

Section: Foreword

RICHMOND, CA LABORATORY

QUALITY ASSURANCE PROGRAM MANUAL

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QUALITY ASSURANCE MISSION STATEMENT

Our mission is to ensure that all of the Eberline Analytical Corporation, Richmond, CA Laboratory's systems, services, processes, and deliverables are of a quality that meets or exceeds client requirements; and to foster a Richmond 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.

FOREWORD

Quality Assurance, essentially, 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 the procedure, policy, or activity is written, implemented, and performed. This spirit produces empowerment and motivation in all employees to achieve the highest level of quality. This esprit de corps must start with the President of Eberline Services, Inc. and extend to all employees. The result of this attitude is "Quality Assurance."

This philosophy is realized and implemented through the policy guidelines presented in this Richmond Laboratory Quality Assurance Program Manual, and is based on premises that:

- People are our greatest asset and are ultimately responsible for the quality of the items and services we provide.
 Therefore, our most important objective is to treat each person 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 they must be provided appropriate facilities, equipment, and proper training.
- A culture of quality embodied within the entire Richmond 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 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 also lead to reduced costs and allow the ultimate objective of providing the highest quality items and services at the lowest costs to be a viable goal.
- Quality is also a perception of our clients. Our actions in quality assurance must assure our clients that the Richmond, CA Laboratory organization provides the quality for systems, services, processes, and deliverables that will meet or exceed their requirements and expectations.

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Section: Statement of Compliance

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STATEMENT OF COMPLIANCE

This Quality Assurance Program Manual addresses the basic requirements of NQA-1 and requirements outlined in several regulatory manuals, standards, and regulations. Matrix comparison to some of these documents is included on pages 9 through 15. Additional regulatory requirements are listed in Section 1.0. This manual is organized as follows:

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	Page 4	Statement of Compliance
	Page 5	Revision/Review Record
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17.0	Page 52	Corrective Actions
18.0	Page 54	Quality Assurance Reports to Management
Appendix A Appendix B		Eberline Services' Corporate Positions Richmond, CA Laboratory Positions



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REVISION/REVIEW RECORD

Page No.	Rev. No.	Rev. date	Review Date	Reviewed by:
Entire Manual	Original	04-14-95	04-14-95	L. A. Johnson
Entire Manual	01	11-15-95	11-15-95	L. A. Johnson
Entire Manual	02	11-05-96	11-05-96	L. A. Johnson
Entire Manual	03	11-19-97	11-19-97	L. A. Johnson
Entire Manual	04	12-11-98	12-11-98	L. A. Johnson
Entire Manual	05	05-21-99	05-21-99	L. A. Johnson
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Revised	to Eberline Service	es, Analytical Services	Group, Quality Assurance Progr	ram Manual
Entire Manual	07	11-10-00	11-10-00	L. A. Johnson
Entire Manual	08	07-20-01	07-20-01	L. A. Johnson
Entire Manual	09	07-17-02	07-17-02	L. A. Johnson
Entire Manual	10	03-17-03	02-27-03	L. A. Johnson
Revised	to Eberline Servi	ces, Richmond, CA Lab	oratory Quality Assurance Progr	am Manual
Entire Manual	11	09-25-03	09-25-03	L. A. Johnson
Entire Manual	12	08-27-04	08-27-04	L. A. Johnson
Entire Manual	13	05-06-05	05-06-05	L. A. Johnson
Entire Manual	14	05-12-06	05-12-06	L. A. Johnson
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Revised to Eb	erline Analytical C	orporation, Richmond, (CA Laboratory Quality Assurance	e Program Manual
Entire Manual	16	08-22-08	07-18-08	K. Yamamoto



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MATRIX COMPARISON

NQA-1, 1994 Cross Reference to - Richmond, CA Laboratory Q.A. Program Manual

NQA-1-1994 -Quality Assurance Requirements for Nuclear Facility Applications (Basic Requirements)			Richmond, CA 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
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10 CFR Part 50, Appendix B Cross Reference to Richmond, CA Laboratory Q.A. Program Manual

NRC 10 CFR Part 50 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."			Richmond, CA Laboratory Quality Assurance Program Manual
Criterion No.	TITLE	QAM SECT	TITLE
l	Organization	2.0	Organization and Responsibility
11	Quality Assurance Program	3.0	Quality Assurance Objectives
111	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
Х	Inspections	14.0	Internal Quality Control
ΧI	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



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DOE Quality Systems for Analytical Services and DOD Quality Systems for Environmental Laboratories Cross Reference to Richmond, CA Laboratory Q.A. Program Manual

	DOE QSAS		Richmond, CA Laboratory Quality Assurance Program Manual
4.2.3 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
(1)	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)	Interlaboratory 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)	Analytical results reporting	12.0	Data Reduction, Verification, and Reporting
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Hanford Analytical Services Quality Assurance Requirements Documents Cross Reference to - Richmond, CA Laboratory Q.A. Program Manual

	HASQARD Volume 1		Richmond, CA Laboratory Quality Assurance Program Manual
RQMT	TITLE	QAM SECT	TITLE
2.0	Organization and Responsibility	1.0 2.0 3.0	Introduction and Description Organization and Responsibility Quality Assurance Objectives
3.0	Personnel Qualification and Training	4.0	Personnel Indoctrination and Training
4.0	Procedures	5.0 9.0	Instructions and Procedures Control of Process
5.0	Corrective Actions and Quality Improvement	14.0 17.0	Internal Quality Control Corrective Actions
6.0	Documents and Quality Records	5.0 9.0 13.0 16.0	Instructions and Procedures Control of Process Document Control Quality Assurance and Inspection Records
7.0	Software Systems Quality Assurance	12.0	Data Reduction, Verification, and Reporting
8.0	Procurement Controls	6.0 7.0 8.0	Procurement Document Control Material Receipt and Control Material Storage and Control
9.0	Equipment Preventative Maintenance	10.0	Preventive Maintenance
10.0	Assessments	2.0 15.0	Organization and Responsibilities Audits
11.0	Quality Assurance Reporting	18.0	Quality Assurance Reports to Management
		N/A	Title Page
		N/A	Authorization and Approval Statement
		N/A	Table of Contents
		11.0	Control of Measurement & Test Equipment



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NELAC Chapter 5 Cross Reference to - Richmond, CA Laboratory Q.A. Program Manual

	NELAC Chapter 5 "Quality Systems"		Richmond, CA Laboratory Quality Assurance Program Manual
5.4.2.3 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
(1)	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)	Interlaboratory 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
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10 CFR Part 830.122 Cross Reference to Richmond, CA Laboratory Q.A. Program Manual

10CFR 830.122 "Quality Assurance Criteria"			Richmond, CA Laboratory Quality Assurance Program Manual
Criterion No.	TITLE	QAM SECT	TITLE
830.122 (a)	Management/Program	1.0 2.0	Introduction Organization and Responsibility
(b)	Management/Personnel Training and Qualification	4.0	Personnel Indoctrination and Training
(c)	Management/Quality Improvement	3.0 14.0 17.0	Quality Assurance Objectives Internal Quality Control 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 8.0 10.0 14.0	Material Receipt and Control Material Storage and Control Preventive Maintenance 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 14.0 15.0	Control of Measurement and Test Equipment Internal Quality Control Audits
(i)	Assessment/Management Assessment	2.0	Organization and Responsibility
(j)	Assessment/Independent Assessment	2.0 15.0	Organization and Responsibility Audits
N/A		N/A	Title Page
N/A		N/A	Authorization and Approval Statement



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EPA SW-846 Cross Reference to - Richmond, CA Laboratory Q.A. Program Manual

EPA SW-846 (Essential Elements)			Richmond, CA 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	
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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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SECTION 1.0 INTRODUCTION AND DESCRIPTION

1.1 PREFACE

The management of Eberline Services, Inc., Richmond, CA 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 form 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.

1.3 **SCOPE**

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

In addition to the documents identified in the Matrix Comparison Section, this Manual complies with applicable requirements of the following regulations:

- 1.3.1 NRC 10 CFR Part 21, "Reporting of Defects and Non-compliance."
- 1.3.2 ANSI/ANS-10.3-1995, "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/R2, "EPA Requirements for Quality Assurance Program Plans."
- 1.3.5 HPS N13.30 1996, "Performance Criteria for Radiobioassay."
- 1.3.6 EPA 2185, "Good Automated Laboratory Practices" (GALP)
- 1.3.7 DOE STD- 1112-98, "DOE Laboratory Accreditation Program for Radiobioassay"



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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 will be coordinated with management who will validate improvement and disseminate the information to all affected personnel. Management will also, if required, 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 Richmond Laboratory quality culture.

Management provides facilities, resources, tools, equipment, scheduling, and training to ensure personnel can perform their duties effectively. Deputies for key managerial personnel have been identified to ensure continuity of process. *In the absences of key managerial personnel, deputies for these positions are authorized to perform their duties.*

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

Laboratory personnel are required to train to the Quality Assurance Program and to implement the policies and procedures in their work. 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.

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., may be addressed.

The following titled designations of positions are used within the Richmond, CA Laboratory:

- Laboratory Manager: Refers to the General Manager of the Richmond, CA Laboratory.
- **Technical Director:** Refers to the individuals who provide technical direction or advice for laboratory operations and/or special programs, research projects, or activities.
- Operations Manager: Refers to the individual within a laboratory who is responsible for the technical operations.
- Program Manager: Refers to an individual in the laboratory who is responsible for client service activities
 and is the single point of contact with a client for the laboratory.



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- **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.
- Q.C. Coordinator: Refers to the individual who is responsible for the laboratory's Quality Control (Q.C.)
 Program.
- Facilities Support Superintendent: Refers to the individual who is responsible for managing and operating the facilities including building and systems maintenance, repair, and security.
- Purchasing Agent: Refers to the individual who is responsible for the procurement of material, components, supplies, reagents, equipment, and services.
- Environmental Compliance Officer: Refers to the individual who is responsible for ensuring hazardous wastes are processed as required by local, state, and federal regulations.
- Laboratory Health & Safety Officer: Refers to the individual who is responsible for the implementation of the Safety Program.
- Radiation Safety Officer: Refers to the individual who is responsible for the implementation of the Radiation Safety Program.
- Document Control Custodian: Refers to the individual who is responsible for the control of technical and project specific documents, procedures, and manuals.
- Information Technology Specialist: Refers to the individual who is responsible for the administration and control of all data management systems at Eberline Services, Richmond.

See Appendix B for the names of individuals assigned to the positions described above, and the names of individuals assigned as deputies for key managerial positions.

1.5 **DESCRIPTION**

This document outlines the organization of the Q.A. function, describes and 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.



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1.6 CONFIDENTIAL AND PROPRIETARY INFORMATION

Richmond 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 Eberline Services, Inc. organization concerning the security of proprietary and confidential information. A copy of the agreement will be retained in the employee's personnel file.

1.7 **CUSTOMER COMPLAINTS**

All customer complaints will be addressed by the Technical Director, Program Manager, or staff member with the most 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 will 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 customer complaints will be recorded and maintained in the customer's project file.

1.8 DATA INTEFGRITY, ETHICAL AND LEGAL RESPONSIBILITIES

Quality Assurance Procedure (QAP)-06 has been promulgated for the education and training of personnel in the areas of Data Integrity, ethical and legal responsibilities including the potential punishment and penalties for improper, unethical, or illegal actions. QAP-15 provides the methodology for periodic monitoring and recording of data integrity, and ethical observations.

1.9 **ACCREDITATIONS**

The laboratory has been granted certification by different agencies, organizations, and states. The laboratory maintains proficiency as required by the certifying agency. The Quality Assurance Manager maintains credentials and lists of certifying agencies. List will include the following:

1.9.1 <u>U. S. Department of Energy Consolidated Audit Program (DOECAP)</u>

The Richmond laboratory has been audited by the U.S. Department of Energy, Consolidated Audit Program to provide across the board certification for all DOE operations.

1.9.2 <u>National Environmental Laboratory Accreditation Conference (NELAC)</u>

The laboratory has been granted NELAP accreditation by the State of California.



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1.9.3 <u>Nuclear Utilities Procurement Issues Committee (NUPIC)</u>

The Richmond laboratory participates in this program by the Nuclear Utilities to perform 10 CFR Part 61 required analysis.

1.9.4 State

The laboratory is accredited under NELAC by the state of California and other states through NELAP reciprocity.



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SECTION 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 organization 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**

Management at all levels will periodically assess the integrated quality assurance program and its performance. Problems that hinder the organization from achieving its objectives will be identified and corrected.

- 2.2.1 The Q.A. Manager is responsible for the establishment and execution of the Q.A. Program as outlined herein and for defining and measuring the overall Program effectiveness.
- 2.2.2 The Q.A. Manager has direct access to the Laboratory Manager for matters pertaining to quality assurance that cannot be resolved.
- 2.2.3 The Q.A. Manager operates independently from line management and will report to the Laboratory Manager, providing the required authority and organizational freedom to ensure that appropriate action can be taken in implementing an effective Program. The Q.A. Manager has independence from cost, scheduling, and production considerations, and has the authority to control processing, delivery, installation, or use until proper disposition of a non-conformance, deficiency, or condition adverse to quality that has been identified.
- 2.2.4 The Q.A. Manager is responsible to review the Q.A. Program on a continuing basis and recommend revisions to the Program as necessary to ensure compliance with the latest revisions of applicable standards. A formal review of the Program will be performed annually.
- 2.2.5 Quality related activities may be assigned to designated qualified personnel. Responsibility for quality control functions resides with the Q.A. Manager.
- 2.2.6 The Q.A. Manager and designated personnel are authorized to sign client related Certificates of Conformance and/or Compliance.

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- The Document Control Custodian will maintain a log of names, with signature and initials, for all 2.2.7 individuals who are responsible for signing or initialing any laboratory record.
- The responsibility for compliance to the general workmanship and standard practices is vested in the 2.2.8 first line level of supervision. Supervisors will provide training and ensure employee compliance.
- All employees are responsible for supporting the Program in principle and in detail and shall retain 2.2.9 responsibility for the quality of their work.
- The Q.A. Manager will annually provide a summary of quality assurance activities to the Laboratory 2.2.10 Manager for review of the Program, to evaluate its adequacy and assure its effective implementation.

ASSESSMENT 2.3

- The Laboratory Manager shall periodically and at least annually conduct a review of the laboratory's 2.3.1 quality system and environmental testing activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:
 - the suitability of policies and procedures,
 - reports from managerial and supervisory personnel,
 - the outcome of recent internal audits,
 - corrective and preventive actions,
 - assessments by external bodies,
 - the results of inter-laboratory comparisons or proficiency tests,
 - changes in the volume and type of the work,
 - client feedback,
 - complaints; and
 - other relevant factors, such as quality control activities, resources, and staff training.
- Findings from management reviews and the actions that arise from them shall be recorded. The 2.3.2 management shall ensure that those actions are carried out within an appropriate and agreed timescale.

DOCUMENTATION 2.4

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.



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2.5 **ORGANIZATION CHARTS**

- 2.5.1 The Analytical Services Group corporate organization is illustrated in Figure 1. See Appendix A for the names of individuals holding titles to the positions.
- 2.5.2 The Richmond laboratory organization is illustrated in Figure 2. See Appendix B for the names of individuals assigned to the positions.



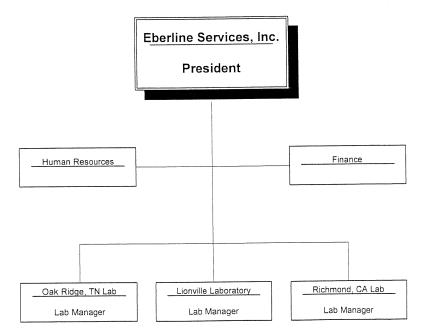
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Figure 1 **Analytical Services Group CORPORATE ORGANIZATION**

Eberline Services Analytical Services Group





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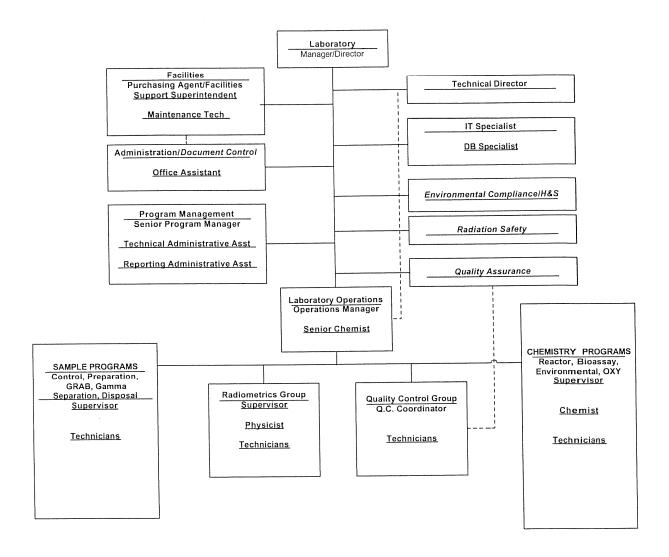
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Figure 2 Richmond, CA Laboratory ORGANIZATION





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SECTION 3.0 QUALITY ASSURANCE OBJECTIVES

3.1 **OBJECTIVES**

The Richmond, CA 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 Richmond 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 documents program provides valid records of the control measures applied to all factors bearing on the final results of investigations.
- 3.1.6 To ensure the assessment of results provides feedback to improve the process.
- 3.1.7 To foster a culture in which there is a commitment to achieve a rising standard of quality, which demands that the quality for systems, services, processes, and deliverables, and the methods utilized to achieve that quality, 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.



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3.3 **RESPONSIBILITY**

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, through their supervisor, 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.

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 corrected. Corrective actions will be implemented and followed up to ensure effectiveness.



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SECTION 4.0

PERSONNEL INDOCTRINATION AND TRAINING

4.1 QUALIFIED PERSONNEL

- 4.1.1 Personnel within the Richmond laboratory who perform activities that will affect quality will have indoctrination, training, and job evaluation conducted on an individual basis to ensure that suitable proficiency is achieved and maintained. A job description, identifying position qualification and duty requirements, will be provided the individual and also included in each individual's training records.
- 4.1.2 All personnel will have training outlining their data integrity, ethical, and legal responsibilities, including the potential disciplinary actions 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 education concomitant with technical complexity of duties.

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 an annual review of assigned personnel for evidence of unethical, improper, or illegal activities. Documentation of the review will be retained in the individual's training files.
- 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.
 - 4.2.3.4 Emphasis on "doing it right the first time."



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4.2.4	New employees will receive detailed information concerning safety policies, and general corporate policies. A current copy of the Chemical made available to employees who will familiarize themselves with this	Hygiene Plan will be
4.2.5	Milestone achievements or unique training will be noted by the supervitraining records. Available certificates of training, education, or a maintained with the individual's training records.	
4.2.6	Supervisors will monitor individual work habits to ensure proficiency is progressive improvement, and to identify any needed supportive training requirements will be developed by the individual's supervisor.	
4.2.7	When applicable, employees will be informed of the requirements "Reporting of Defects and Non-Compliance," and will familiarize the regulation. Familiarization will be made a matter of record.	
4.2.8	Requirements for personnel training and the details for composition training records are outlined in the Richmond Laboratory Quality Assura 02 "Personnel Indoctrination and Training."	



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SECTION 5.0 INSTRUCTIONS AND PROCEDURES

5.1 **POLICY**

The policy at the Richmond laboratory is to use written and approved procedures for routine activities and for analytical and operational processes that ensure data is produced that meets the minimum method QA/QC requirements. Applicable procedures are available to operating personnel. A current copy of the appropriate procedure will be maintained in each chemistry laboratory/operating department. Departures from routine procedures due to non-standard situations or specific requests by clients, will be approved by management and will be fully documented.

5.2 TECHNICAL PROCEDURES

Technical procedures are descriptions of particular protocols for testing or operations. Technical procedures will be developed when there is no published reference procedure for a test or process, and the Operations Manager, Technical Director, or Q.A. Manager deem it necessary.

- 5.2.1 Qualification requirements for personnel performing operations and criteria used to determine the proficiency of the operator will be defined.
- 5.2.2 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.
- 5.2.3 Each technical procedure will identify any chemicals/reagents required for completion of the process. Material Safety Data Sheets (MSDSs) for those chemicals/reagents will be readily available, and training applicable to the MSDSs will be conducted.
- 5.2.4 Each technical procedure will identify the hazardous wastes generated as a result of the process. Training will be conducted to the procedures used for processing wastes generated within the applicable chemistry laboratory.

5.3 PROCEDURE MANUALS

Procedure manuals consist of the individual technical procedures for a laboratory area or for an operation combined into one document. The procedures within the manual define all parameters of the operations being performed to include required accuracy and completeness of specific measurement parameters involved. Procedures will be incorporated into procedure manuals. Signature on the Authorization and Approval page applies to all procedures in the manual.



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5.4 **FORMAT AND DISTRIBUTION**

- 5.4.1 Procedures will comply to the format prescribed in the laboratory document control procedure and will be approved by the Technical Director, the Senior Chemist, or the responsible supervisor, the relevant manager and the Q.A. Manager.
- 5.4.2 Distribution of procedure manuals will be in accordance with the laboratory's document control procedure. The original copy of each department's procedure manual will be retained by the Document Control Custodian.

5.5 **REVIEW**

Procedures and manuals will be reviewed for accuracy and adequacy at least annually or whenever procedural method changes occur, and updated as appropriate.

5.6 **REVISION**

- 5.6.1 The appropriate supervisor, or designated representative, is responsible for revisions or changes to the applicable procedure manuals.
- 5.6.2 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.
- 5.6.3 A procedure or manual that has been revised will be issued as soon as possible.
- 5.6.4 The Q.A. Manager will be advised of any changes in procedures required to satisfy specifications of the client.
- 5.6.5 The Document Control Custodian will be responsible for retention of the original copy of each superseded procedure, marked "Revised" or "Obsolete." The original copy of each superseded or obsolete technical procedure will be designated for lifetime retention.



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SECTION 6.0 PROCUREMENT DOCUMENT CONTROL

6.1 **PURCHASING**

Procurement of material, components, supplies, reagents, equipment, and services necessary to carry on operations at the Richmond, CA 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.

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 AND CERTIFICATE OF CONFORMANCE

All materials and processes requiring certification and certificates of conformance are identified on the face of the purchase order or by attachment thereto. 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**

Subcontractor laboratories must have an established and documented laboratory quality system that complies with the NELAC Quality Systems requirements, the DoD QSM requirements, or the DOE QSAS requirements, if applicable. The subcontractor laboratories must be certified by NELAP and be approved by the specific DoD Component laboratory approval process or be approved by the DOE Procurement Representative, as applicable. Subcontractor laboratories must demonstrate the ability to generate acceptable results from the analysis of proficiency testing samples. Subcontractor laboratories must receive project-specific approval from the DoD or the DOE client, if applicable, before any samples are analyzed.

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. Vendor evaluation and qualification will be through accreditation as a secondary standard calibration laboratory (NVLAP - NIST); an audit by Richmond laboratory personnel or an acceptable audit agency; or facility inspection, test reports, or receipt inspections, when the quality of the materials can be verified by these methods; or by a history of material or services