 11 Technology Drive in North Chelmsford, Massachusetts. LSASD is the scientific support organization for the Region and consists of four operational units, the Quality Assurance Branch (QAB), the two Field Services Branches (FSB 1 and FSB 2) and the Laboratory Services Branch (LSB). Refer to Appendix B-2 for the LSASD organizational chart.

The LSB, two FSB and QAB Branch Managers report to the Director of LSASD. Both the Chemistry and Biology Laboratory rely on support from other branches for waste management, health and safety, purchasing, and environmental management.

The quality management program described in this *Quality Manual* applies to data activities conducted by LSASD personnel within the LSASD facility, at sites outside of LSASD, 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.

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

#### 4.1.1 Biology Laboratory Organization

The Laboratory Services Branch, which includes the Biology Laboratory, currently includes:

- Microbiology Laboratory
- Chlorophyll Laboratory

Each laboratory has a Laboratory Lead who oversees routine individual laboratory activities. Individuals perform multiple functions within the Biology Laboratory. The Biology Laboratory is under the LSB and its manager. On-site ESAT contractors perform laboratory functions within all of the laboratories.

#### 4.1.2 Chemistry Laboratory Organization

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 LSB Branch Manager. On-site ESAT contractors perform laboratory functions within all of the laboratories.

#### 4.1.3 Field Services

The Field Services Branches consists of four teams that provide field support for regional programs, including support for states and tribes:

- Air Monitoring Team
- Waste Team
- Ecology Monitoring Team
- Investigations Team

Field activities include field sampling and assessment, investigations, inspections, waste site assessment, ambient monitoring and research studies. Studies are conducted and technical support provided to programs including Air, Water, Superfund, Brownfields, RCRA, TSCA, and FIFRA that protect environmental resources and the public health. The Branches are also responsible for implementation of state and tribal air and water monitoring programs.

## 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. LSASD 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. LSASD conforms to the EPA Scientific Integrity Policy, 2/16/2012

[https://www.epa.gov/sites/default/files/2014-02/documents/scientific\\_integrity\\_policy\\_2012.pdf](https://www.epa.gov/sites/default/files/2014-02/documents/scientific_integrity_policy_2012.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 LSASD 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, procedures are in place to ensure independent review of their work.

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.

## 5 MANAGEMENT

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

### 5.1 Management Requirements

The LSASD Management Team includes the Office Director and Deputy Director, and FSB 1, FSB 2, LSB and QAB Branch Managers. LSASD documents its commitment to good professional practice and to the quality of its products in its Quality Policy statement in Section 5.3.

LSASD 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 17025:2017 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 program. 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 LSASD that each manager designates backup staff to maintain continuity of operation during absences (Table 5-1).

## **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 LSASD Director**

The LSASD Director (Director) is responsible for the overall quality, safety, financial, technical, human resource and service performance of LSASD. 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 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 LSASD Deputy Director**

The LSASD Deputy Director will act in the Director's stead when they are not available and will assume all the responsibilities listed above.

### **5.2.3 LSASD 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-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 Quality Program of Laboratory and Field Sampling QA program;
- Ensure the laboratories as well as the applicable field sampling methods are in compliance with ISO/IEC 17025:2017;
- 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 and approving relevant SOPs in concurrence with the appropriate Branch Manager;
- 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, Deputy Director, and/or Branch Managers on QA issues;
- Maintaining knowledge of analytical test methods for which data review is performed and of quality system as defined under ISO/IEC 17025:2017;
- Monitoring and maintaining laboratory certifications; and
- Coordinating implementation of LSASD QA program with laboratory and field technical directors.

Authority:

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

#### 5.2.4 Field Services Branches

The QA activities of the field service branches (FSB 1 and FSB 2) are directed by their respective FSB Branch Manager. In addition, all staff play a vital role in assuring the quality of their work. Responsibilities and levels of authority within the two FSB are described below.

##### 5.2.4.1 FSB1 Branch Manager

Responsibilities:

- Ultimate responsibility for the quality of data reported by FSB1 which covers air and waste programs;
- Responsible for the unit following the EPA Region 1 QMP and the NERL *Quality Manual*;
- Conducts annual planning process with Region 1 program offices, 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 LSASD management to discuss the various FSB 1 projects and coordinate LSASD support as needed from all other LSASD branches;
- Reports to Region 1 program management and other customers on status of projects and requested assistance at end of year;
- Reviews, edits, and approves FSB 1 QAPPs, SOPs, policies and final reports;
- Responsible for data management



- Implements applicable Region 1 Quality Assurance Field Activities Procedure (QAFAP) standards; and
- 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.

#### *5.2.4.2 FSB2 Branch Manager*

- Ultimate responsibility for the quality of data reported by FSB2 which covers water (ecological monitoring) and investigation programs;
- Responsible for the unit following the EPA Region 1 QMP and the NERL *Quality Manual*;
- Conducts annual planning process with Region 1 program offices, 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 LSASD management to discuss the various FSB 2 projects and coordinate LSASD support as needed from all other LSASD branches;
- Reports to Region 1 program management and other customers on status of projects and requested assistance at end of year;
- Reviews, edits, and approves FSB 2 QAPPs, SOPs, policies and final reports;
- Responsible for data management
- Implements applicable Region 1 Quality Assurance Field Activities Procedure (QAFAP) standards; and
- 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.

#### *5.2.4.3 Ecology Monitoring Team –(under FSB2)*

##### **Responsibilities:**

- Responsible (or designee) for communication between the Boston office and the FSB 2 sampling team;
- Assigns a Project Manager (PM) to each accepted project;
- Reports to the Branch Manager on projects progress, activities, assessment, problems, and deficiencies;
- Maintains and reviews QAPPs, site specific SAPs, and SOPs for projects within the 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;
- Responsible for ensuring tiered review of field activities and data; and
- Ensure the field methods included within the scope of accreditation under ISO/IEC 17025:2017 are in compliance with ISO/IEC 17025:2017.

#### *5.2.4.4 Investigations Team – (under FSB2)*

##### Responsibilities:

- Responsible (or designee) for communication between the Boston program offices and the FSB 2 Investigations Team;
- Assigns a Project Leader/Sampling Leader/Inspector to each accepted project and/or inspection;
- Reports to the Branch Manager on projects progress, inspections, activities, assessment, problems, and deficiencies;
- Maintains and reviews applicable QAPPs, site specific SAPs, and SOPs for projects within the team;
- Assist in reviews and updates of the Investigations Team Generic and existing Site-Specific SAPs, Project Plans, and SOPs annually to ensure they are current and accurate;
- Convenes team meetings on an as needed basis;
- Responsible for ensuring tiered review of field activities and data; and
- Ensure the field methods included within the scope of accreditation under ISO/IEC 17025:2017 are in compliance with ISO/IEC 17025:2017.

#### *5.2.4.5 Air Monitoring Team – (under FSB 1)*

##### Responsibilities:

- Responsible (or designee) for communication between the Boston program offices and the FSB 1 Air Monitoring Team;
- Assigns a Project Leader/Sampling Leader/Inspector to each accepted project and/or inspection;
- Reports to the Branch Manager on projects progress, inspections, activities, assessment, problems, and deficiencies;
- Maintains and reviews applicable QAPPs, site specific SAPs, and SOPs for projects within the team;
- Assist in reviews and updates of the Air Monitoring Team's existing Site-Specific SAPs, Project Plans, and SOPs annually to ensure they are current and accurate;

- Convenes team meetings on an as needed basis; and
- Responsible for ensuring tiered review of field activities and data.

#### *5.2.4.6 Waste Management Team – (under FSB 1)*

##### Responsibilities:

- Groundwater sampling support including monitoring well sampling, low flow sampling, and porewater sampling;
- Geoprobe support utilizing a Track mount 54DT or a wheel mount 540M. These rigs have the capability of collecting soil core samples up to 70 ft, installing temporary monitoring wells for groundwater sample collection, and delineating subsurface VOCs using a Membrane Interface Probe (MIP);
- Surface water sampling including from ambient systems, channels, pipe outfalls, stormwater drains, etc.;
- Sampling and field support for hazardous waste sampling at treatment, storage, and disposal (TSD) and other facilities needed for ECAD RCRA support as well as LCRD RCRA corrective action sites;
- Soil/sediment sampling using hand augers, coring devices, and borers;
- Geologic characterization of soils;
- Delineating groundwater gain zones in shallow streams/lakes using temperature;
- Provides support for the Criminal Investigation Division as needed on waste sampling (i.e., RCRA waste, non-CWA) actions; and
- Down-hole camera support to identify fracture zones in open boreholes or view conditions inside monitoring wells.

#### *5.2.4.7 Laboratory and Field Personnel*

##### Responsibilities:

- Having a working knowledge of the QA program as documented in this *Quality Manual*;
- Writing, 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 data review.

### 5.2.5 Laboratory Services Branch

The QA activities of the LSB are directed by the LSB Manager. The implementation of the QA program within the Chemistry and Biology Laboratories is the responsibility of the LSB 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 branch are described below.

#### 5.2.5.1 LSB Branch Manager

Responsibilities:

- Ultimate responsibility for the quality of data produced by LSB;
- Responsible for the unit following the EPA Region 1 QMP and the NERL *Quality Manual*;
- Conducts planning process with customers to identify and prioritize assistance needs and projects;;
- Works with the LSASD management to discuss the various LSB projects and coordinate LSASD support as needed from FSB1, FSB2, and QAB;
- Reviews and approves LSB QAPPs, SOPs, policies and final reports.
- Responsible for LSB data management, both electronically and the printed filing system (project folders);
- 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 and Biology Laboratories to ensure the suitability and effectiveness of its program, and ensure corrective actions are carried out in a timely manner.

Authority:

The Branch Manager is the final authority within the Chemistry and Biology Laboratories on all issues dealing with data quality. The Branch Manager 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.

#### 5.2.5.2 Chemistry Laboratory Leader

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 Laboratory 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 Laboratory Leader and the appointment of the deputy.

Responsibilities:

- Ensure the Chemistry Laboratory is in compliance with ISO/IEC 17025:2017;
- 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;
- Schedule and oversee, as TOCOR, work performed by ESAT contractors.
- Review and approve data reports; and
- Manage contracted testing services where appropriate

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 Chemistry Laboratory Leader has the authority to accept or reject data based on compliance with the well-defined QC criteria, or based on technical reasons.

### 5.2.5.3 *Biology Laboratory Leader*

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 Laboratory Leader is absent for (fifteen (15) calendar days or more), a deputy 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 Laboratory Leader and the appointment of the deputy.

Responsibilities:

- Reports to the Branch Manager 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 Biology Laboratory analyses
- Interacts with customers on laboratory requests to assure the laboratory can meet client requirements and proper planning documentation in place.
- Schedule and oversee, through the ESAT TOCOR, work performed by ESAT contractors

- Maintaining current SOPs for analytical procedures.
- Ensure the Biology laboratories are in compliance with ISO/IEC 17025:2017

#### 5.2.6 Regional Quality Assurance Manager

The EPA New England Regional Quality Assurance Manager (RQAM) is responsible for developing, maintaining and implementing the Regional Quality Program in accordance with the approved Regional Quality Management Plan (QMP). The RQAM reports to the LSASD QA Branch Manager. Specific roles and responsibilities assigned to the RQAM and QA Branch are detailed in Section 1.3.2 of the QMP and include the following:

- The EPA NE QA Branch 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 Branch are available to provide technical assistance and QA/QC guidance during the planning and implementation of environmental information operations. In addition, they perform technical system audits and regional data review activities.
- The QA Branch 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.

#### 5.2.7 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.

#### 5.2.8 Laboratory Key Personnel and Back Up Personnel

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

<b>Table 5-1 Key Personnel and Back Up Personnel</b>		
<b>Key Personnel</b>	<b>Back Up to Key Personnel</b>	<b>Key Personnel/ BackUp Personnel</b>
LSASD/NERL Director	Deputy Director	B. Deabay/vacant
LSASD/NERL Deputy Director	Director	vacant/B. Deabay
LSB Manager	Chemistry & Biology Technical Directors	R. Reinhart/D. Boudreau & J. Paar
FSB1 Manager	FSB1 Senior Air Monitoring Scientist	L. Biton/A. Murphy
FSB2 Manager	Investigations Technical Director	E. Magnan/J. Keefe
QAB Manager	RQAM	B. Hogan/A. Pepe
LSB Chemistry Technical Director	Senior Analyst	D. Boudreau/P. Philbrook
LSB Biology Technical Director	Senior Analyst	J. Paar/N. Raines
LSASD QAO	RQAM	M. Freedman/A. Pepe
FSB2 Investigations Team Technical Director	FSB2 Manager	J. Keefe/ E. Magnan
FSB2 EMT Technical Director	FSB2 Manager	T. Faber/E. Magnan
FSB1 Senior Air Monitoring Scientist	FSB1 Manager	A. Murphy/ L. Biton
FSB1 Senior Waste Management Specialist	FSB1 Manager	W. Sommer/L. Biton

### 5.3 Quality Policy

LSASD conforms to the regional Quality Policy documented in the EPA New England Quality Management Plan (QMP): <https://work.epa.gov/sites/default/files/2021-10/epa-region-1-qmp-1.pdf>

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 17025:2017, 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 the Quality Management Program**

The quality management program is defined through the policies and procedures provided in this NERL *Quality Manual*, and written 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 Region 1 Document Control System accessible to all LSASD 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) and administrative SOPs. A complete list of the most current SOPs is available on the DCS, accessible to all LSASD staff. SOPs include an effective date, revision number, and signature of approval and the controlled versions are available to all personnel through the DCS. 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 information 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. LSASD Generic Program QAPPs are maintained as controlled documents in the DCS.



### 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:

1. Agency and Regional Ethics and Quality Policies
2. Region 1 Quality Management Plan
3. NERL *Quality Manual*
4. QAPPs, SAPs and SOPs
5. Written technical direction

## **6 DOCUMENTATION and DOCUMENT CONTROL**

LSASD 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 LSASD include but are not limited to SOPs, policy statements, plans, specifications, calibration tables, charts, memoranda, laboratory and field records and reports. These may be on various media (hard copy or electronic) and they may be digital, analog, photographic or written.

The management of LSASD 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.

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, policies logbooks and forms. Controlled documents are maintained as electronic documents. 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. Records are managed, archived or disposed of in accordance with Agency record procedures.

### **6.1 Controlled Documents**

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

The procedure for the development and revision of SOPs will follow the LSASD SOP on the Management of SOPs, most current revision. Other stand-alone forms used for laboratory or field documentation will use the following additional guidelines:

Documents shall contain a header located at the top-right corner of each page. The following information is to be included in the header:

- Unique identifier: branch name (FSB, LSB, QAB, LSASD (for office-wide documents)), document type (SOP, CHLST, FORM, etc), abbreviated title, revision number)
- Title of Document
- Revision number
- Date of current revision
- Page # and total # of pages in document

Note: this should be consistent with information entered into the DCS.

The unique identifier should not exceed 30 characters. For example:

LSBCHKLST-ChloraChecklist1  
Chlorophyll *a* Collection Checklist  
Revision #1  
January 1, 2021  
Page 1 of 1

#### 6.1.1 Quality Manual

This *Quality Manual* is maintained as a controlled document in accordance with LSASD 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, LSASD environmental information operations, including sampling and analytical activities, are conducted under approved generic Quality Assurance Project Plans (QAPPs) and associated Sampling and Analysis Plans (SAPs), or project specific QAPPs, that are current and accurate. This requirement applies to all environmental information operations performed by EPA or directly for EPA through EPA-funded extramural agreements, such as grants, contracts, and inter-agency agreements. Refer to EPA New England QMP Section 7.0 for additional information regarding generic and project-specific QAPPs.

##### 6.1.5.2 Generic QAPPs

FSB 1 and FSB 2 develop and maintain Generic Program QAPPs as controlled documents in the DCS.

##### 6.1.2.2 Project-Specific QAPPs and SAPs

Project-specific QAPPs and SAPs are developed and maintained as approved documents in project folders.

#### 6.1.3LSASD Standard Operating Procedures (SOPs)

SOPs are developed and maintained as controlled documents in electronic format. 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 in accordance with LSASD's SOP for Management of SOPs, most current revision. All current versions of approved SOPs are assigned a document control and revision number.

Procedural changes no matter how small will be considered for incorporation into standard laboratory practices. If the revision is needed, the SOP will be revised and it will be implemented as soon as practical. 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 and all laboratory personnel will be alerted of the need to review the revision.

#### 6.1.4 LSASD Logbooks

LSASD logbooks used to document procedures and activities both in the laboratory and field are maintained as controlled documents. All logbooks are assigned an unique identifier and archived once a new logbook is put into use.

#### 6.1.5 LSASD Forms

A variety of forms are used in the laboratory and field to document procedures including, but not limited to, standard preparation, calibrations, tier review etc. All forms are assigned an unique identifier and archived when new forms are put into use.

## **7 REVIEW OF WORK REQUESTS**

LSASD 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. LSASD 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**

LSASD personnel participate in annual and ongoing planning meetings within LSASD and with the EPA Boston office 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, LSASD 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 FSB 2/EMT Preplanning and Review Procedures**

Projects routinely undertaken by FSB 2'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 FSB 2 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 Branch Manager. The primary method for requesting lab services is via the Lab Request PowerApp. Requests outside of this app are generated through the planning process with FSB1 and FSB2. Preplanning of samples is done after approval of the work by the Branch 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. If the lab cannot support a request, the requestor is notified by the Branch 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 LSASD 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**

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## SAMPLE PLANNING MEMORANDUM

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**TO:**

**FROM:**

**SUBJECT:**

**DATE:**

**CC:**

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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.

## **8 REGIONAL and NATIONAL CONTRACT SERVICES**

LSASD is a government laboratory and contracts directly for analytical services. Both regional and national contracts are used for laboratory support. See also Section 9.

### **8.1 Regional Contracts – Commercial Laboratories**

As discussed in Section 7, LSASD reviews all work requests to ensure that it has adequate resources and capabilities, and that test methods are applicable to the customers' needs. When LSASD does not have the capacity or capability to analyze the samples, the client is notified of the need to seek alternative options. LSASD does not subcontract samples; but may contract directly with a commercial laboratory for sample analysis. However, this data is produced independent of the Laboratory Services Branch and is not treated as LSASD data falling under our ISO accreditation. See Section 9 for details on purchasing services.

### **8.2 National Contracts - Environmental Services Assistance Team (ESAT)**

#### **8.2.1 ESAT Contract Procedures**

The Environmental Services Assistance Team (ESAT) contract supports LSASD. 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 LSASD. ESAT staff adheres to all LSASD technical requirements and policies.



## 9 PURCHASING SERVICES AND SUPPLIES

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*:

<https://work.epa.gov/sites/default/files/2021-10/epa-region-1-qmp-1.pdf>

LSASD 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. A controlled document consisting of a list of vendors that supply products and services of the required quality will be maintained and verified annually that the list is up to date. Vendors will be selected based on accreditation, specifications as defined by the test being performed, as well as the quality control criteria as defined by the method, SOP, SAP or as requested by the client. The quality of the supplies or services of the vendors will be verified by staff with input from the QAO or management, as necessary, and will include a management sign-off when the order is placed. These vendors are then added to the verified list for future referral. The quality provided by the vendors will be verified when new products or services are retained. Vendors will be removed from the list if it is determined the quality level is not sufficient to meet the needs of the laboratory. Laboratory personnel procure services and supplies using appropriate procurement forms. LSASD coordinates with the Boston office and tracks procurements over \$10,000 through the EPA Acquisition System (EAS). All procurements and contracts originating in the LSASD must meet established administrative and QA requirements in the Federal Acquisition Regulations (FAR 46.202-4 and 52.246-11), the EPA Acquisition Guide (EPAAG), Chapter 46 Quality Assurance, Section 46.2.1 Contract Quality Requirements. 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 \$10,000

All supplies are requested by staff, approved by their manager, assigned by the approval official and purchased by a purchase card holder. Once received, they are inspected at the loading dock for package integrity. The Facilities Office notifies the originator/card holder of the receipt. Original packing slips are provided to the purchase card holder. All chemical 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 unusable due to damage or wrong item, the staff who initiated the purchase, notifies the card holder 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. The LSASD Health and Safety officer reviews and signs off on applicable purchase requests as well as ensures chemicals are recorded into or removed from the chemical inventory system as appropriate.

## **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 by the Health & Safety Officer. 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 records, 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 originators and approved by the Branch Managers, and assigned by the approving official. Purchase orders are maintained by LSASD purchase card 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 and field 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, field 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 LSASD by regional purchasing agents. Procurement requests are maintained by LSASD technical

and purchasing 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 Branch Manager, MSD 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.

## 10 SERVICE TO THE CLIENT

LSASD 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**

LSASD 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.

LSASD has a feedback system specifically for projects completed for the Superfund and Emergency Management Division (SEMD). Once a SEMD request is marked as complete, the requester gets an email with a link to a survey. That information is collected and used to improve LSASD's internal processes.

## **11 COMPLAINTS**

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 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.

## 12 CONTROL OF NON-CONFORMING ENVIRONMENTAL TESTING WORK

LSASD 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). LSASD identifies non-conforming work through customer complaints, quality control, instrument calibration, evaluating consumable materials, staff observation, final report review, management reviews, LIMS reports on qualifier usage 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 LSASD’s compliance to its own policies and procedures.

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

LSASD 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).



## **13 IMPROVEMENT**

LSASD 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)
- Training (Section 20 – Personnel)
- Client feedback and complaints (Section 10 – Service to Client)
- 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.

## **14 CORRECTIVE ACTION**

LSASD 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 LSASD QAO, Laboratory Leads, Technical Directors, or Branch Managers 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 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 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 to ensure the nonconformity was addressed and all documentation supporting the CA is completed. Corrective action reports must be filed as soon as possible after a finding occurs. For unacceptable PT results and internal QC checks, 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 QAO within two weeks after notification of the unacceptable result. The procedure outlined in 14.2 and 14.3 will then be followed to ensure appropriate resolution.

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):**

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**Originator Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Person Contacted:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**CORRECTIVE ACTION PLANNED:**

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**Laboratory Lead Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**FOLLOW UP:**

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**Laboratory Lead Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

## **15 PREVENTIVE ACTION**

LSASD 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.

## 16 CONTROL OF RECORDS

Records are maintained for all laboratory activities, at minimum in accordance with Federal Regulations. LSASD 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

LSASD keeps records of all procedures to which a sample is subjected while in its possession. LSASD 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 LSASD 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**

LSASD 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 EPA Boston office. Any records stored on-site at the LSASD Laboratory facilities in Chelmsford will also be forwarded to EPA 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.

## **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. Electronic logbooks and bench sheets are tracked either with an audit-trail macros created in Microsoft Excel or through built-in version tracking history—standard with the Microsoft software used. Both mechanisms track the changes made, the

user who made them, and the date and time they were made. Digital bench sheets are included as part of the final data packages while the logbooks are stored on the OneDrive of the primary analyst

## **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
- 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 project folders are inventoried and archived.

## **16.6 Archiving and Document Retention**

All laboratory reports are saved electronically on an internal Oracle APEX database. Complete project files/data packages are either stored electronically on a SharePoint site and tagged with the appropriate federal records retention schedule or as hardcopies stored locally. These records are held until the retention schedule for that project file expires. 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.



## **17 AUDITS**

LSASD conducts audits to measure laboratory performance and verify compliance with accreditation/certification and project requirements. Audits provide LSASD 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 17025:2017 Sections 4 and 5) and one half of our methods (grouped at technology level). To ensure all technologies are audited within a two-year period, a two-year audit plan is created by the QAO and approved by the LSASD management team. This plan covers all LSASD 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 LSASD management team.

Audits are conducted by the QAO or staff designated by branch 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, which culminates with staff interviews, and is distributed to management and relevant staff. If a deficiency requiring Corrective Action is observed, it is discussed with the appropriate Branch 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 are maintained by the LSASD QAO.

### **17.2 External (On-site) Assessments**

Periodic audits are conducted by an external accrediting body to maintain LSASD's ISO/IEC 17025:2017 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 Microbiology and Chlorophyll Laboratories accredited test methods. 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 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. 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 and WS, 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 and WS, testing results are submitted for each endpoint value 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 QAO maintains annual PT performance information as well as continuing and annual DOCs.

### **17.3.2 Chemistry Laboratory**

#### **Laboratory Performance Audits (External PE Samples; WS, WP and 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 17025:2017 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 (BAPAT):** 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.

## **18 MANAGEMENT REVIEWS**

LSASD 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;
- Staff training;
- SOP review, current DCS;
- Planning tool;
- Risk assessment of field and laboratory activities;
- Accomplishments.

### **18.2 Procedures**

The LSASD management team shall meet at least annually to conduct a review of the LSASD'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 Program.

Annual internal audit findings will be documented and submitted for review to the appropriate laboratory and field 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 Program. 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 QAO. The lab QAO 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, if needed
- k. plans and goals
- l. comments and recommendations

The QA Report to Management is reviewed by the Branch Managers for evaluation and consideration. After discussion with the QAO, they may request corrective action based upon the findings of the report. This document is also used as a mechanism to review the overall Quality Program 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 LSASD 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).

## 19 ETHICS AND DATA INTEGRITY INVESTIGATIONS

LSASD is committed to ensuring the integrity of its data and providing defensible data of known and documented quality to its clients. keystones of this commitment are the annual Ethics and Data Integrity Training as well as an annual ethics training specific to LSASD..

Elements of these trainings include:

- LSASD’s Ethics Policy (Appendix A) is attested to annually by all management and staff during the annual Ethics and Data Integrity Refresher Training 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.
- Review of common situations encountered during field and laboratory activities that could raise ethics and/or data integrity concerns and how to address them

### 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;
- 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 annually for all LSASD 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 DCS 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.

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**

Scientific integrity at EPA is the responsibility of every employee, contractor, grantee, volunteer and collaborator who conducts, utilizes, supervises, manages, communicates, or influences scientific activities. The Scientific Integrity Policy exists against a complicated regulatory backdrop. For example, the Scientific Integrity Policy works in conjunction with policies and procedures for addressing research misconduct, information quality,

quality assurance, and peer review. The policy also works in conjunction with statutes such as the Freedom of Information Act and Federal Advisory Committee Act.

Confidential reporting of data integrity issues can be made to LSASD management.

More information on EPA's Scientific Integrity policy can be found at <https://work.epa.gov/region-1/r1-scientific-integrity-program> and <https://www.epa.gov/scientific-integrity>

Personnel may also directly contact the Region 1 Office of Regional Counsel 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.

LSASD personnel may also contact the Region 1 Office of Regional Counsel (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.



## **20 PERSONNEL**

LSASD 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 SOP, most current revisions.

### **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 ISO accredited field sampling and 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.

LSASD provides requirements with respect to education, training and skills of laboratory staff. These are outlined and officially documented in 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 maintained within the Branch by the Branch Manager. 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 and field samplers are trained in methods, laboratory and field procedures by LSASD 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 or field staff. The current version of the SOP is available in .PDF format from the DCS. Depending on the experience of the new analyst or field staff, the next training phase can be to perform the analysis under supervision of the senior analyst or field staff, or perform the test independently with secondary review of the final data.

To evaluate the effectiveness of training, all analysts and field samplers 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 LSASD quality system, and instructed in the quality control program.

### 20.3.2 Training Records

Individual training records are maintained by each employee in their training files. The training records for each employee may include:

- 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 DCS.
- The most up-to-date record can be obtained and printed in real-time from the DCS.
- Records of technical training (certificates or other documentation).
- Course listing from the FedTalent database.
- Records of Demonstration of Capability and records of Continued Demonstration of Proficiency.
- Records of the annual Ethics and Data Integrity Training.

## 21 ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS

### 21.1 Environmental Conditions

The LSASD facility is designed and organized to facilitate testing of environmental samples. A description of the building may be found in the *LSASD Occupant Emergency Plan* in the DCS. LSASD operates under an Environmental Management System (EMS) as described in the EMS Manual available at: <https://work.epa.gov/region-1/environmental-management-system-ems-policy> and maintained in the DCS.

#### 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
- 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 LSASDSOPTempMon-SmartVP0\_Final.pdf. All freezers and refrigerators are monitored daily for temperature. 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.

#### 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-AirCheckSOP, most current revision.

### 21.2 Work Areas

Work areas include access and entryways to the laboratory wing, 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.

### 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-BUILDING, most current revision) 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.

## **22 ENVIRONMENTAL METHODS AND METHOD VALIDATION**

Standard Operating Procedures (SOPs) are available for all activities associated with the collection and 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 LSASD. 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 DCS for a current listing of LSASD 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 DCS.

### **22.1 Method Selection**

LSASD primarily uses approved reference methods and/or those documented in approved QAPPs (Refer to Section 25). LSASD 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 - ORD Applied Research (ROAR) program (previously EPA Regional Applied Research Effort (RARE)) 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 ROAR 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 LSASD 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 Demonstration of Capability**

A laboratory or field method can be performed by analysts and field samplers who have completed a Demonstration of Capability (DOC). 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 staff 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 and field 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) (40 CFR 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

Where available, LSASD utilizes well-recognized test methods which specify limits to major sources of uncertainty (e.g., a balance accurate to  $\pm 0.1$  g) and provide data reporting instructions so that the reported results do not give the wrong impression of the uncertainty. LSASD provides customers QC data with each final report. Acceptance requirements for all QC are also included on the report to communicate compliance with the specified standard and provide an estimate of the uncertainty associated with the final results of the dataset. Where applicable, a statement on the estimated uncertainty of measurement will be included, when it is relevant to the validity of the test result, requested by the customer or the uncertainty may affect compliance to a regulatory limit.

**22.4.1** If requested to provide a more rigorous estimate of the uncertainty of a test result, the analyst in consultation with the Branch Manager and Team Leader will use one of the following two options.

**22.4.1.1** Estimation of Uncertainty using Laboratory Control Samples (adapted from: Georgian, 2000, Environmental Testing and Analysis). This method uses the limits of

historical LCS data to estimate results to a 95% confidence interval using the following equation:

$$\text{Uncertainty} = 100(c/\bar{R})(1 \pm L/\bar{R})$$

Where: c = measured concentration of the analyte

L = the half width of the control range, that is,  $(UCL - LCL)/2\bar{R}$  = mean historical LCS recovery

Because the LCS is a measure of the performance of the entire analytical process, including instrument calibration, this is LSASD's preferred method of estimating uncertainty because it can estimate the uncertainty of the entire analytical process with actual analytical results.

#### **22.4.1.2 Standard Methods 1030B Measurement Uncertainty**

*Note: LSB also uses the results from Proficiency Testing Samples to assess bias.*

#### **22.4.2 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. For point estimate endpoint control charts warning limits are +/- 2 SD. For hypothesis testing endpoint control charts warning limits are established as within +/- one test concentration of the mode. Out of control limits are set at +/- 3SD and +/- 2 concentrations around the mode, respectively. Control charts generated are maintained by the relevant labs as prescribed in the applicable methods.

#### **22.4.3 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.



#### 22.4.4 Use of Known Standards

##### 22.4.4.1 *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.

##### 22.4.4.2 *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, LSASD uses procedures to check calculations and data transfers (both manual and automated).

#### 22.5.1 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.

##### 22.5.1.1 *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.

#### 22.5.1.1.2 *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 Data Review Procedures

Data review procedures are documented in Section 27.7.

## **23 CALIBRATION REQUIREMENTS: Equipment and Instrumentation**

### **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 LSASD SOPs. Equipment is operated only by authorized and trained personnel (Refer to Section 20). LSASD has procedures for the use, maintenance, handling and storage of equipment which are readily available to laboratory and field 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 specifications and relevant standard specifications. Upon receipt, new equipment will often require professional installation by the manufacturer. The responsible analyst will work with the Branch Manager and 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. Field equipment documentation is maintained in Rooms 152 and 212. 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 Room 152 for easy access by all staff. Manuals used in the chemistry laboratories are in individual lab rooms.

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

LSASD 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-ADMLIMS, most current revision 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 and field SOPs. Records are kept for all repair and maintenance activities, including service calls.

### **23.2.1 Support Equipment Maintenance**

Preventive maintenance schedules and 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
- Walk-in Sample Refrigerator (Rm 190)
- LN2 Vacuum Pump
- Hoods, including grain size analysis hood
- Laboratory HVAC Systems
- Chilled Water System
- UPS
- Back-up Generator
- Wastewater Treatment System
- Outside walk-in refrigerator

### **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 applicable SOPs for specific details on support equipment operation and calibration:

Freezers, Refrigerators and Ovens: All are monitored daily for temperature. Incubators and water baths used in microbiological testing are monitored twice per day Monday-Friday unless in use on weekends. 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 SOPs. Instrument malfunction is documented in Instrument Maintenance Logs or Instrument Folders, which become part of the permanent records. A description of what was done to repair the malfunction and proof of return to control are also documented in the log.

#### 23.3.2 Instrument Calibration

Detailed information on instrument calibration may be found in method-specific 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.

## 24 MEASUREMENT TRACEABILITY

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

### 24.1 Traceability Procedures

#### 24.1.1 Preparation of Biological Media, Standards and Reagents

All materials are prepared in accordance with LSASD SOPs referencing approved ASTM and EPA methods. All chemicals are procured from reputable providers, historically noted for acceptable quality, at the purity specified or higher in the method. Most materials are purchased at the concentrations required at time of use. Those that are not purchased at the concentrations required are prepared for use from high purity stock to concentrations necessary for use.

#### 24.1.2 Documentation of Traceability

##### *24.1.2.1 Consumable Materials Traceability*

The LSASD Chemical Inventory System (CIS) is used as a central database to document all pertinent information for consumables received for use in the laboratory and field. 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, 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 vialled materials that are tracked by each department in standards logbooks. Manufacturers' expiration dates are typically considered 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 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-MSDSMANA, most current revision.

#### 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, 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.

## **25 PROJECT PLANNING AND SAMPLE COLLECTION**

LSASD provides sampling services through the FSB 1 and FSB 2. Sampling procedures are maintained in the DCS by the responsible SOP custodians.

### **25.1 Preplanning and Review Procedures**

The LSASD may be requested to perform analytical work by outside organizations or individuals in addition to LSASD field samplers. Projects routinely undertaken 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 the two FSB managers in consultation with Boston program management.

At this stage in the process, one option that can be taken is that at his/her discretion, the branch manager unilaterally may accept or reject such work. Once projects are selected, Project Leads 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). QAPPs require review and approval from the QA Branch.

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., LSB Branch Manager, Chemistry Team Leader or FSB 1/FSB 2 assigned Project Leads. This will be done prior to 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 and management as necessary.

### **25.2 Quality Assurance Project Plans and Sampling and Analysis Plans**

All LSASD environmental information operations, including sampling and analytical activities, must be conducted under an approved generic Quality Assurance Project Plan (QAPP) with associated Sampling and Analysis Plan (SAP) or project specific QAPP. 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. 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 program 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.

FSB 1 and FSB 2 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 DCS.

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 as necessary. 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.

## **26 SAMPLE HANDLING: Receipt, Custody and Disposition**

### **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-ADMLOGN, most current revision and ECASOP-Bio Lab Sample Receipt, most current revision. All samples are accompanied by a chain-of-custody (COC) form

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 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 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 prior to test initiation. Data related to such samples meeting this exception would not be qualified for not meeting sample receipt requirements for temperature.

#### **26.1.1 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.
- 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, a stapled copy of the COC, the study name, the date of receipt, recipient initials and storage location. Samples will be designated for storage in the appropriate laboratory freezer. 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 LSASD sample login for the entrance into the LIMS of sample for analysis at LSASD. 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, 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 26-2) 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 (LSASD 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 – verify accuracy

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 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 or tracked electronically. Detailed procedures are described in the SOP for Sample Login, Tracking, Disposition and Disposal (ADMLOGN.SOP, most current revision) and ECASOP-Bio Lab Sample Receipt, most current revision. 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.

#### 26.1.2 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.

#### 26.1.3 Analyses Contracted to ESAT

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

#### 26.1.4 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-ADMEVID, most current revision.

## **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 ADMLOGN.SOP, most current revision or biology samples are disposed of according to disposal practices described in ECASOP-Bio Lab Sample Receipt, most current revision.

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 ADMLOGN.SOP, most current revision. 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 Regional technical requirements, policies, and implement contract specific QA/QC procedures as applicable.

### 26.3.4 Analyses Contracted to Outside Laboratories

LSASD does not subcontract samples; but may contract directly with a commercial laboratory for sample analysis. However, this data is produced independent of the Laboratory Services Branch and is not treated as LSASD data falling under our ISO 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-ADMLABWLOGN, most current revision
- Sample Log-in, Tracking and Sample Disposition, ADMADMLOGN, most current revision

- Sample Control Procedures for Samples Entering the Biology Laboratory, ECASOP-Bio Lab Sample Receipt, most current revision

## **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-WASTEMAN, most current revision and the *SOP for Sample Login, Tracking, Disposition and Disposal*, ADMLOGN, most current revision and ECASOP-Bio Lab Sample Receipt, most current revision for detailed procedures.

## **26.6 Sample Transport**

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

**CHAIN OF CUSTODY RECORD**

[illegible]

1-19324



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

## US EPA REGION 1 SAMPLE RECEIPT CHECKLIST

<b>PROJ #:</b>	<b>RECEIPT DATE:</b>
<b>SURVEY NAME: LOCATION:</b>	<b>REC'D BY:</b>
<b>OSC/PO:</b>	<b>SITE ID:            SUPERFUND   YES/NO</b>
<b>COMMENTS:</b>	
WERE SAMPLES SHIPPED? YES: FEDEX / UPS/ OTHER  TRACKING #: _____ DATE/SENT: _____  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	
WAS SAMPLE PRESERVATION DOCUMENTED?                      YES / NO COC (circle)     Sample Container (circle)	
APPROPRIATE SAMPLES VOLUME FOR REQUESTED ANALYSIS?                      YES / NO	
SAMPLES AND COC MATCH?                      YES / NO	
IF ANY PROBLEMS WAS PROJECT MANAGER NOTIFIED? YES / NO BY WHOM?	
APPROPRIATE SAMPLE CONTAINERS?                      YES / NO	
SAMPLES WITHIN HOLDING TIMES?                      YES / NO	
ALL ANALYSIS SPECIFIED ON COC?                      YES / NO	
DATE/TIME OF COLLECTION ON COC                      YES/NO	
TURN-AROUND TIME:	

IR GUN TEMPERATURE VERIFICATION RM. 190 - SAMPLE LOGIN

COLE PARMER IR MODEL 39850-12

S/N 2508400101-022

F1 Flask Temp \_\_\_\_\_ °C

COLE PARMER Temp \_\_\_\_\_ °C = \_\_\_\_\_ °F

**Note:** IR gun must be  $\pm 0.5$  °C of flask temp.

## **27 QUALITY ASSURANCE FOR ENVIRONMENTAL TESTING**

LSASD 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.

### **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 Microbiology Laboratory Controls

#### 27.3.1.1 *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 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 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. update

### 27.3.3 Chlorophyll Laboratory Controls

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

#### 27.3.4 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 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.

#### 27.3.5 Blanks

##### 27.3.5.1 *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.

##### 27.3.5.2 *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.

##### 27.3.5.3 *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.

##### 27.3.5.4 *Field Blanks*

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

##### 27.3.5.5 *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.

#### 27.3.6 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

#### 27.3.7 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.

#### 27.3.8 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.

#### 27.3.9 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, 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, current revision.

### **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 LSASD 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 Team Leader.

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 update**

**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: Example 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?

- ☐ 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

### Figure 27-3: FSB 2 - EMT Project Review Checklist Form

Project Name: \_\_\_\_\_ Sampling date (s): \_\_\_\_\_  
Field Team Lead: \_\_\_\_\_ Project Lead: \_\_\_\_\_

**Primary Review** (review all that apply)

- ☐ Reviewed sonde data according to WQ Sonde Data Review SOP
- ☐ Sonde data qualified and significant figures reported according to WQ Sonde Data Review SOP
- ☐ All sonde pre cal, post verification signed pdf stored in project folder on S drive
- ☐ The correct units and time zones (EST, EDT, UTC) displayed with the data
- ☐ All sonde raw and final data files stored in project folder on S drive
- ☐ Reviewed field notes and field measurement for completeness and accuracy
- ☐ Field logbook records converted to pdf and in project folder on S drive
- ☐ Signed SAP as pdf in project folder on S drive
- ☐ Chain of Custody form as pdf in project folder on S drive
- ☐ Contract lab results are identified in the final data
- ☐ Any notes, memos, or noted deviations are in project folder on S drive
- ☐ Site description and locational data presented in final data file
- ☐ Duplicates and blanks checked against QC criteria; data flagged not meeting the criteria
- ☐ All laboratory data reports received, and pdfs are in the project folder on S Drive
- ☐ Holding times checked and data qualified for results not meeting it in final data file
- ☐ Results, non detected reporting limits, and qualifiers reported with final data file
- ☐ All final data compiled, formatted for release, converted to pdf and in project folder on S drive

**All above primary review tasks completed - Reviewer Name and Date:** \_\_\_\_\_

**Secondary Review** (review all that apply)

- ☐ All manual data entry double checked for transcription errors (minimum 10%)
- ☐ Reviewed sonde post verification records and all necessary qualifiers noted
- ☐ Reviewed sonde field side by side (QC) measurements and qualifiers noted
- ☐ All lab qualifiers and necessary reporting limits in final data file
- ☐ All data presented clearly in final data file

**All above secondary review tasks completed - Reviewer Name and Date:** \_\_\_\_\_

**QA Review** (review all that apply)

- ☐ All listed documentation above in project folder
- ☐ Any qualifiers and data usability limits are clearly noted and explained
- ☐ Final data summary complete

**All above QA review tasks completed - Reviewer Name and Date:** \_\_\_\_\_

**FSB 2 Manager approval Name and Date:** \_\_\_\_\_

## **28 REPORTING RESULTS**

It is LSASD'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 are generated through the use of LIMS and Crystal Reports. All our data reports include the information described below..

##### **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, LSASD;
- 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 Leader 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 DCS.

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 an electronic and hard copy report which are 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”: [https://s0101abopk002/apex/r1\\_workspace/r/r1-laboratory-reports/home](https://s0101abopk002/apex/r1_workspace/r/r1-laboratory-reports/home).

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 Branch Manager 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 LSASD. 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 FSB 1 or FSB 2 analytical work performed by an outside contract lab, the original report from the contractor is kept with the customer file in the chemistry laboratory.

## **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: LSASD 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 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

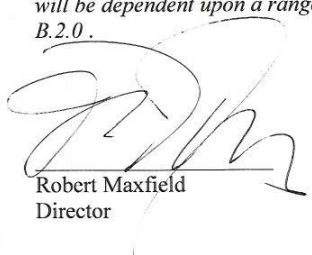
### ETHICS POLICY

**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

5/25/12  
Date

## APPENDIX A-2 EPA's Principles of Scientific Integrity



### 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.

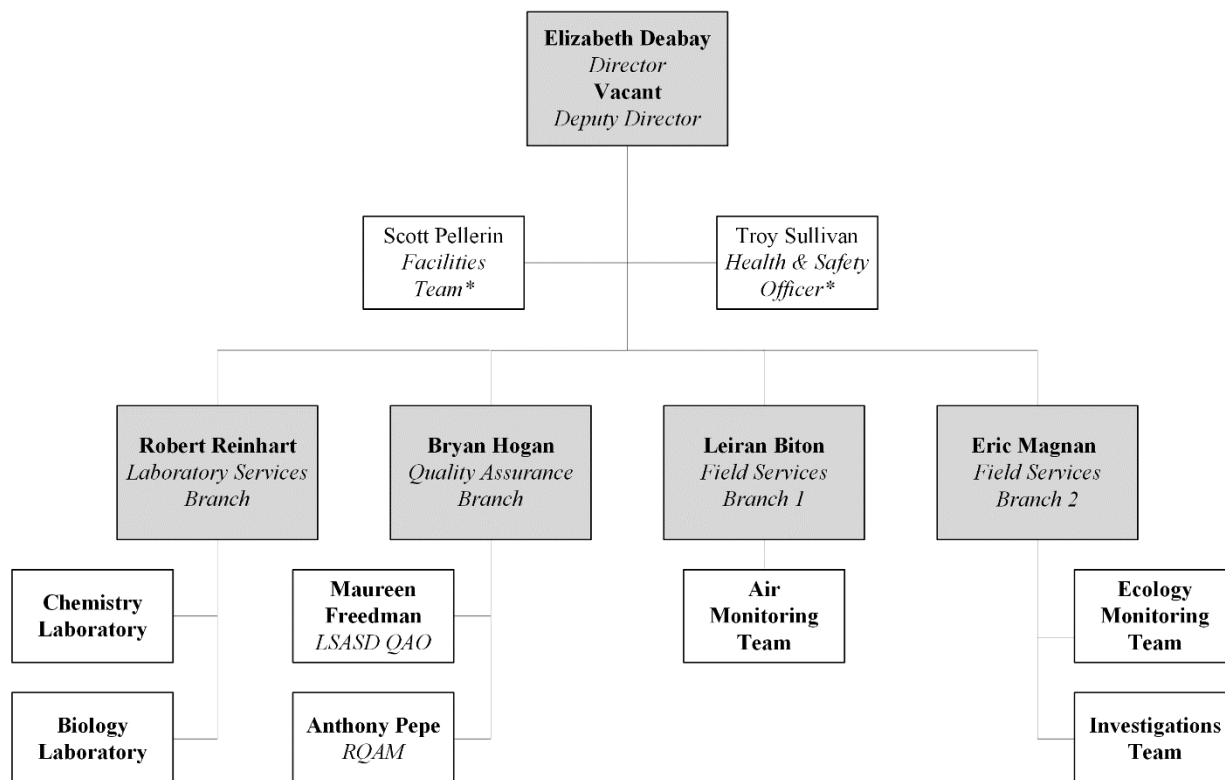
## APPENDIX B-1 EPA Region 1 Organizational Chart

*Effective: April 28th 2019*

### EPA REGION 1



## APPENDIX B-2 Laboratory Services and Applied Science Division Organizational Chart



\*Facilities and Health and Safety staff report to Mission Support Division

## APPENDIX C Floor Plan

