



Eberline Analytical Oak Ridge Laboratory Quality Assurance Program Manual

AUTHORIZATION AND APPROVAL STATEMENT

This **Eberline Analytical** - Oak Ridge Laboratory,
"Quality Assurance Program Manual"
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MISSION STATEMENT

Our mission is to ensure that all of The Eberline Services, Oak Ridge Laboratory's systems, services, processes, and deliverables are of a quality that meets or exceeds client requirements; and to foster a Laboratory culture in which there is a commitment to a rising standard of quality. This culture demands that the quality of those systems, services, processes, and deliverables and the methods used to achieve that quality be continuously improved.

Quality Assurance is a spirit that pervades all aspects of an organization. It is the quality attitude developed by a quality culture in an organization. It is the spirit in which any organization, procedure or activity is documented, implemented and performed. This spirit produces empowerment and motivation in all employees to achieve the highest level of quality. The result of this attitude is "**Quality Assurance.**"

The policy guidelines are presented in this Eberline Analytical Laboratory Quality Assurance Program Manual, and are based on the philosophy and premises that:

- People are our greatest asset and are ultimately responsible for the quality of the items and services we provide. Therefore, each person is treated with the greatest possible respect and consideration.
- Employees are inherently proud and want to produce top quality and on time services and deliverables. In order to do this they must be made aware of the quality requirements that are expected and must be provided appropriate facilities, equipment, and proper training.
- A culture of quality embodied within the entire Eberline Analytical Laboratory organization is the most effective way to provide support for the employee's commitment to quality.
- Management support is paramount, and organizational responsibilities must ensure integration of quality requirements in the day-to-day operations.
- All systems, services, processes, and deliverables can be planned, performed, assessed, and improved.
- Improvements allow operations to become more efficient and result in contractual requirements performed "on time" and done "right the first time."
- Quality improvements lead to reduced costs and allow the ultimate objective of providing the highest quality items and services to be a viable goal.

Quality is our client's perception of us. Our actions must assure our clients that the Oak Ridge Laboratory organization provides for quality systems, services, processes, and deliverables that will meet or exceed their requirements. To this end, each employee must understand and exercise the highest standards of ethics in the performance of their duties and ensure the integrity of the data they report.



STATEMENT OF COMPLIANCE AND MATRIX COMPARISON

This Quality Assurance Program Manual addresses the basic requirements outlined in several regulatory manuals, standards, regulations, and national laboratory programs. Matrix comparison to some of these documents is included in the following pages. Additional regulatory requirements are listed in Section 1.0.

NQA-Quality Assurance Requirements for Nuclear Facility Application
National Environmental Laboratory Accreditation Conference (NELAC), USEPA; 2003, the NELAC Institute (TNI), 2009
USEPA Requirements for the Certification of Laboratories Analyzing Drinking Water; 2005
ISO/IEC 17025: 2005 for the General Requirements for the Competence of Calibration and Testing
DOE Quality Systems for Analytical Services (QSAS) Document
DoD Quality Systems Manual for Environmental Laboratories (DoD QSM)
PJLA Accreditation Compliance Requirements

This manual is organized as follows:

Name, Title, Authorization and Approval
Table of Contents
Mission Statement
Statement of Compliance and Matrix Comparison
Introduction and Description
Organization and Responsibility
Quality Assurance Objectives
Personnel Qualification and Training
Instructions and Procedures
Procurement Document Control
Material Receipt and Control
Material Storage and Control
Control of Process
Preventative Maintenance
Control of Measurement and Test Equipment
Data Reduction, Verification, and Reporting
Document Control
Internal Quality Control
Audits
Quality Assurance and Inspection Records
Corrective Action
Quality Assurance Reports to Management



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MATRIX COMPARISON

NQA-1, Cross Reference to Eberline Analytical Laboratory Q.A. Program Manual

NQA-1- Quality Assurance Requirements for Nuclear Facility Applications (<i>Basic Requirements</i>)		Eberline Analytical Laboratory Quality Assurance Program Manual	
BASIC RQMT	TITLE	QAM SECT	TITLE
1.	Organization	2.0	Organization and Responsibility
2.	Quality Assurance Program	3.0 4.0	Quality Assurance Objectives Personnel Indoctrination and Training
3.	Design Control	N/A	Does not apply
4.	Procurement Document Control	6.0	Procurement Document Control
5.	Instructions, Procedures, and Drawings	5.0	Instructions and Procedures
6.	Document Control	13.0	Document Control
7.	Control of Purchased Items and Services	7.0	Material Receipt and Control
8.	Identification and Control of Items	8.0	Material Storage and Control
9.	Control of Process	9.0	Control of Process
10.	Inspection	14.0	Internal Quality Control
11.	Test Control	14.0	Internal Quality Control
12.	Control of Measurement and Test Equipment	11.0	Control of Measurement and Test Equipment
13.	Handling, Storage, and Shipping	8.0	Material Storage and Control
14.	Inspection, Test, and Operating Status	14.0	Internal Quality Control
15.	Control of Nonconforming Items	8.0	Material Storage and Control
16.	Corrective Actions	17.0	Corrective Actions
17.	Quality Assurance Records	16.0	Quality Assurance and Inspection Records
18.	Audits	15.0	Audits
	N/A	N/A	Title Page
	N/A	N/A	Authorization and Approval Statement
	N/A	1.0	Introduction and Description
	N/A	10.0	Preventive Maintenance
	N/A	12.0	Data Reduction, Verification, and Reporting
	N/A	18.0	Quality Assurance Reports to Management



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MATRIX COMPARISON

10 CFR Part 50, Appendix B Cross Reference to Eberline Analytical Laboratory Q.A. Program Manual

NRC 10 CFR Part 50 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."		Eberline Analytical Laboratory Quality Assurance Program Manual	
Criterion No.	TITLE	QAM SECT	TITLE
I	Organization	2.0	Organization and Responsibility
II	Quality Assurance Program	3.0	Quality Assurance Objectives
III	Design Control	N/A	Does not apply
IV	Procurement Document Control	6.0	Procurement Document Control
V	Instructions Procedures, and Drawings	5.0	Instructions and Procedures
VI	Document Control	13.0	Document Control
VII	Control of Purchased Material, Equipment, and Deliverables	7.0	Material Receipt and Control
VIII	Identification and Control of Materials, Parts, and Components	8.0	Material Storage and Control
IX	Control of Special Process	9.0	Control of Process
X	Inspections	14.0	Internal Quality Control
XI	Test Control	14.0	Internal Quality Control
XII	Control of Measuring and Test Equipment	11.0	Control of Measurement and Test Equipment
XIII	Handling, Storage, and Shipping	8.0	Material Storage and Control
XIV	Inspection, Tests, and Operating Status	14.0	Internal Quality Control
XV	Nonconforming Materials, Parts or Components	7.0	Material Receipt and Control
XVI	Corrective Actions	17.0	Corrective Actions
XVII	Quality Assurance Records	16.0	Quality Assurance Inspection Records
XVIII	Audits	15.0	Audits
		N/A	Title Page
		1.0	Introduction and Description
		10.0	Preventative Maintenance
		12.0	Data Reduction, Verification, and Reporting
		18.0	Quality Assurance Reports to Management

MATRIX COMPARISON

DOE Order 414.1C Cross Reference to Eberline Analytical Laboratory Q.A. Program Manual

DOE Order 414.1 C "Quality Assurance"			Eberline Analytical Laboratory Quality Assurance Program Manual
Criterion No.	TITLE	QAM SECT	TITLE
1.	Program	1.0 2.0 3.0 12.0 13.0	Introduction Organization and Responsibility Quality Assurance Objectives Data Reduction, Verification, and Reporting Document Control
2.	Personnel Training and Qualification	4.0	Personnel Indoctrination and Training
3.	Quality Improvement	17.0	Corrective Actions
4.	Documents and Records	16.0 18.0	Quality Assurance Records Quality Assurance Reports to Management
5.	Work Process	5.0 9.0 10.0 14.0	Instructions and Procedures Control of Process Preventive Maintenance Internal Quality Control
6.	Design	N/A	Does not apply
7.	Procurement	6.0 7.0 8.0	Procurement Document Control Material Receipt and Control Material Storage and Control
8.	Inspection and Acceptance Testing	11.0 14.0 15.0	Control of Measurement and Test Equipment Internal Quality Control Audits
9.	Management Assessment	2.0	Organization and Responsibility
10.	Independent Assessment	15.0	Audits
N/A		N/A	Title Page
N/A		N/A	Authorization and Approval Statement

MATRIX COMPARISON

DoD and DOE Consolidated Quality Systems (QSM) for Environmental Laboratories Cross Reference to Eberline Analytical Laboratory QA Program Manual.

This cross reference applies also to NELAC Chapter 5.4.2.3

NELAC Chapter 5 "Quality Systems"		Eberline Analytical Laboratory Quality Assurance Program Manual	
4.2.6 RQMT	TITLE	QAM SECT	TITLE
	Title Page		Title Page
(a)	Policy statement, objectives, commitment by top management	1.0 3.0	Introduction and Description Quality Assurance Objectives
(b)	Organization and Management structure, Org Charts	2.0	Organization and Responsibility
(c)	Relationship between management, technical operations, support services and the quality system	2.0	Organization and Responsibility
(d)	Document control and records retention	16.0	Quality Assurance & Inspection Records
(e)	Job Descriptions	4.0	Personnel Indoctrination and Training
(f)	Approval signatories, signed concurrences	A&A	Authorization and Approval Statement
(g)	Traceability of measurements	14.0	Internal Quality Control
(h)	List of test methods	9.0	Control of Process
(i)	Review for facility and resource availability	9.0	Control of Process
(j)	Calibration or verification test procedures	5.0	Instructions and Procedures
(k)	Procedures for handling submitted samples	9.0	Control of Process
(l)	Major equipment and measurement standards	9.0 11.0	Control of Process Control of Measurement & Test Equipment
(m)	Calibration, verification, & maintenance	11.0	Control of Measurement & Test Equipment
(n)	Inter laboratory comparison, proficiency testing, reference material, internal Q.C.	14.0	Internal Quality Control
(o)	Corrective actions	17.0	Corrective Actions
(p)	Departures from policy/procedures	5.0	Instructions and Procedures
(q)	Complaints	1.0	Introduction and Description
(r)	Confidentiality and Proprietary rights	1.0	Introduction and Description
(s)	Audits and Data reviews	12.0 15.0	Data Reduction, Verification, and Reporting Audits
(t)	Personnel experience and training	4.0	Personnel Indoctrination and Training
(u)	Ethical and legal responsibilities	1.0	Introduction and Description
(v)	Analytical results reporting	12.0	Data Reduction, Verification, and Reporting
(w)	Table of Contents	TOC	Table of Contents

MATRIX COMPARISON

10 CFR Part 830.122 Cross Reference to Eberline Analytical Laboratory Q.A. Program Manual

10CFR 830.122 "Quality Assurance Criteria"			Eberline Analytical Laboratory Quality Assurance Program Manual
Criterion No.	TITLE	QAM SECT	TITLE
830.122 (a)	Management/Program	1.0	Introduction
		2.0	Organization and Responsibility
(b)	Management/Personnel Training and Qualification	4.0	Personnel Indoctrination and Training
(c)	Management/Quality Improvement	3.0	Quality Assurance Objectives
		14.0	Internal Quality Control
		17.0	Corrective Actions
(d)	Management/Documents and Records	5.0	Instructions and Procedures
		9.0	Control of Process
		12.0	Data Reduction, Verification, and Reporting
		13.0	Document Control
		16.0	Quality Assurance Records
		18.0	Quality Assurance Reports to Management
(e)	Performance/Work Process	7.0	Material Receipt and Control
		8.0	Material Storage and Control
		10.0	Preventive Maintenance
		14.0	Internal Quality Control
(f)	Performance/Design	N/A	Does not apply
(g)	Performance/Procurement	6.0	Procurement Document Control
(h)	Performance/Inspection and Acceptance Testing	11.0	Control of Measurement and Test Equipment
		14.0	Internal Quality Control
		15.0	Audits
(i)	Assessment/Management Assessment	2.0	Organization and Responsibility
(j)	Assessment/Independent Assessment	2.0	Organization and Responsibility
		15.0	Audits
N/A		N/A	Title Page
N/A		N/A	Authorization and Approval Statement

MATRIX COMPARISON

EPA SW-846 Cross Reference to - Eberline Analytical Laboratory Q.A. Program Manual

EPA SW-846 (Essential Elements)		Eberline Analytical Laboratory Quality Assurance Program Manual	
BASIC RQMT	TITLE	QAM SECT	TITLE
1.	Title Page	N/A	Title Page
2.	Table of Contents	N/A	Table of Contents
3.	Project Description	1.0	Introduction and Description
4.	Project Organization and Responsibility	2.0	Organization and Responsibility
5.	Q.A. Objectives	3.0	Quality Assurance Objectives
6.	Sampling Procedures	N/A	Does not apply to laboratory
7.	Sample Custody	9.0	Control of Process
8.	Calibration Procedures and Frequency	11.0	Control of Measurement and Test Equipment
9.	Analytical Procedures	5.0 9.0	Instructions and Procedures Control of Process
10.	Data Reduction, Validation, and Reporting	12.0	Data Reduction, Verification, and Reporting
11.	Internal Quality Control Checks	14.0	Internal Quality Control
12.	Performance and System Audits	15.0	Audits
13.	Preventive Maintenance	10.0	Preventive Maintenance
14.	Specific Routine Procedures Used to Assess Data Precision, Accuracy, and Completion	14.0	Internal Quality Control
15.	Corrective Action	17.0	Corrective Actions
16.	Quality Assurance Reports to Management	18.0	Quality Assurance Reports to Management
N/A		N/A	Authorization and Approval Statement
N/A		4.0	Personnel Indoctrination and Training
N/A		6.0	Procurement Document Control
N/A		7.0	Material Receipt and Control
N/A		8.0	Material Storage and Control
N/A		13.0	Document Control
N/A		16.0	Quality Assurance and Inspection Records



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MATRIX COMPARISON EPA QA/R-5 "EPA Requirements for Quality Assurance Project Plans"

EPA QA/R-5, "EPA Requirements for Quality Assurance Project Plans"		Eberline Analytical Laboratory Quality Assurance Program Manual	
RQMT	TITLE	SECT	TITLE
A	Project Management		
A1	Title and Approval Sheet		Title Page Authorization and Approval (A&A) Statement
A2	Table of Contents		Table of Contents Page Headers (document control)
A3	Distribution List		Title Page
A4	Project/Task Organization	1.4 2.1 2.2 2.5	Introduction Organizational Structure Responsibility Organization Charts
A5	Problem Definition/Background	3.0 9.0 14.0	Quality Assurance Objectives Control of Process Internal Quality Control
A6	Project/Task Description	9.0	Control of Process
A7	Quality Objectives and Criteria	3.0	Quality Assurance Objectives
A8	Special Training/Certification	4.0	Personnel Indoctrination and Training
A9	Documents and Records	5.0 9.2 13.0 16.0	Instructions and Procedures Documented Procedures Document Control Quality Assurance and Inspection Records
B	Data Generation and Acquisition		
B1	Sampling Process Design (Experimental Design)	N/A	
B2	Sampling Methods	N/A	
B3	Sample Handling and Custody	14.4	Sample Custody
B4	Analytical Methods	5.0 9.0	Instructions and Procedures Control of Process
B5	Quality Control	14.0	Internal Quality Control
B6	Instrument/Equipment Testing, Inspection, and Maintenance	10.0 11.0	Preventive Maintenance Control of Measurement and Test Equipment
B7	Instrument/Equipment Calibration and Frequency	11.0	Control of Measurement and Test Equipment
B8	Inspection/Acceptance of Supplies and Consumables	7.0 8.0	Material Receipt and Control Material Storage and Control
B9	Non-direct Measurements	10.0	Data Reduction, Verification, and Reporting
B10	Data Management	10.0	Data Reduction, Verification, and Reporting
C	Assessment and Oversight		
C1	Assessments and Response Actions	15.0 17.0	Audits Corrective Action
C2	Reports to Management	18.0	Quality Assurance Reports to Management
D	Data Validation and Usability		
	Data Review, Verification, and Validation	12.0	Data Reduction, Verification, and Reporting



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EPA QA/R-5, "EPA Requirements for Quality Assurance Project Plans"		Eberline Analytical Laboratory Quality Assurance Program Manual	
RQMT	TITLE	SECT	TITLE
D1		14.3	Data Verification
D2	Verification and Validation Methods	12.0	Data Reduction, Verification, and Reporting
D3	Reconciliation with User Requirements	12.0	Data Reduction, Verification, and Reporting



1.0 INTRODUCTION AND DESCRIPTION

1.1 PREFACE

Eberline Analytical – Oak Ridge Laboratory is a radiochemistry laboratory that specializes in providing services for radiological assays to the environmental industry. Radionuclides are quantified within materials such as surface water, ground water, drinking water, wastewater, soil, sediment, sludge, vegetation, and hazardous waste. Bioassay (urine) analysis is performed for total uranium. The objective of the laboratory is to produce the highest quality data that are accurate, precise, legally defensible, and meet our clients data needs and requirements in a timely and cost effective manner.

The management of Eberline Services, Oak Ridge Laboratory is committed to a rigorous Quality Assurance (Q.A.) Program. While this commitment is necessary for the normal conduct of business, our basic policies dictate the highest standards of ethics and integrity in the conduct of our affairs. This philosophy and the specific procedures to attain policy objectives from the framework of our Q.A. Program. We will provide only those services that are within our qualifications and with confidence that our Q.A. Program and all related operating procedures dictate reliable performance of those services.

1.2 PURPOSE

This manual outlines management's Q.A. policy and establishes a requirement that procedures be promulgated and implemented to accomplish all of the quality assurance elements necessary to fulfill our responsibility to meet or exceed client or regulatory specifications. It also provides a means for creating mutual understanding regarding our Q.A. program and reliability techniques with our subcontractors, suppliers, and clients. This Eberline Services-Oak Ridge Laboratory Quality Assurance Program provides the structure, policies and responsibilities for the execution of quality control and quality assessment operations to assure that the laboratory meets defined standards of quality.

1.3 SCOPE

This Quality Assurance Program Manual provides guidance to meet operational Q.A. requirements.

In addition to the documents identified in the Cross Reference Section, this Manual complies with applicable requirements of the following the latest revisions of regulations below:

- 1.3.1 NRC 10 CFR Part 21, "Reporting of Defects and Non-compliance."
- 1.3.2 ANSI/ANS-10.3-, "Documentation of Computer Software."
- 1.3.3 NRC Regulatory Guide 4.15, Rev. 1, "Quality Assurance for Radiological Monitoring Programs - Effluent Streams and the Environment."
- 1.3.4 U.S. EPA QA/R-5, "EPA Requirements for Quality Assurance Program Plans."
- 1.3.5 DOE Order 414.1C "Quality Assurance."
- 1.3.6 ISO/IEC 17025:2005, "General Requirements for the Competence of Calibration and Testing Laboratories."
- 1.3.7 USEPA Directive 2185, "Good Automated Laboratory Practices" (GALP).

1.3.8

1.3.9 A National Environmental Laboratory Accreditation Conference (NELAC) Chapter 5 "Quality Systems", July 2003.

1.3.10 USEPA Manual for the Certification of Laboratories Analyzing Drinking Water, EPA 815-R-004, January 2005.

1.3.11 DoD/DOE Consolidated Quality Systems Manual for Environmental Laboratories

1.3.12 The NELAC (TNI) Standards, Volume 1 (September 2009)

1.4 INTRODUCTION

Quality assurance, as outlined herein, is a tool that allows management to utilize the expertise and experience of all personnel on the job. It requires each worker to be aware of his/her work environment and to continually evaluate methods and processes to ensure that the best and correct operation is being performed. It requests each employee to identify and suggest any improvement to the processes while performing an operation. Improvements or changes shall be coordinated with management who will validate improvement and disseminate the information to all affected personnel. Management shall also, as needed, change procedures and provide additional training. This program also requires that all personnel be qualified, and trained on a continuing basis to maintain that qualification and be assimilated into the Oak Ridge Laboratory quality culture.

Management will provide resources, tools, equipment, scheduling, and training to ensure personnel can perform their duties effectively.

1.4.1 Management will also ensure that internal assessments are performed annually to evaluate management and processes with feedback for review with a goal of improving all areas of operations.

1.4.2 It is only by having a quality assurance culture, with all personnel involved, that a system, service, or product can be provided with full assurance that the best possible work, the best possible product, or the best possible service has been provided.

1.4.3 In order to ensure that this manual is an effective management tool, subjects that are not normally considered quality assurance, i.e. safety, security, etc., are addressed in other management documents.

1.4.4 The following titled designations of positions are used within the Oak Ridge, TN Laboratory:

Laboratory Manager: Refers to the General Manager of the Oak Ridge Laboratory.

Radiation Safety Officer (RSO): Refers to the RSO of the Oak Ridge Laboratory.

Emergency Coordinator: Refers to the individual who is responsible for overseeing and directing activities and protocols associated with emergencies and disasters..

Project Manager: Refers to an individual who is responsible for client service activities and is the single point of contact with a client for the laboratory.

Supervisor: Refers to individuals within the laboratory who are responsible for the operational functions of a group of personnel.

Q.A. Manager: Refers to the individual who is responsible for the Laboratory's Q.A.



Program.

1.5 DESCRIPTION

This document outlines the organization of the Q.A. functions within the laboratory. It depicts the lines of authority, and lists the duties and responsibilities within the organization. It provides direction for the preparation of Procedures Manuals, which provide the detailed methods of processes and analyses that accomplish the goal of quality data in terms of precision, accuracy and reproducibility.

1.6 CONFIDENTIAL AND PROPRIETARY INFORMATION

Oak Ridge Laboratory employees are exposed to confidential and/or proprietary information pertaining to the company and its clients. Information concerning the report of analysis, radiation dosimetry records, audit reports, calibration reports, and other documents relating to a project are considered confidential. This information is to be released only to the client or to the client's authorized representative. Each employee will sign an agreement with the Oak Ridge, TN Laboratory concerning the security of proprietary and confidential information. A copy of the agreement will be retained in the employee's personnel file (at the corporate office in Albuquerque, NM).

1.7 TECHNICAL COMPLAINTS

Technical complaints will be addressed by the Laboratory Manager, Project Manager, Quality Assurance Manager, or staff member with expertise in the area of complaint. If the complaint is not valid, every attempt will be made to satisfy the client. If the complaint is determined to be valid, the cause of the complaint shall be identified and corrected as soon as feasible. Verification that the cause for a valid complaint has been corrected is the responsibility of the individual addressing the complaint. Details of all technical complaints shall be recorded and maintained in the customer's project file. Clients are also encouraged to provide feedback on the Eberline Analytical website via a statement on each client report.

1.8 ETHICAL AND LEGAL RESPONSIBILITIES

Eberline Services-Oak Ridge Laboratory utilizes a clearly stated ethics policy that is discussed with all new employees during orientation. Each employee is required to understand the high standards of ethics and integrity required in order to perform their duties and to ensure the integrity of the data reported in connection with their employment at the Oak Ridge Laboratory. Each employee will understand that intentionally reporting data that are not the actual values obtained, intentionally reporting dates and/or times or data analyses that are not the actual dates and/or times of analyses, intentionally representing another individual's work as their own; or any other action that may affect the integrity of the data reported by the laboratory; will be the cause for dismissal.

1.9 ACCREDITATIONS

Through applications, pre-qualification, performance testing, and external auditing programs; the laboratory has been granted certification by different agencies, organizations, and states. The Laboratory maintains proficiency as required by the clients and regulatory certifying agency. The Quality Assurance Manager maintains credentials and lists of certifying agencies. The list of certifications maintained by the Oak Ridge Laboratory includes:

State of Tennessee, Department of Health – Laboratory Division

State of California, Department of Public Health – ELAP Branch

State of South Carolina, Dept of Health & Environmental Control, Environmental Lab Certification Program



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State of Utah, Department of Health Bureau of Laboratory Improvement
State of New Jersey, Department of Environmental Protection, Office of Quality Assurance
State of New York, Department of Health, Environmental Lab Approval Program
State of North Dakota, Dept. of Health Environ. Lab. Certification Program - Chemistry Division
State of Nevada, Dept. of Conservation Bureau of water Quality Environmental Lab Services
State of Louisiana, Department of Environmental Quality
State of Texas, Texas Commission of Environmental Quality
State of Alabama, Department of Environmental Management
Commonwealth of Virginia, Dept. of General Services Division of Consolidated Lab Services
State of Washington, Department of Ecology
Perry Johnson Laboratory Accreditation, Inc.
Department of Energy (DOE)
Department of Defense (DoD)

2.0 ORGANIZATION AND RESPONSIBILITY

2.1 ORGANIZATIONAL STRUCTURE

The Laboratory Manager has overall responsibility for this Quality Assurance Program (hereafter referred to as the Program). In this capacity, he has delegated the responsibility for formulation, implementation, and execution of the Program to the Laboratory Q.A. Manager.

Current organizational charts, identifying key individuals and the structure of the laboratory, are included in the "Statement of Qualifications." Additional organizational structure, functional responsibilities, levels of authority, and lines of communication for management, direction, and execution of the Program are documented below.

2.2 RESPONSIBILITY

Laboratory Management will periodically assess the integrated quality assurance program, its performance, and its effectiveness. Problems that hinder the organization from achieving its objectives will be identified and corrected.

Management will provide training and qualification to ensure quality products and services. Every employee is responsible for supporting the QA program policies, procedures, and guidance with each employee being responsible for their work. Professional qualifications and experience of all individuals and positions are maintained. Position descriptions and resumes are kept on file in the QA office. The specific duties of selected personnel are described below. Other job descriptions are located within an employee's training file in the QA office.

2.2.1 Laboratory Manager

The Laboratory Manager, under the authority of the President of Eberline Analytical Corporation, is responsible for the overall laboratory productivity and optimization of the efforts of the analytical staff and those who directly support the analytical effort. Staff interacts with the Lab Manager throughout the day. The Laboratory Manager is responsible for the implementation of regulatory standards, and national program requirements (ISO/IEC 17025:2005, NELAP, TNI, DOE, and DoD). The Laboratory Manager is responsible for directing all aspects of the laboratory operations. The Laboratory also fills the role of purchasing manager by serving as the point of contact for laboratory materials/services purchases by generating and submitting purchase orders for corporate accounting.

The duties of the Laboratory Manager include the following.

- Overall direction and general administration.
- Daily operation of the laboratory.
- Review of analytical procedures and practices.
- Recruitment, hiring, assignment, evaluation and termination of personnel.
- Training and professional development of staff.
- Review of proposals, bids, pricing and quotations.
- Perform an annual assessment of the laboratory operation.
- Ensure compliance with regulatory standards and national program requirements including ISO/IEC 17025:2005, NELAP, TNI, DOE, and DoD.

2.2.2 Quality Assurance Manager

As focal point for QA/QC, the Quality Assurance Manager operates independently from line management while reporting to the Laboratory Manager. The QA Manager has sufficient authority and organizational freedom to identify quality problems, to initiate, recommend or provide

solutions; to verify implementation of solutions, and if necessary, to stop work until the problem is resolved. The QA Manager has independence from cost scheduling, and production considerations. In his capacity, he has the authority to control processing, delivery, installation, or use of items or services until proper disposition of an identified non-conformance, deficiency, or condition adverse to quality. The QA Manager has a direct line of communication to the President of Eberline Analytical Corporation for matters of quality.

The duties and responsibilities of the QA Manager are as follows.

- Develop and implement QA procedures, instructions and plans to maintain and improve quality system.
- Maintain surveillance over all applications of the QA Program; make recommendations for resolution of problems, or further evaluation by management.
- Perform internal audits and monitor external audits; write responses, and ensure corrective actions.
- Issue non-conformances and formal corrective action(s).
- Issue stop-work orders for work that is not in compliance with requirements.
- Direct, and maintain records of analytical performance evaluation programs to ensure full and prompt participation and evaluation of results and derivation of all benefits relating there from.
- Direct, and maintain records of laboratory certification programs.
- Authorized to sign and designate other personnel to sign client related Certificates of conformance and/or non-conformance.
- Ensure compliance with regulatory standards and national program requirements including ISO/IEC 17025:2005, NELAP, TNI, DOE, and DoD.

2.2.3 Project Manager (i.e. Client Services Manager)

The Project Manager reports directly to the Laboratory Manager and is the primary contact for clients requesting information on lab capabilities including pricing and status of projects. The Project Manager manages/oversees client services by communicating client requirements to operations groups, updating clients on progress of samples through the laboratory, and preparing subsequent reports and invoices.

- The duties and responsibilities of the Project Manager are as follows
- Respond to client inquiries with information about services provided in areas of current turnaround times, pricing, sampling information and related matters
- Track the progress of samples through the laboratories and communicates any delays or problems to appropriate personnel/clients
- Technically review orders and contracts for work received
- Ensure compliance with regulatory standards and national program requirements including ISO/IEC 17025, NELAP, TNI, DoD, and DOE.

2.2.4 Health and Safety Manager

The Health and Safety Manager reports directly to the Laboratory Manager and oversees the daily implementation of the laboratory's health and safety program. The program includes an integrated chemical hygiene plan, safety orientation and training, radiation safety plans and training, sample disposal and shipment, and safety checks and audits.

- The duties and responsibilities of the Health and Safety Manager are as follows.
- Administer chemical hygiene, safety, fire extinguisher, etc. training.
- Management of sample disposal in conformance with the waste disposal policy.

- Packaging and shipment of samples, or designation thereof, following DOT regulations.
- Maintain Material Safety Data Sheet (MSDS) documentation.
- Direct spill response.
- Direct safety checks and audits.
- Ensure compliance with regulatory standards and national program requirements including ISO/IEC 17025:2005, NELAP, TNI, DoD, and DOE.

2.2.5 Technical Director

The Technical Director reports directly to the Laboratory Manager and provides technical direction or advice for the laboratory operations and/or special programs, projects, or activities.

- The duties and responsibilities of the Technical Director are as follows.
- Perform technical analysis for specific projects.
- Make recommendations for research and development.
- Certify that personnel with appropriate education and/or technical background perform testing
- Design systems, procedures, and documentation as necessary.
- Assist chemistry supervisors and technicians in technical interpretation of program requirements.
- Monitor the validity of analyses performed and data generated to assure reliable data
- Consult with clients, make recommendations regarding analytical schemes.
- Ensure compliance with regulatory standards and national program requirements including ISO/IEC 17025:2005, NELAP, TNI, DoD, and DOE.

2.2.6 IT Manager (i.e. LIMS Manager)

The IT Manager works under the direction of the Laboratory Manager, and is directly responsible for the maintenance, management, and administration of the LIMS system. In addition to LIMS, the IT Manager also oversees systems, network, and database administration.

- The duties and responsibilities of the IT Manager are as follows.
- Install new software releases and system upgrades
- Configure and maintain organization's network
- Perform systems backups on internal and external web network servers
- Provide help desk support
- Monitor LIMS system configuration to ensure data integrity

2.2.7 Data Review Department Staff

The Data Review Department has been structured to handle the specific project requirements of our clients. The Department is responsible for producing quality control (QC) reports, for ensuring proper assembly of data packages and production of electronic data deliverables (EDDs) that meet the requests of the clients. Data Review personnel, in concert with the QA Manager, will assess the requirements of the various programs and client specific requirements, then interact with the appropriate laboratory personnel to ensure compliance with the client's statement of work. These efforts improve the accuracy and efficiency with which QC reports and data packages are prepared and forwarded to the client. Data deliverables are those items associated with the analyses of samples that are provided to the client.

Data Review staff responsibilities include the following.

- Assuring that analytical data have been correctly entered in the final report.

- Assuring that data are not released without reviews.
- Assuring that all data are released to the correct contact person.
- Producing QC reports.
- Assembling Data Packages.
- Ensuring that submitted EDD are complete, verified and in appropriate format.

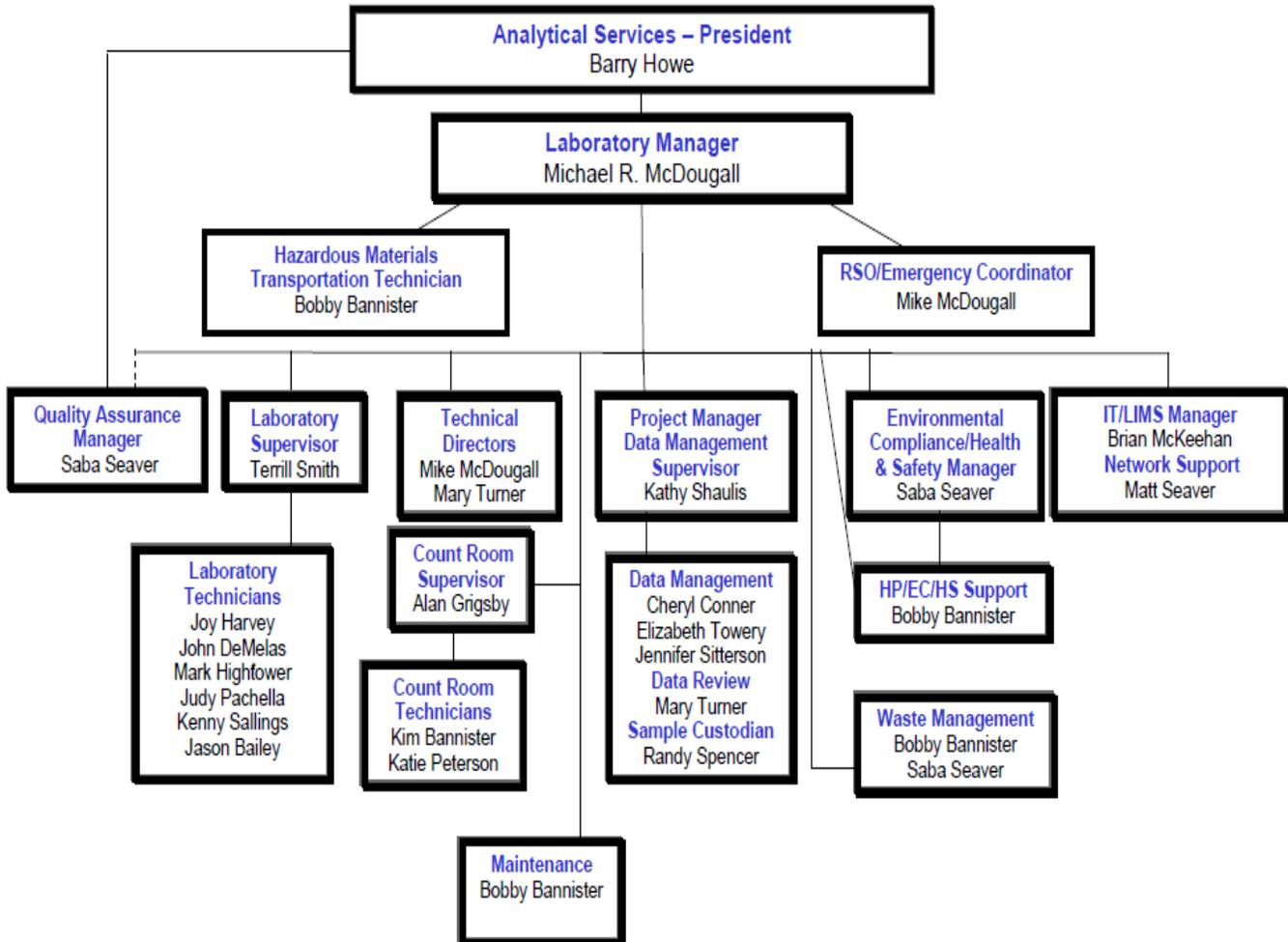
2.3 ASSESSMENT

- 2.3.1 The Laboratory Manager will perform routine and continuous assessment of the management system to identify, correct, and prevent management problems that hinder achievement of the organization's objective. The assessment will focus on broad categories of management issues to determine the effectiveness of the integrated management system.
- 2.3.2 Laboratory Manager's assessments will not be conducted to verify conformance to regulations, product standards, or established procedures, but will evaluate customer and employee perceptions relative to the following key issues.
- Mission and strategic objectives of the organization.
 - Employees' role in the organization.
 - Customers' expectations and degree to which expectations are being met.
 - Opportunities for improving quality and cost effectiveness.
 - Recognizing and enhancing human resource capabilities.
- 2.3.3 Results of the Laboratory Manager's management assessment and recommendations will be documented annually. Decisions and related actions resulting from the recommendations will be properly followed up and evaluated for their effectiveness. Moreover, the opportunity for customer feedback is afforded by means of an on-line customer feedback/satisfaction survey on the laboratory website.

2.4 ORGANIZATION CHARTS

- 2.4.1 The Oak Ridge Laboratory Organization is illustrated in Figure 2.1

Figure 2.1
Eberline Analytical Laboratory Organization





3.0 QUALITY ASSURANCE OBJECTIVES

3.1 OBJECTIVES

The Eberline Analytical Laboratory Q.A. Program is organized to meet the following objectives.

- 3.1.1 To ensure performance of those actions that provide confidence that quality is achieved.
- 3.1.2 To provide an effective control for the verification of characteristics of all systems, services, and processes that produce data of the required quality.
- 3.1.3 To ensure that systems, services, processes, and deliverables meet the rigid quality and reliability standards of the Oak Ridge Laboratory. Also, to ensure that individual client criteria pursuant to these standards are met.
- 3.1.4 To provide a continuing monitoring service for review of operating procedures, and for overall effectiveness and evaluation of the Q.A. Program. Also, to provide observations and recommendations for improvement in all areas of laboratory operations where quality may be affected.
- 3.1.5 To ensure the program provides valid records of the control measures applied to all factors bearing on the result of investigations.
- 3.1.6 To ensure the assessment of results provides feedback to improve the process.
- 3.1.7 To foster a culture of commitment to achieve a rising standard of quality that demands that the methods utilized to achieve the quality systems, services, processes, and deliverables be continuously monitored and improved.

3.2 QUALITY IMPROVEMENT

Operational processes will be reviewed continually by management and employees to detect and prevent problems and to ensure quality improvement. Any item or process that does not meet established requirements will be identified, controlled, and corrected. The cause of problems will be identified with corrections made to prevent recurrence. Item reliability, process implementation, and quality-related information will be reviewed and the data analyzed to identify items and processes needing improvement.

3.3 RESPONSIBILITIES

Employees are an integral part of the organization and are responsible to be aware of their work environment, to review operational processes and materials utilized, to identify any problems, and to make suggestions and recommendations for improvement. Employees are empowered to make and/or recommend corrections to improve operations and to prevent recurrence of the problems. Employees are also empowered, through their supervisor, to stop work where detrimental ethical, contractual, quality, safety, or health conditions exist. Management will immediately be made aware of any situations requiring work stoppage.

All employees are responsible for supporting the Program in principle and in detail and shall retain responsibility for the quality of their work.

Management is responsible to be actively involved in the quality improvement process to ensure proper focus is maintained and for resolution of difficult issues. Management will maintain a "no fault" attitude to encourage employees to identify problems that compromise safety and reliability. Management will consider all recommendations for quality improvement and will recognize

employee contributions.

3.4 CORRECTIONS

Items and processes that do not meet established requirements must be identified, documented, analyzed, and resolved. Corrective actions will be implemented and followed up to ensure effectiveness.

No laboratory analytical data will be revised or corrected after reporting to clients without full documentation of the process. The documentation must show: a) what necessitated the change; b) details of the change in terms of re-run records or recalculation; c) approval process for the change; d) formal client notification.

4.0 PERSONNEL QUALIFICATION AND TRAINING

4.1 QUALIFIED PERSONNEL

- 4.1.1 The Oak Ridge Laboratory personnel who perform activities that affect quality will have education, experience and training to ensure that suitable proficiency is achieved and maintained. A job description, identifying position qualification and duty requirements, will be included in each individual's training records.
- 4.1.2 All personnel will have training outlining their ethical and legal responsibilities, including the potential punishment and penalties for improper, unethical, or illegal actions.
- 4.1.3 Personnel performing technical functions or processes will have known and documented related work experience and minimum qualifications of education.

4.2 RESPONSIBILITY

- 4.2.1 Supervisors are responsible for initial evaluation of capabilities and qualifications of assigned personnel and will assign those personnel to perform functions based on the individual's qualifications and abilities.
- 4.2.2 Supervisors and managers are responsible for the day-to-day monitoring of assigned personnel for evidence of unethical, improper, or illegal activities.
- 4.2.3 Appropriate training is the responsibility of the supervisors with support from management. Training will address specific needs and will vary according to each job's requirements and previous experience of the employee, and will ensure:
 - 4.2.3.1 Understanding of the fundamentals of the work and its context,
 - 4.2.3.2 Understanding of the processes and tools being used, the extent and sources of variability in those processes and tools, and the degree to which control over the variability is maintained,
 - 4.2.3.3 Emphasis on correct performance of the work, understanding why quality requirements exist, and potential consequences of improper work, and
 - 4.2.3.4 Emphasis on "doing it right the first time." A particular emphasis is placed on employee safety.
- 4.2.4 Management will provide ALL employees the resources, tools, equipment, scheduling, and structured training to ensure personnel can perform their duties effectively. New employees will receive detailed information concerning the general corporate policies and the specific laboratory safety practices, and security policies. Training shall be conducted on an individual basis to achieve and maintain suitable proficiencies. The training will include, but will not be limited to:
 - Ethical and Legal responsibilities
 - Health and Safety
 - Radiation Protection
 - Waste Management
 - Quality Assurance
 - Laboratory Procedures
 - LIMS Operation



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- 4.2.5 Access to all laboratory documents and procedures will be available at all times to all employees who will be expected to familiarize themselves with these documents.
- 4.2.6 Milestone achievements or unique training will be noted by the supervisors via entry in the training records. Available certificates of training, education, or awards will also be maintained with the individual's training records.
- 4.2.7 Supervisors will monitor individual work habits to ensure proficiency is maintained, to note progressive improvement, and to identify any needed supportive training. Additional training requirements will be developed by the individual's supervisor.
- 4.2.8 As needed, employees will be informed of the requirements of special clients/programs necessary to achieve their duties and responsibilities. Familiarization will be made a matter of record.
- 4.2.9 All personnel training records will be maintained in the QA office. The details for maintenance of training requirements and records are outlined in the Oak Ridge Laboratory Management Procedure, MP-042 "Personnel Training."

5.0 INSTRUCTIONS AND PROCEDURES

5.1 POLICY

Eberline Analytical Laboratory policy uses written and approved procedures for routine activities and for analytical and operational processes. Applicable Laboratory procedures are available to all personnel. The most current revision of the appropriate procedure will be maintained and documented on the laboratory computer server. Departures from routine procedures due to non-standard situations or specific requests from clients will be approved by management and fully documented.

In addition to analytical procedures (AP) the laboratory maintains Management Procedures (MP) that describe the policy and approach for performing quality functions. Separate procedures for Health and Safety, Radiation Protection and Waste Management, are also maintained.

5.1.1 ANALYTICAL PROCEDURES

Analytical procedures are descriptions of particular protocols for testing or operations. Analytical procedures will be developed based on published reference procedures for each test or process, and authorized for use by the Laboratory Manager.

5.1.2 Qualification requirements for personnel performing operations and criteria used to determine the proficiency of the operator will be documented.

5.1.3 Each technical procedure will include a list of Personal Protective Equipment (PPE) required for the operation being performed. Training for the identification, operation, use, limitations, and disposal of the PPE will be conducted.

5.1.4 Each technical procedure will identify any chemicals/reagents required for completion of the operation. Material Safety Data Sheets (MSDSs) for those chemicals/reagents will be readily available, and training applicable to the MSDSs will be conducted.

5.1.5 Training will be conducted to the procedures used for processing wastes generated within the appropriate chemistry laboratory.

5.2 PROCEDURE MANUALS

Management Procedures describe protocol for non-analytical processes. Additionally, Management Procedures consist of general guidance applied to both analytical and non-analytical aspects of laboratory operations. This includes, but is not limited to, topics such as data integrity, computer security, and personnel training.

5.3 FORMAT AND DISTRIBUTION

5.3.1 Procedures will comply with the format prescribed in the laboratory management procedure (MP-004, Preparation and Modification of Procedures and Guidance Documents) and will be approved by the QA Manager and the Laboratory Manager.

5.3.2 Employee access to the most current revision of procedures and manuals will be through the Laboratory computer server. Any distribution of controlled copies of any Laboratory procedure will be in accordance with the laboratory's document control protocol.

5.3.3 The Laboratory Manager is responsible for the maintenance and security of the original electronic version of all laboratory procedures and manuals and for ensuring that the most current revision of the procedures and manuals are promptly posted and accessible to all employees.

5.4 REVIEW

Laboratory technical procedure, manuals and Quality Assurance Plan will be reviewed annually

and whenever program or procedural changes occur with updates as appropriate. Such reviews will be documented. All effected laboratory personnel and document holders will be made aware of any changes. Training of laboratory personnel on new changes will be conducted as necessary.

5.5 REVISION

- 5.5.1 The appropriate supervisor, or designated representative, is responsible for revisions or changes to the applicable procedure manuals.
- 5.5.2 Revisions are reviewed and approved by the organization(s) and personnel responsible for the original document. When possible, revisions or changes will be accomplished on a page replacement basis.
- 5.5.3 The Q.A. Manager will be advised of any changes in procedures required to satisfy specifications of the client.
- 5.5.4 The final revision shall be reviewed, approved, and authorized by the Laboratory Manager and Q.A. Manager. The electronic copy is placed on the laboratory server for access.
- 5.5.5 The Q.A. Manager will be responsible for the electronic retention of past revised and superseded procedures. The Q.A. Manager will also be responsible for maintaining the server location where current revisions are stored for employee reference.



6.0 PROCUREMENT DOCUMENT CONTROL

6.1 PURCHASING

Procurement of material, components, supplies, reagents, equipment, and services necessary to carry on the business interests of Eberline Analytical Laboratory is initiated by purchase requisition and controlled by the use of an authorized purchase order number. To the extent necessary, purchase orders will require suppliers to have a Q.A. program consistent with the requirements of this document. Detailed information on procurement is outlined in MP-033 "Procurement of Quality Related Items/Services".

6.2 PURCHASE REQUISITION REVIEW

Purchase requisitions or change orders are reviewed by purchasing department personnel to ensure conformance to the procurement requirements. As applicable, quality related requisitions are reviewed by Q.A. personnel prior to being processed. Change orders undergo the same review process.

6.3 CERTIFICATION/CERTIFICATE OF CONFORMANCE

All materials and processes requiring certification and certificates of conformance are identified on the face of the purchase requisition. Adequate information is provided to ensure supplier compliance to the required specifications. The Q.A. Manager is responsible for the retention, filing, and recall of material certification or certificates of conformance.

6.4 SUBCONTRACTS

When subcontracting analytical work, Eberline Analytical Laboratory Management will ensure that the subcontractor can meet all the technical specification, maintain the appropriate certification (NELAP, DOE, DoD, State) and that the prospective subcontractor has a QA program consistent with the requirements of this document. The Oak Ridge Management will secure the client's written approval for subcontracting their analytical work prior to commencement of the subcontract. Documentation of the written approval will be kept on file and available for regulatory review upon request. The Q.A. Manager is responsible for evaluation and acceptance of the subcontractor's Q.A. program.

6.5 VENDORS

6.5.1 For procurement of quality-related items or services, the Q.A. Manager is responsible for vendor evaluation and approval. Analytical service vendor evaluation and qualification will be through accreditation as a secondary standard calibration laboratory (NVLAP, NIST); an audit by Oak Ridge Laboratory personnel or an acceptable audit agency; or facility inspection, test reports, or receipt inspections, when the quality of the materials or service can be verified by these methods. Documentary evidence that products and services conform to procurement requirements will be provided and retained. A list of approved vendors will be maintained by the Procurement Office.

6.5.2 The effectiveness of the control of quality by contractors and subcontractors will be assessed at intervals consistent with the importance, complexity, and quantity of the product or services.

6.5.3 The purchasing department is responsible for maintaining a record of quality related materials received from vendors including any reports for non-conforming material.

6.6 QUALITY RELATED SERVICES

Q.A. personnel will review the purchase requisitions for quality related services. Those services that are determined to be quality related will include, as applicable, a statement, or wording, in the body of the purchase order or by attachment identifying the applicable requirement.

7.0 MATERIAL RECEIPT AND CONTROL

7.1 POLICY

Only material components, supplies, reagents or standards with acceptable quality characteristics and from qualified vendors will be allowed into the laboratory.

7.2 RESPONSIBILITY

Receipt and initial verification of all materials and equipment received by the Oak Ridge Laboratory, either purchased or contract (client) supplied, is the responsibility of the receiving or designated individual. Technical verification for materials and equipment will be performed by the requisitioner or Q.A. Manager, whichever is applicable. Quality related purchase order items will be receipt inspected by Q.A. personnel.

7.3 MATERIAL CONTROL

Purchased material is controlled by the Laboratory Supervisor or designated individual.

7.3.1 The receiving and stock control clerk, or designated individual, is responsible for the expedient and correct routing of all initially accepted received materials to stock, or to the requisitioner.

7.3.2 Purchasing personnel are responsible for maintaining a record of materials received from vendors, including, any non-conforming material.

7.4 NON-CONFORMING MATERIAL

When received material, affecting quality, has been determined to be non-conforming, the requisitioner will work with the purchasing agent and will be responsible for proper processing.

7.5 RECORDS

Records of receipt of services and supplies that affect the quality of laboratory operation will be identified with date of receipt, expiration date, source, lot or serial identifier, and calibration or certification records as appropriate.

8.0 MATERIAL STORAGE AND CONTROL

8.1 POLICY

All materials and supplies in storage will have the necessary protection to preclude deterioration, corrosion, or damage during storage life and will carry identification sufficiently clear to ensure that only those materials specified by process instructions will be withdrawn from material storage and issued for processing.

Only analytical grade chemicals and reagents, bearing such grade identification will be utilized by the Laboratory. Each container will be assigned a unique identification number upon receipt. The date of receipt will be posted on each container. The use and the retention (shelf life) of such chemical will be monitored by the Laboratory Supervisor.

All standards used by the Laboratory must be NIST certified. Each standard must be accompanied with a certificate showing the name, composition, concentration, reference number and NIST Certification. The use and distribution of these standards will be monitored by the LIMS. The certificate and certification documents of standards will be controlled by the QA department.

8.2 RESPONSIBILITY

Only authorized personnel will have the responsibility for control and issue of materials or supplies. Materials and supplies will be stored to allow for ready identification. Care will be taken to preclude mixing of rejected material and supplies with those that are qualified for issue.

9.0 CONTROL OF PROCESS

9.1 STANDARD PRACTICES

Standard practices applicable to services provided by the Oak Ridge Laboratory are contained in documented procedures and this Q.A. Program Manual. Every effort is made to implement and fulfill the requirements of Federal and local laws, rules, guidance(s), and directives as may be applicable to the operational practices within the Oak Ridge Laboratory. These may include but are not limited to:

- 9.1.1 Federal and State rules and regulations.
- 9.1.2 Consensus standards related to the services performed (e.g., American National Standards Institute).
- 9.1.3 Regulatory Guides published by the Nuclear Regulatory Commission, Department of Energy, the Environmental Protection Agency, and the Department of Defense.
- 9.1.4 Specific contractual agreements with clients.
- 9.1.5 Where conflicts may occur among any of the above items, the client will be notified and requested to specify the practice to be followed.

9.2 DOCUMENTED PROCEDURES

Routine analytical operating procedures are documented. Each laboratory procedure includes quality control criteria that are applicable to that process. The laboratory management will develop, promulgate, and implement procedures that document the operations performed in the laboratory. Additionally, the following general procedures or documents, as applicable, will be developed:

- 9.2.1 Quality Assurance Procedures
- 9.2.2 Radiation Safety Manual and Procedures
- 9.2.3 Sample Control Procedures
- 9.2.4 Purchasing Policies and Procedures
- 9.2.5 Data Review Procedures
- 9.2.6 Environmental Compliance Procedures
- 9.2.7 Safety Procedures
- 9.2.8 Chemical Hygiene Plan
- 9.2.9 Hazard Communications Program
- 9.2.10 LIMS Procedures
- 9.2.11 Management Procedures
- 9.2.12 Analytical Procedures

9.3 RESPONSIBILITY

The Laboratory Manager, or designated representative, determines which instructions or procedures require quantitative or qualitative acceptance criteria and specify the appropriate criteria on special contracts or projects.

9.4 WORK POLICY

All work to be performed by the Oak Ridge Laboratory on client samples is authorized by the client and controlled through a Laboratory Information Management System (LIMS) work order document which incorporates the client's requirements. (Or by some other document deemed necessary by the Laboratory Manager or Project Manager as directed by the customer)

- 9.4.1 The work order specifies those analyses necessary to assure compliance with contractual obligations.
- 9.4.2 The Project Manager or designated personnel –under the authority of the Laboratory Manager, are responsible for notifying the Q.A. Manager and performing laboratory departments, through the appropriate supervisor, of all contract requirements including reporting format and quality control criteria. This may be done by reference to other documents (e.g., Purchase Order, statement of work, technical specifications, etc.) that delineates the contract requirements.
- 9.4.3 The Project Manager or designee –under the authority of the Laboratory Manager-, will ensure planning, scheduling, and resources are considered when contracting for or accepting work.
- 9.4.4 When subcontracting analytical services, the Project Manager or designated individual under the authority of the Laboratory manager-, will assure that:
- The client is notified in writing of the intention to subcontract any portion of the testing to another party.
 - If the work is covered under NELAP, the work will be placed with a laboratory accredited under NELAP for the tests to be performed.
 - Records, demonstrating that the above requirements have been met, are retained in the project folder.

10.0 PREVENTIVE MAINTENANCE

10.1 POLICY

Preventive maintenance is performed as required on instrumentation and equipment to prevent down time and to ensure reliable performance. The laboratories maintain instrument redundancy that precludes the requirement for a repair and maintenance capability for instrumentation. Maintenance and/or repair of equipment are performed by the equipment manufacturer or authorized representative under contract or purchase order.

10.2 MAINTENANCE

Preventive maintenance procedures will be developed for use where instructions are not provided in the manufacturer supplied operator's manual. As applicable, each department will maintain a major equipment and measurement standards list. A record of instrument maintenance, calibration, and repair, if applicable, will also be maintained. The supervisors and operating personnel are responsible for complying with the department maintenance schedule.

10.3 SPARE PARTS

Supervisors will ensure that an adequate inventory of spare parts and consumables is requisitioned and maintained for instrumentation in their area in order to prevent down time or compromise operating conditions.

11.0 CONTROL OF MEASUREMENT AND TEST EQUIPMENT**11.1 MEASUREMENT AND TEST EQUIPMENT CALIBRATION POLICY**

This section establishes the controls and calibration requirements for all analytical and nuclear measurement equipment. An equipment list will be maintained indicating calibration status.

- 11.1.1 All equipment whose operation and function directly affect the quality of service will be inspected/calibrated at established intervals. As applicable, equipment will be suitably identified to reflect calibration status. If an instrument is determined to be out-of-tolerance, it will be segregated, or otherwise clearly identified as inoperable. Records of each calibration will be kept in appropriate logbooks or files. Instruments whose calibrations are performed during method operations are calibrated and controlled in accordance with the method requirements. Run logs will be maintained for this category of instrumentation.
- 11.1.2 The equipment used to determine the quality characteristics and accuracy of instruments will be checked and verified either internally (dependent upon capability), or by qualified calibration services.
- 11.1.3 Frequency of inspection/calibration will be based on use of the equipment or instrument, environmental conditions in which it is used, its inherent stability, manufacturer's recommendation, and the wear or deterioration resulting from its use.
- 11.1.4 Certified standards are used for all primary calibrations. National Institute of Standards and Technology (NIST) or NIST traceable, Environmental Protection Agency (EPA), New Brunswick Laboratory (NBL), or Department of Energy (DOE) standards are used, when available, for the primary calibrations or verification of primary calibrations.
- 11.1.5 All preparations of standard solutions are recorded in a standards preparation logbook or file. Identities of standards are such that a secondary standard or dilution can be traced, through subsequent actions, back to the initial certification. Records of these reference standards are organized in a secure location in the QA office.
- 11.1.6 Quality control check standards are used to record instrument sensitivity and linearity and to verify proper response. Methods and calibration entries are dated, initialed, and documented by the analyst.
- 11.1.7 Measuring and test equipment are tagged as to calibration or operating status for periodic processes performed on a scheduled interval of greater than one month. For processes performed more frequently, separate documentation will be available for verification of operational status. Instruments that are too small to be tagged or are subject to a wide variety of calibrations shall have separate documentation of status available.

11.2 RESPONSIBILITY

Testing and/or calibration of equipment and instruments will be performed under the direction of the supervisor, the Lab Manager, or the QA Manager and performed under suitable environmental conditions.

11.3 PROCEDURES

All tests and calibrations will be performed in accordance with written procedures that contain provisions for ensuring that all prerequisites for the given test have been met, including appropriate equipment to be used.



11.4 CERTIFICATION AND CERTIFICATES OF CALIBRATION

11.4.1 To the extent possible, calibration will be traceable to NIST. Records of traceability will be maintained along with records of routine calibrations of each instrument or measurement system. Where no NIST traceability exists, the basis used for calibration will be documented.

11.4.2 Equipment records will be maintained to indicate past and current status, and to provide reproducibility and traceability of results.

11.5 RADIOACTIVE SOURCE CALIBRATION

Radioactive sources used as calibration standards will be periodically calibrated and controlled. Current calibration certificates will be kept on file.

11.6 CALIBRATION RECORDS

Supervisors will ensure that calibration data for instruments and radioactive sources is recorded in the instrument logbook, on data work sheets, on computer files and/or control charts. When required, new calibration charts will be prepared when there is measurable change in calibration effect on instruments that have been calibrated. If an instrument is determined to be out of tolerance, it will be segregated or otherwise clearly tagged as inoperable and not used until repaired.

11.7 REPORTS GENERATED FROM USE OF A DEFICIENT INSTRUMENT

If a major deficiency in an instrument or device is detected during periodic calibration procedures, the technician will immediately notify the supervisor, the operations manager, and the Q.A. Manager. A conference will immediately be scheduled to investigate and decide what corrective action is to be taken on past data and reports resulting from the use of the deficient instrument or device. A record of corrective actions will be maintained.

11.8 PERFORMANCE CHECKS OF RADIATION SCREENING INSTRUMENTS

Performance checks will be made to ensure the continuing capability of radiation screening instruments. Procedures will include efficiency checks and background determinations. The procedure and frequency of each check is optimized for each detector system to provide assurance of the detector's performance. Documentation of the checks and the results are kept for all operations.

12.0 DATA REDUCTION, VERIFICATION, AND REPORTING**12.1 USE OF COMPUTER HARDWARE AND SOFTWARE**

Computer programs used in the production or support of client data are either purchased, or developed using approved development methodology. Such programs are independently validated, verified, and documented. Changes are controlled to assess the potential impact of the change on the performance of the program.

12.2 DATA REDUCTION AND VERIFICATION

Sample receipt and distribution through the laboratory is documented by the Sample Custodian. Sample handling, subsampling, and preparation for counting measurement are documented by the laboratory technicians.

12.2.1 The successful completion of an analysis is monitored by the Counting Room staff. The Laboratory Manager, or designated individual, performs the final review and approves the data.

12.2.2 Calculation methods, transcriptions, and data flow, plus times and locations of the various tiers of review are detailed in the specific procedure.

12.3 REPORTING

The Project Manager or designated individual is responsible for providing the client with the required analytical results. Reports to clients will be reviewed for accuracy and completeness and, where required, analytical methods and minimum/method detection limits (MDL) will be reported. Laboratory reports of analyses will be signed by an authorized individual who, along with the person who signed the data sheets, can attest to the fact that the data was generated in accordance with established procedures.

13.0 DOCUMENT CONTROL**13.1 POLICY**

The primary formal communication methods within the Oak Ridge Laboratory departments are documents that inform or direct activities affecting purchasing, sample analyses and reporting, instrument calibration and/or testing, radiation controls, proper handling of wastes, radiation safety, and Health and Safety. These documents are controlled by the Q.A. Program Manual, Operating Procedure Manuals, other documented procedures, or by interoffice memoranda. Drawings and specifications are not controlled as separate documents but are included in controlled procedures where applicable. The QA Office controls logbooks used to document the analysis of samples (see MP-023, Documentation of Analytical Laboratory Notebooks).

13.2 RESPONSIBILITY

- 13.2.1 The Q.A. Manager is primarily responsible for maintaining files of all controlled documents and will:
- Review the Quality Assurance Program Manual and provide recommendations for updating.
 - Ensure that all holders of controlled documents receive updates to the documents.
 - Maintain files of controlled document distribution indicating document title, number, revision number, assigned date, and the name of the individual to whom the document is assigned.
 - Forward revisions of controlled documents to assigned individuals. An acknowledgment form will accompany each document revision for verification of receipt and to provide disposition instructions for the superseded pages
 - Maintain a Master List of current procedures which includes procedure number, procedure title, current revision number, and date on which the current revision became effective. The list will be continually updated to reflect all new revisions or new procedures issued. An electronic copy of this list shall be available for employee reference at all times.
- 13.2.2 Uncontrolled copies of controlled documents will be distributed only if marked "Uncontrolled."
- 13.2.3 Superseded and/or obsolete documents are isolated from use or destroyed. Upon training to new revisions, employees sign to verify the destruction of all uncontrolled copies of obsolete revisions.
- 13.2.4 Each employee is responsible for requesting revisions or changes to operating procedures for their area of responsibility.
- 13.2.5 The Q.A. Manager will be advised of any changes in procedures required to satisfy client specific requirements.
- 13.2.6 Client information and records such as contract requirements, project descriptions, analytical data and results submitted to the client; and all laboratory records associated with such submittal will be maintained by the laboratory for a minimum of 5 (Five) years. Clients will be contacted and queried for disposition instructions for their related documentation.
- 13.2.7 If or when the laboratory may transfer ownership, is decommissioned, or goes out of business, ALL clients will be notified and asked to provide specific direction regarding the transfer or disposition of documents and records related to their project(s).

14.0 INTERNAL QUALITY CONTROL

14.1 LABORATORY ANALYTICAL SERVICES

Precautions are taken in the chemistry laboratories to avoid cross-contamination of samples and to ensure the reporting of accurate results. Quality control samples are analyzed along with routine samples to indicate when results may be in error due to improper operation or calibration of equipment, inadequate training of personnel, a deficiency in the procedure, or cross-contamination from other samples.

14.1.1 Laboratory Precision - Laboratory management personnel are responsible to ensure that analytical results are reproduced internally within acceptable limits.

14.1.2 Precision and Accuracy - Replicate standards and/or samples are used to estimate the precision of each analytical test procedure for a known matrix. Data control limits are established to satisfy the requirements of specific measurements based on prior knowledge of the measurement system and method validation studies. Certified standards and/or spiked samples are used to estimate chemical recovery and accuracy for these procedures for known matrices.

14.1.3 Calibration and Performance Checks of Nuclear Measurement Systems - Reference standards are used for calibrating nuclear measurement systems. In addition to calibration of all instrumentation, routine monitoring is performed to ensure the continuing integrity of the instrument performance. All quality control samples utilized to verify acceptability of instrument calibrations shall be prepared from a source independent of reference standards used for calibrating. This per batch laboratory control sample continually confirms the integrity of the calibration, thus fulfilling the requirements of initial calibration verification (ICV). Additional monitoring parameters performed include efficiency checks, background determinations, and energy calibrations. The procedure and frequency of each check is optimized for each detector system to provide assurance of the detector's performance. Documentation of the checks and the results are kept for all systems. The supervisor is responsible for these calibration and performance checks.

14.1.4 Duplicate Analysis - Duplicate aliquots of randomly selected samples will be processed on a routine basis. The analyst will always process samples in accordance with approved operating procedures. The evaluation of the duplicate analysis will be based on examination of the difference between the duplicates. A statistical analysis of the data may be performed when a cursory evaluation indicates problems with the results. If the two results agree within the three standard deviation limits, a more detailed evaluation will generally not be necessary. Results of duplicate analyses will be included in the monthly Q.C./Q.A. report.

14.1.5 Detection and Elimination of Bias - Where possible, calibration will be with standards that are traceable to NIST. However, traceability to NIST is not always possible and reliance on other suppliers may be necessary (e.g., International Atomic Energy Agency, U.S. Department of Energy, U.S. Environmental Protection Agency, or commercial supplier such as Analytix, Amersham Biosciences, AEA Technology, etc.). Standards in the appropriate geometry or form will be used to determine efficiency of instruments on a periodic basis. In the calibration process, the ideal standard will be a known quantity of the radionuclide to be measured, prepared in exactly the same geometry as the samples and counted under the same conditions. In this way, factors such as self-absorption, backscatter, sample geometry, and detector efficiency will be accounted for empirically.

- 14.1.6 Spiked Samples - A known quantity of calibrated radioactive standard solution will be added to an aliquot of the sample or to a "blank" sample for replicate analysis. When the entire analytical system is operating properly, the laboratory record will demonstrate the accuracy and precision of the data. Divergent data from the spiked sample will point out problem areas. If the data is consistently higher or lower than the known value, bias in the analytical procedure is indicated. This may require a search for personnel errors, re-standardization of carriers or tracers, and/or recalibration of counting equipment.
- 14.1.7 Background Determination - The type of equipment and environmental factors contribute to variation in the counting rate of instrument background. The background of each system instrument will be determined and recorded with sufficient frequency to provide a firm statistical basis for that measurement and to ensure response to potential instrument problems or other artifacts such as controlled contamination.
- 14.1.8 These background determinations will include use of the items that most closely duplicate the analytical configuration in type, geometry, and with any associated fixtures. In some cases, true blanks are not available, but the closest practicable analog is used.
- 14.1.9 Some systems are sufficiently stable to require no change in backgrounds used for data reduction (e.g., uranium daughter gamma-rays found in gamma spectra due to adjacent building materials and earth). In this case, backgrounds will be compared to historical data to insure sufficient stability. Other systems experience enough variability to require computed backgrounds based upon running averages.
- 14.1.10 Background data will be recorded in the logbook or computer file for that specific instrument along with calibration data and instrument maintenance records.
- 14.1.11 Blanks - Blank samples are routinely analyzed to verify control of contamination and process. Results of processed blanks will be included in the monthly Q.C./Q.A. report.
- 14.1.12 Collaborative Testing - The Oak Ridge Laboratory participates in collaborative testing or inter-laboratory comparison programs. Natural or synthetic samples prepared to contain known concentrations of certain radionuclides are sent to participating laboratories by an independent referee group such as the DOE Radiological and Environmental Sciences Laboratory DOE, Idaho Falls, Idaho (MAPEP); by a NELAC approved provider such as the Environmental Resources Agency (ERA), Environmental Measurements Laboratory (EML), or by customer(s).

These programs enable Oak Ridge Laboratory personnel to document the precision and accuracy of radioactivity measurements, identify instrumental and procedural problems, and compare performance with other laboratories.

14.2 QUALITY CONTROL AND DATA REPORTS

14.2.1 Quality Control Reports

Quality control results will be summarized, and include with every sample/group of samples.

14.2.2 Data Reports

Routine performance requires documentation of all pertinent information with the basic documents dated and initialed or signed. Required documentation will be the initial work order, Chain-of-Custody (CoC), or document that records all pertinent information such as the identity of the sample and analyses to be performed. The data report will include technical analysis notes, logbooks, work sheets all raw data and other information used in performing the analysis. The report of analysis will be the final report of the data to the client and is issued in accordance with the laboratory's procedure for review and processing, as well as any client specific requirements.

14.3 DATA VERIFICATION

Routine performance requires inclusion of all pertinent information with basic documents dated and initialed or signed. The work order has recorded such information as the identity of the samples and analyses to be performed. All raw data and other information used in performing the analyses are documented.

14.3.1 Electronic Deliverables Verification - Project managers, or designated individuals, are responsible for ensuring that electronic deliverables are complete and accurate.

14.4 Sample Custody

Samples are assigned a unique laboratory identification number, marked on a label that is applied directly to the container and which identifies the work order and laboratory fraction. Sample control personnel are designated sample custodians for strict (legally defensible) CoC samples. Locked buildings, refrigerators, freezers, and cabinets are available for CoC samples. Sample custody forms or technician analysis notes are used for tracking all samples through the analytical process. Details for radiological survey of samples, sample security, sample disposal, etc. are outlined in approved Sample Control Procedures. Sample chemistry and nuclear counting requirements are assigned by the Laboratory Manager, or designated individuals.

15.0 AUDITS**15.1 POLICY**

Eberline Analytical Laboratory has established a comprehensive system of planned and documented audits to verify compliance with all aspects of the Q.A. Program. An audit is defined as a documented activity performed in accordance with written procedures or checklists to verify, by examination and evaluation of objective evidence, that applicable elements of the Q.A. Program have been developed and effectively implemented in accordance with specific requirements. Audits will be performed by persons not having direct responsibility for those areas being audited.

15.1.1 Customer Access to the Eberline Analytical Laboratory Facilities and Personnel - The client is frequently responsible for auditing the Oak Ridge Laboratory's performance relative to contractual requirements. The exact nature of this responsibility is relative to the nature of the regulatory or licensing requirements, the significance of the services, and the technical expertise available or inherent within the client's organization. The need for, and frequency of, client audits is dependent upon the above factors. A client may authorize an independent agency to perform an audit on its behalf. When possible, the facilities, equipment, and records (proprietary information excluded) of Eberline Analytical Laboratory will be made available for client inspection along with the necessary personnel to permit verification of quality characteristics.

15.1.2 The Q.A. Manager will coordinate and participate in audits conducted by the client or the client's representative.

15.1.3 Internal Audits - The Q.A. Manager will audit the laboratory operations to verify compliance with established procedures and requirements set forth in the Q.A. Program Manual. Use of a checklist will insure items in compliance are noted as well as any requirements for improvement.

15.1.4 External Audits - External audits of organizations providing services to the Analytical Services Group are scheduled at a frequency commensurate with the status and importance of the activity.

15.2 RESPONSIBILITY

Audits will be directed by the Q.A. Manager with assistance from designated personnel.

15.2.1 The Q.A. Manager will be responsible for an independent quality assurance audit of each department.

15.2.2 The Q.A. Manager will be responsible for assuring that audits are performed by knowledgeable professionals.

15.3 DOCUMENTATION

Audit results will be documented by the Q.A. Manager.

15.3.1 The Laboratory Manager shall be provided a copy of the audit report.

15.3.2 The QA Manager will determine if there are any corrective actions required and the individual responsible for implementing the corrective action

15.4 DEFICIENT AREAS

15.4.1 The responsible Manager will ensure correction of the identified deficiencies.

15.4.2 The Q.A. Manager will verify that action is taken to correct any deficiency and will take follow-up action to ensure that corrections have been completed.

15.4.3 The Q.A. Manager will ensure close out, with documentation, of the audit after corrective actions have been completed.

15.4.4 For uncorrected or unresolved deficiencies, after due diligence, the Q.A. Manager will petition the Laboratory Manager to bring to bear his authority for resolution of the deficiencies.

15.5 FREQUENCY OF AUDITS

The Q.A. Manager will ensure internal audits are conducted on an annual basis. Additional selective audits will be conducted when one or more of the following conditions exist:

15.5.1 When significant changes are made in functional areas of the Q.A. Program, including significant reorganization or procedure revisions.

15.5.2 When assessment of the Program's effectiveness is considered necessary.

16.0 QUALITY ASSURANCE AND INSPECTION RECORDS

16.1 POLICY

Records that provide objective evidence of the quality of work are generated and maintained. These records include controlled logbooks, customer instructions, sample analyses data sheets, and results of reviews, inspections, tests, audits, corrective actions, reports, and training records. Also included are related data such as personnel qualifications, procedures, and equipment records.

16.2 RESPONSIBILITY

The responsibility for initiation, completeness, and reliability of Q.A. records is vested in the appropriate supervisor, with periodic verification checks by the Q.A. Manager. All Oak Ridge Laboratory personnel performing processes or services associated with the work being performed will assist in the efforts.

16.3 RECORDS

16.3.1 Inspection and test records will, at a minimum, identify the inspector or data recorder, the type of observation, the results, the action taken in connection with any deficiencies noted, and the date of the inspection or test.

16.3.2 All required records will be legible and of a quality that can be copied. Records shall be completed using reproducible ink. Errors or incorrect entries will be lined through with a single line, dated, and initialed by the recorder.

16.3.3 Correspondence from clients may be made available for inspection at the discretion of client representatives and authorization from the originating organization.

16.3.4 Q.A. records will be identified and controlled by customer number and/or client identification as applicable.

16.4 STORAGE OF RECORDS

16.4.1 Quality assurance records will be firmly attached in binders, placed in folders or envelopes, and, if applicable, cross referenced by client identification and stored in a secure area.

- 16.4.2 Q.A. records will be properly stored and made available to the client upon request.
- 16.4.3 Records will be maintained in a secured and protective storage area.
- 16.4.4 Records will be identified and be retrievable.
- 16.4.5 CoC records are included with the sample set records.
- 16.4.6 Longer retention or duplication of records is available at the specific direction from the client.
- 16.4.7 Laboratory management will be responsible for governing access to, and controlling the records.
- 16.4.8 Analytical reports and source calibration data will be retained for a minimum of five years after results are reported to the client.
- 16.4.9 Procurement records will be retained for a minimum of five years or as required by the contract.
- 16.4.10 All records and analyses performed pertaining to (NELAC) accreditation will be kept for a minimum of 5 years and would be available for inspection by the accrediting authorities during this period even without prior notification to the laboratory.

17.0 CORRECTIVE ACTION

17.1 POLICY

The Oak Ridge Laboratory policy is to ensure continuous acceptable quality levels for services provided. Conditions adverse to quality will be identified and corrected as soon as practical.

17.2 CORRECTIONS

17.2.1 CORRECTIVE ACTION REPORT (CAR)

In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action shall be documented and reported to appropriate levels of management. Follow-up action shall be taken to verify implementation of this corrective action and documented via a Corrective Action Follow-Up form. The Corrective Action Report (CAR) Form shall be used to document this condition. Typically, the Q.A. Manager will initiate investigation and corrective action by issuing a Corrective Action Report (CAR) in any of the following situations:

- When an audit reveals circumstances that will adversely affect quality (Audit Finding) as determined by the Q.A. Manager.
- When any results of an inter-comparison study are out of control, or for non-participation.
- When procedural or technical problems arise and the Q.A. Manager determines that they will significantly affect quality.

17.3 NON-CONFORMANCE REPORT (NCR)

A non-conformance is a deficiency in a characteristic, procedure, or documentation that renders the quality of an item unacceptable, however, is not considered a significant condition that would

require an investigation by use of a CAR. In the laboratory, non-conformances can include physical defects, incorrect or inadequate documentation, and deviations from an established protocol, plan, or documented technical requirement. This condition is documented using a Non-Conformance Report (NCR) Form.

17.4 RESPONSIBILITY

All laboratory personnel are responsible to communicate any evidence of unacceptable quality performance to their supervisor, the responsible manager, and/or the Q.A. Manager.

17.4.1 The responsible manager will ensure investigation of a condition adverse to quality, determine assignable cause, and provide recommendation(s) for corrective action.

17.4.2 The responsible manager will ensure action is initiated to correct the assignable cause of the adverse condition and to determine and initiate the specific corrective action(s) necessary to preclude recurrence.

17.4.3 The Q.A. Manager will review CARs, NCRs, and routine Q.C. reports for evidence of unacceptable quality.

17.4.4 Copies of the completed CARs and NCRs will be kept on file by the Q.A. Manager.

17.5 CLIENT NOTIFICATION

The client will be notified when any Corrective Action is initiated due to evidence of unacceptable quality that is related to their contract.

18.0 QUALITY ASSURANCE REPORTS TO MANAGEMENT

18.1 POLICY

Eberline Analytical Laboratory policy is to keep management apprised of all quality assurance problems, actions taken to correct them, and any actions taken to prevent recurrence.

18.2 QUALITY ASSURANCE REPORTS

18.2.1 Quality Assurance Reports are prepared quarterly by the QA Manager and submitted to upper management. The reports shall include discussion of inter-comparison studies, status of corrective actions, and quarterly QA objectives.

18.2.2 The Q.A. Manager will report all general or system audit results, problems, corrective actions, and replies.

Document Revision History

Revision	Effective Date	Changes From Previous Revision
7	8/1/13	<ul style="list-style-type: none"> • Document Revision History table implemented • Added Emergency Coordinator to title designations of positions in Section 1.4.4 • Updated list of accreditations in section 1.9 to reflect all current certifications • Updated Laboratory Organization Chart • Removed requirement for employees to maintain hard copies of procedures in work area.
8	8/1/14	<ul style="list-style-type: none"> • Updated ISO/IEC 17025 references throughout procedure to specify ISO/IEC 17025:2005 • Added IT Manager (i.e. LIMS Manager) to Section 2.0 Organization and Responsibility • Added Project Manager (i.e. Client Services Manager) to Section 2.0 Organization and Responsibility • Added purchasing management to the list of Laboratory Manager responsibilities in Section 2.2.1 • Added language in Section 2.2 to explicitly state job description requirements for Technical Director and Quality Manager defined under NELAC
9	8/1/15	<ul style="list-style-type: none"> • Changed references to the QAP Manual in Matrix Comparison Tables from "Oak Ridge, TN Laboratory" to "Eberline Analytical Laboratory" • Updated the Matrix Comparison Table on page 10 to cross-reference DoD/DOE Consolidated QSM; removed obsolete DOE QSAS and DoD QSM references • Removed obsolete documents in Section 1.3 • Updated Figure 2.1 (Organization Chart) to reflect staff changes • Revised Section 5.3.1 to reference MP-004 <i>Preparation and Modification of Procedures and Guidance Documents</i>; removed reference to obsolete procedure MP-021. • Added specific reference to MP-033 <i>Procurement of Quality Related Items/Services</i> to Section 6.1 (Purchasing)



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		<ul style="list-style-type: none">• Changed employee title from Sample Receiving Technician to Sample Custodian in Section 12.2• Removed item 15.2.3 to reflect current practice
10	8/8/16	<ul style="list-style-type: none">• Updated Laboratory Organization Chart to reflect personnel changes.• Added language to Section 14.1.3 to clarify fulfillment of QSM initial calibration verification requirements.
11	8/8/17	<ul style="list-style-type: none">• Updated Laboratory Organization Chart to reflect personnel changes.• Added language to Section 6.4 requiring written approval prior to subcontracting analytical work for DOE clients.• Revised Section 7.3.2 to reflect current practice.
12	8/7/18	<ul style="list-style-type: none">• Updated Laboratory Organization Chart (Figure 2.1) to reflect personnel changes.• Revised Section 5.3 to remove obsolete term and replace with a discussion of Management Procedures.• Removed references to “Department Manager” and “Operations Manager” in Section 11.2 and replaced with “Lab Manager” and “QA Manager”