Cover Page:

Quality Assurance Manual

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Quality Assurance Manual
Approval Signatures

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Technical Director, (Radiochemistry/Metals) – Steve Wheland	1/10/08 Date

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SECTION 3
INTRODUCTION
(NELAC 5.1 - 5.3)

3.1 INTRODUCTION AND COMPLIANCE REFERENCES

TestAmerica Richland's Quality Assurance Manual (QAM) is a document prepared to define the overall policies, organization objectives and functional responsibilities for achieving TestAmerica's data quality goals. Each TestAmerica laboratory maintains a local perspective in its scope of services and client relations and maintains a national perspective in terms of quality.

The QAM has been prepared to assure compliance with the *U.S. Department of Energy, Quality Systems for Analytical Services*, current revision, 2003 National Environmental Laboratory Accreditation Conference (NELAC) standards and ISO/IEC Guide 17025 (2005). In addition, the policies and procedures outlined in this manual are compliant with the various accreditation and certification programs listed in Appendix 5. The relevant NELAC section is included in the heading of each QAM section.

The QAM has been prepared to be consistent with the requirements of the following documents:

- HASQARD, *Hanford Analytical Services Quality Assurance Requirement Documents.* Project Hanford Management Contractor, current revision.
- EPA 600/4-79-019, *Handbook for Analytical Quality Control in Water and Wastewater Laboratories,* EPA, March 1979.
- EPA SW-846, *Test Methods for the Evaluation of Solid Waste, 3rd Edition,* September 1986; Update I, July 1992; Update II, September 1994; and Update III, December 1996.
- *U.S. Department of Energy* Order 414.1, *Quality Assurance*, current revision.
- AIHA LQAP Policy Document, current revision.
- Nuclear Regulatory Commission (NRC) quality assurance requirements.
- ASTM D7282-06, Standard Practice for Set-up, Calibration, and Quality Control of Instruments Used for Radioactivity Measurements, ASTM, current revision.

Richland is primarily a radiochemistry laboratory. The main sections of this manual will reflect overall program requirements and radiochemical information. Specific inorganic requirements will be addressed in an addendum to this manual.

3.2 TERMS AND DEFINITIONS

A Quality Assurance Program is a company-wide system designed to ensure that data produced by Richland conforms to the standards set by state and/or federal regulations. The program functions at the management level through company goals and management policies, and at the analytical level through Standard Operating Procedures (SOPs) and quality control. The TestAmerica program is designed to minimize systematic error, encourage constructive, documented problem solving, and provide a framework for continuous improvement within the organization.

Refer to Appendix 4 for the Glossary/Acronyms.

3.3 SCOPE / FIELDS OF TESTING

Richland analyzes hundreds of environmental and industrial samples every month. Sample matrices vary among air, drinking water, effluent water, groundwater, hazardous waste, sludge, filters, soils, food products, animal tissue, vegetation, D&D material, bioassay (urine and feces). The Quality Assurance Program contains specific procedures and methods to test samples of differing matrices. The Program also contains guidelines on maintaining documentation of analytical process, reviewing results, servicing clients and tracking samples through the laboratory. The technical and service requirements of all requests to provide analyses are thoroughly evaluated before commitments are made to accept the work. Measurements are made using published reference methods or methods developed and validated by the laboratory.

The methods covered by this manual include the most frequently requested methodologies needed to provide analytical services in the United States and its territories. The specific list of test methods used by the laboratory can be found in the QA files. The approach of this manual is to define the minimum level of quality assurance and quality control necessary to meet requirements. All methods performed by Richland shall meet these criteria as appropriate. In some instances, quality assurance project plans (QAPPs), project specific data quality objectives (DQOs) or local regulations may require criteria other than those contained in this manual. In these cases, the laboratory will abide by the requested criteria following review and acceptance of the requirements by the Laboratory Director and the Quality Assurance (QA) Manager. In some cases, QAPPs and DQOs may specify less stringent requirements. The Laboratory Director and the QA Manager must determine if it is in the lab's best interest to follow the less stringent requirements.

3.4 MANAGEMENT OF THE MANUAL

3.4.1 Review Process

The manual is reviewed annually by the QA Manager and laboratory personnel to assure that it reflects current practices and meets the requirements of Richland's clients and regulators. Occasionally, the manual may need changes in order to meet new or changing regulations and operations. The QA Manager will review the changes in the normal course of business and incorporate changes into revised sections of the document. The updates will be reviewed by the QA Manager, Laboratory Director, Technical Director(s), relevant operational staff and Corporate Quality Assurance (if a change is made to the Corporate template) and then formally incorporated into the document in periodic updates. The QAM is based on a Corporate QAM Template that is prepared and approved by the Chief Operating Officers (COOs) and Corporate Quality Assurance. This template is reviewed annually by the COOs, Corporate Quality, and each laboratory. Necessary changes are coordinated by the Vice President of Quality and Environmental Health & Safety (EHS) and distributed to each laboratory for inclusion in the laboratory specific QA Manuals.

Policies in the QAM that require immediate attention may be addressed through the use of Corporate QA/QC Policy Memoranda. QA/QC Policy Memoranda are published from time to time to facilitate immediate changes to QA/QC Policy. QA/QC Policy Memoranda supersede the QAM and all other SOPs (refer to Section 5.3). All policy memoranda are dated, archived

and distributed by their placement into the front of the QAM between the signature page and Section 2. At a minimum, each policy memorandum is approved by the same authorized signatories as shown on the cover page of the QA Manual. In addition, Corporate QA/QC Policy Memoranda are signed by the COOs and VP of Quality and EHS. The QA/QC Policy Memoranda are incorporated into the QAM during the periodic updates. Policy memorandum may also include an expiration date if appropriate. An example format can be found in Figure 3-1. A similar procedure is followed for local laboratory changes.

When an approved revision of a Richland controlled document is ready for distribution, obsolete copies of the document are replaced with the current version of the document. The previous revision of the controlled document is archived by the QA Department.

3.4.2 Control

This manual is considered confidential within TestAmerica and may not be altered in any manner by other than a duly appointed representative from TestAmerica. If the document has been provided to external users or regulators, it is for the exclusive purpose of reviewing Richland's quality systems and shall not be used in any other way without the written permission of an appointed representative of TestAmerica. The procedure for control of distribution is incorporated by reference to the Richland SOP database.

The order of precedence in the event of a conflict between policies is outlined in Section 5.3 of this Quality Assurance Manual.

Figure 3-1. Example - Format for a QA/QC Policy Memorandum

Corporate (or Laboratory) QA/QC Policy Memorandum # _____

Effective Date: _____ Expiration Date: When Appropriate QAM Section is Revised

Corporate: *(Only needed for Corporate Memorandum – Delete if Laboratory)*

_____ _____
COO - West Date Vice-President, QA and EHS Date

_____
COO - East Date

Local:

_____ _____ _____
Technical Director Approval Date Quality Assurance Approval Date

_____ _____
Laboratory Director/Manager Approval Date Date

1. **Purpose**

2. **Procedure**

3. **Attachments**

4. **References/Cross References**

SECTION 4
ORGANIZATION AND MANAGEMENT
(NELAC 5.4.1)

4.1 OVERVIEW

TestAmerica Richland is part of a national network of laboratories known as TestAmerica. This Quality Assurance Manual (QAM) is applicable to the Richland laboratory only.

TestAmerica Richland
2800 George Washington Way
Richland WA 99354
EPA ID# WA00023

The Corporate organization chart can be found in Figure 4-1 and the laboratory's organization chart can be found in Appendix 2. The locations of other TestAmerica labs are as follows:

Aerotech Environmental Laboratories (AEL)
TestAmerica Anchorage
TestAmerica Austin
TestAmerica Buffalo
TestAmerica Buffalo Grove
TestAmerica Burlington
TestAmerica Cedar Falls
TestAmerica Chicago
TestAmerica Connecticut
TestAmerica Corpus Christi
TestAmerica Dayton
TestAmerica Denver
TestAmerica Edison
TestAmerica Honolulu
TestAmerica Houston
TestAmerica Irvine
TestAmerica King of Prussia
TestAmerica Knoxville
TestAmerica Los Angeles
TestAmerica Mobile
TestAmerica Morgan Hill
TestAmerica Nashville
TestAmerica North Canton
TestAmerica Ontario
TestAmerica Orlando
TestAmerica Pensacola
TestAmerica Phoenix
TestAmerica Pittsburgh
TestAmerica Portland
TestAmerica San Francisco
TestAmerica Savannah
TestAmerica Seattle
TestAmerica Spokane
TestAmerica St. Louis
TestAmerica Tacoma
TestAmerica Tallahassee
TestAmerica Tampa
TestAmerica Valparaiso
TestAmerica Watertown
TestAmerica West Sacramento
TestAmerica Westfield

4.2 ROLES AND RESPONSIBILITIES

In order for the Quality Assurance Program to function properly, all members of the staff must clearly understand and meet their individual responsibilities as they relate to the quality program. The following descriptions define each role in its relationship to the Quality Assurance Program.

4.2.1 Quality Assurance Program

The responsibility for quality lies with every employee of Richland. All employees have access to the QAM and are responsible for knowing the content of this manual and upholding the standards therein. Each person carries out his/her daily tasks in a manner consistent with the goals and in accordance with the procedures in this manual and the laboratory's SOPs. All

TestAmerica employees are responsible for implementing the Quality Program. All TestAmerica employees have Stop Work Authority.

4.2.2 Chairman/Chief Executive Officer (CEO)

The Chairman/CEO is the Chairman of the Board of Directors and is ultimately responsible for the quality and performance of all TestAmerica facilities. Together with the President/CEO of the Analytical Division, the Chairman/CEO establishes the overall quality standard and data integrity program for the company, providing the necessary leadership and resources to assure that the standard and integrity program are met.

4.2.3 President/Chief Executive Officer (CEO)

The President/CEO is a member of the Board of Directors and is ultimately responsible for the quality and performance of all TestAmerica facilities. Together with the Chairman/CEO, the President/CEO establishes the overall quality standard and data integrity program for the Analytical Division, providing the necessary leadership and resources to assure that the standard and integrity program are met.

4.2.4 Chief Operating Officer (COO) – East and West

The COOs serve as the ranking executives for all respective analytical laboratory operational functions and report to the President/CEO of the Analytical Division. They are responsible for the daily management of all analytical laboratories, long-term planning and development of technical policies and management plans. They ensure the attainment of corporate objectives through the selection, development, motivation, and evaluation of top management personnel. The COOs approve all operating budgets and capital expenditures. The COOs sign-off on the final QAM template that contains company policies for implementing the Quality Program.

4.2.5 General Manager (GM)

Each GM reports directly to a COO. Each GM has full responsibility for the overall administrative and operational management of their respective laboratories. The GM's responsibilities include allocation of personnel and resources, long-term planning, setting goals, and achieving the financial, business, and quality objectives of TestAmerica. The GM ensures timely compliance with corporate management directives, policies, and management systems reviews. The GM is also responsible for restricting any laboratory from performing analyses that cannot be consistently and successfully performed to meet the standards set forth in this manual.

4.2.6 Vice President of Quality and Environmental Health and Safety (VP-QA/EHS)

The Vice President of QA/EHS reports directly to the Chairman/CEO. With the aid of the Analytical Division and Non-Analytical Division Senior Management Teams, Laboratory Director/ Managers, Quality Directors, EHS Directors, QA Managers and EHS Coordinators, the VP-QA/EHS has the responsibility for the establishment, general overview and Corporate maintenance of the Quality Assurance and Environmental, Health and Safety Program within TestAmerica. Additional responsibilities include:

- Review of QA/QC aspects of Corporate SOPs, national projects and expansions or changes in services.
- Coordination/preparation of the Corporate QAM Template that is used by each laboratory to prepare its own laboratory-specific QAM.

- Maintenance of Corporate Policies, Quality Memorandums and SOPs. Maintenance of data investigation records that are reported to Corporate Management.
- Work with various organizations outside of TestAmerica to further the development of quality standards and represent TestAmerica at various trade meetings.
- Preparation of a monthly report that includes quality metrics across the Analytical Division and a summary of any quality related initiatives and issues.
- With the assistance of the Corporate Senior Management Teams and the EHS Directors, development and implementation of the TestAmerica Environmental, Health and Safety Program.

4.2.7 Quality Directors (Corporate)

The Quality Directors report to the VP-QA/EHS. Together with the VP-QA/EHS, the Quality Directors have the responsibility for the establishment, general overview and maintenance of the Analytical Division's Quality Assurance Program within TestAmerica. The Quality Directors are responsible for:

- Oversight of the QA/QC programs within each laboratory. This includes a final review of each laboratory-specific QAM and receipt of each laboratory's QA monthly report.
- Review of QA/QC aspects of national projects.
- Assistance with certification activities.

4.2.8 Ethics and Compliance Officers (ECOs)

TestAmerica has designated two senior members of the Corporate staff to fulfill the role of Ethics and Compliance Officer (ECO) – VP-QA/EHS and VP-Client and Technical Services. Each ECO acts as a back-up to the other ECO and both are involved when data investigations occur. Each ECO has a direct line of communication to the entire senior Corporate and lab management staff.

The ECOs ensure that the organization distributes the data integrity and ethical practices policies to all employees and ensures annual trainings and orientation of new hires to the ethics program and its policies. The ECO is responsible for establishing a mechanism to foster employee reporting of incidents of illegal, unethical, or improper practices in a safe and confidential environment.

The ECOs monitor and audit procedures to determine compliance with policies and to make recommendations for policy enhancements to the CEOs, COOs, Laboratory Director/Manager or other appropriate individuals within the laboratory. The ECO will assist the laboratory QA Manager in the coordination of internal auditing of ethical policy related activities and processes within the laboratory, in conjunction with the laboratories regular internal auditing function.

The ECOs will also participate in investigations of alleged violations of policies and work with the appropriate internal departments to investigate misconduct, remedy the situation, and prevent recurrence of any such activity.

4.2.9 Vice President of Client and Technical Services

The Vise President (VP) of Client and Technical Services is responsible for offerings to clients including risk management, technical assistance, legal compliance and contract administration.

The VP of Client and Technical Services provides support and direction to the Managers of these areas, and supports the COOs in decisions regarding long term planning, resource allocation and capital expenditures.

4.2.10 Director of Technical Services

The Director of Technical Services is responsible for establishing, implementing and communicating TestAmerica's Analytical Division's Technical Policies, SOPs, and Manuals. Other responsibilities include conducting technical assessments as required, acting as a technical resource in national contracts review, coordinating new technologies, establishing best practices, advising staff on technology advances, innovations, and applications.

4.2.11 Chief Information Officer (CIO)

The CIO is responsible for establishing, implementing and communicating TestAmerica's Information Technology (IT) Policies, SOPs and Manuals. Other responsibilities include coordinating new technologies, development of electronic communication tools such as TestAmerica's intranet and internet sites, ensuring data security and documentation of software, ensuring compliance with the NELAC standard, and assistance in establishing, updating, and maintaining Laboratory Information Management Systems (LIMS) at the various TestAmerica facilities.

4.2.12 Environmental Health and Safety Directors (EHSDs) (Corporate)

The EHSDs report directly to the VP-QA/EHS. The EHSDs are responsible for the development and implementation of the TestAmerica Environmental, Health and Safety program. Responsibilities include:

- Consolidation and tracking all safety and health-related information and reports for the company, and managing compliance activities for TestAmerica locations.
- Coordination/preparation of the corporate Environmental, Health and Safety Manual Template that is used by each laboratory to prepare its own laboratory-specific Safety Manual/ CHP.
- Preparation of information and training materials for laboratory EHS Coordinators.
- Assistance in the internal and external coordination of employee exposure and medical monitoring programs to insure compliance with applicable safety and health regulations.
- Serving as Department of Transportation (D.O.T.) focal point and providing technical assistance to location management.
- Serving as Hazardous Waste Management main contact and providing technical assistance to location management.

4.2.13 Laboratory Director

Richland's Laboratory Director is responsible for the overall quality, safety, financial, technical, human resource and service performance of the whole laboratory and reports to their respective GM. The Laboratory Director provides the resources necessary to implement and maintain an effective and comprehensive Quality Assurance and Data Integrity Program.

Specific responsibilities include, but are not limited to:

- Ensures that personnel are free from any commercial, financial and other undue pressures which might adversely affect the quality of their work.

- Has signature authority for QAM, SOPs, other QA documents, final reports and contracts.
- Ensures TestAmerica's human resource policies are adhered to and maintained.
- Ensures that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory.
- Ensures that appropriate corrective actions are taken to address analyses identified as requiring such actions by internal and external performance or procedural audits.
- Ensures client specific reporting and quality control requirements are met.
- Annually assesses the effectiveness of the QAM within the operation

4.2.14 Quality Assurance (QA) Manager

The QA Manager has responsibility and authority to ensure the continuous implementation of the quality system based on ISO 17025. The QA Manager shall have documented training and/or experience in the QA/QC procedures and be knowledgeable in the quality system as defined under NELAC.

The QA Manager reports directly to the Laboratory Director and has access to Corporate QA for advice and resources. This position is able to evaluate data objectively and perform assessments without outside (i.e., managerial) influence. Specific responsibilities include, but are not limited to:

- Having functions independent from laboratory operations for which he/she has quality assurance oversight. Has oversight of quality related procurement.
- Maintaining and updating the QAM. Has signature authority for laboratory quality documents.
- Monitoring and evaluating laboratory certifications; scheduling and oversight proficiency testing samples.
- Monitoring and communicating regulatory changes that may affect the laboratory to management. Ensure compliance with the NELAC standard.
- Training and advising the laboratory staff on quality assurance/quality control procedures that are pertinent to their daily activities.
- Having a general knowledge of the analytical test methods for which data audit/review is performed (and/or having the means of getting this information when needed).
- Arranging for or conducting internal audits on quality systems and the technical operation.
- The laboratory QA Manager will maintain records of ethics-related training, including the type and proof of attendance.
- Maintain, improve, and evaluate the corrective action database and the corrective and preventive action systems.
- Notifying laboratory management of deficiencies in the quality system and ensuring corrective action is taken. Procedures that do not meet the standards set forth in the QAM or laboratory SOPs are temporarily suspended following the procedures outlined in Section 13.
- Monitoring standards of performance in quality control and quality assurance.

- Coordinating document control of SOPs, MDLs, control limits, and miscellaneous forms and information.
- Review of external audit reports and data validation requests.
- Development of suggestions and recommendations to improve quality systems.
- The QA Manager shall have the final authority to accept or reject data, and to stop work in the event that procedures or practices compromise the validity and integrity of analytical data.
- Is not directly involved with cost, schedule or production functional areas.
- Perform trend analysis to identify out-of-control conditions and initiate appropriate corrective actions.

4.2.15 Technical Director

The Technical Director(s) report(s) directly to the Laboratory Director. He/she is accountable for all analyses and analysts with respect to ISO 17025 and NELAC. The scope of responsibility ranges from the new-hire process and existing technology through the ongoing training and development programs for analysts and instrumentation. Specific responsibilities include, but are not limited to:

- Coordinating, writing and reviewing preparation of all test methods, i. e., SOPs, with regard to quality, integrity, regulatory and optimum and efficient production techniques, and subsequent analyst training and interpretation of the SOPs for implementation and unusual project samples. He/she insures that the SOPs are properly managed and adhered to at the bench.
- Has signature authority for QAM and other QA documents.
- Reviewing and approving proposals, in accordance with an established procedure for the review of requests and contracts.
- Monitoring the validity of the analyses performed and data generated in the laboratory. This activity begins with reviewing and supporting all new business contracts, insuring data quality, analyzing internal and external non-conformances to identify root cause issues and implementing the resulting corrective and preventive actions, facilitating the data review process (training, development, and accountability at the bench), and providing technical and troubleshooting expertise on routine and unusual or complex problems.
- Providing training and development programs to applicable laboratory staff as new hires and, subsequently, on a scheduled basis.
- Coordinates audit responses with supervisors and QA Manager.

4.2.16 LIMS Administrator

The LIMS Administrator reports directly to the Laboratory Director. In the pursuit of his/her duties, he/she:

- Establishes and maintains the laboratory information system (LIMS) for tracking all samples in the laboratory.
- Updates and enhances LIMS.

- Programs and tests software modifications/changes.
- Coordinates testing to ensure that all LIMS software accurately performs its intended functions.
- Maintains historical files of software, software operating procedures (manuals), software changes/modifications (Change Log) and software version numbers.
- Maintains log of repairs and service performed on LIMS hardware.
- Develops and verifies security practices to assure the integrity of LIMS data. Identifies threats, potential threats, and future threats.
- Maintains awareness of any environmental conditions of the facility housing the LIMS that may compromise LIMS raw data and informs management.

4.2.17 Operations Manager

The Operations Manager manages and directs the analytical production sections of the laboratory. He/She reports directly to the Laboratory Director. More specifically, he/she:

- Evaluates the level of internal/external non-conformances for all departments.
- Continuously evaluates production capacity and improves capacity utilization.
- Continuously evaluates turnaround time and addresses any problems that may hinder meeting the required and committed turnaround time from the various departments.
- Develops and improves the training of all analysts in cooperation with the Technical Director and QA Manager and in compliance with regulatory requirements.
- Is responsible for efficient utilization of supplies.
- Constantly monitors and modifies the processing of samples through the departments.
- Responsible for timely compliance with audits and corrective actions, as applicable.
- Assists in maintaining a working environment which encourages open, constructive problem solving and continuous improvement.

4.2.18 Supervisors

Supervisors report to the Operations Manager. Each one is responsible to:

- Ensure that analysts in their department adhere to applicable SOPs and the QA Manual.
- With regard to analysts, participates in the selection, training, development of performance objectives and standards of performance, appraisal (measurement of objectives), scheduling, counseling, discipline, and motivation of analysts and documents these activities in accordance with systems developed by the QA and HR Departments. They evaluate staffing sufficiency and overtime needs. Training consists of familiarization with SOP, QC, Safety, and computer systems.
- Encourage the development of analysts to become cross-trained in various methods.
- Provide guidance to analysts in resolving problems encountered daily during sample prep/analysis in conjunction with the Technical Director, Operations Manager, and/or QA Manager.
- Ensure all logbooks are maintained, current, and properly labeled or archived.

- Report all non-conformance conditions to the QA Manager, Technical Director, Operations Manager, and/or Laboratory Director.
- Maintain adequate and valid inventory of reagents, standards and other relevant resources required to perform daily analysis.
- Achieve optimum turnaround time on analyses and compliance with holding times.
- Assist with writing responses to external and internal audit issues.

4.2.19 Laboratory Analysts

Laboratory analysts are responsible for conducting analysis and performing all tasks assigned to them by the supervisor. The responsibilities of the analysts are listed below:

- Perform analyses by adhering to analytical and quality control protocols prescribed by current SOPs, this QA Manual, and project-specific plans honestly, accurately, timely, safely, and in the most cost-effective manner.
- Document standard and sample preparation, instrument calibration and maintenance, data calculations, sample matrix effects, and any observed non-conformance on worklists, benchsheets, lab notebooks and/or the Non-Conformance Database.
- Report all non-conformance situations, instrument problems, matrix problems and QC failures, which might affect the reliability of the data, to their supervisor, the Technical Director, and/or the QA Manager.
- Suggest method improvements to their supervisor, the Technical Director, and the QA Manager.
- Work cohesively as a team in their department to achieve the goals of accurate results, optimum turnaround time, cost effectiveness, cleanliness, complete documentation, and personal knowledge of environmental analysis.

4.2.20 Manager of Project Management/Customer Service Manager

The Manager of Project Management reports to the Laboratory Director and serves as the interface between the laboratory and the laboratory's clients. The staff consists of the Project Management team. With the overall goal of total client satisfaction, the functions of this position are outlined below:

- Technical training and growth of the Project Management team.
- Technical liaison for the Project Management team.
- Human resource management of the Project Management team.
- Responsible to ensure that clients receive the proper sampling supplies.
- Accountable for response to client inquiries concerning sample status.
- Responsible for assistance to clients regarding the resolution of problems concerning COC.
- Ensuring that client specifications, when known, are met by communicating project and quality assurance requirements to the laboratory.
- Notifying the supervisors of incoming projects and sample delivery schedules.

- Accountable to clients for communicating sample progress in daily status meeting with agreed-upon due dates.
- Responsible for discussing with client any project-related problems, resolving service issues, and coordinating technical details with the laboratory staff.
- Responsible for staff familiarization with specific quotes, sample log-in review, and final report completeness.
- Monitor the status of all data package projects in-house to ensure timely and accurate delivery of reports.
- Inform clients of data package-related problems and resolve service issues.

4.2.21 Sample Custodian

- Ensures implementation of proper sample receipt procedures, including COC requirements
- Reports nonconformances associated with condition-upon-receipt of samples
- Logs samples into the LIMS
- Ensures that all samples are stored in the proper environment
- Assists Environmental Health and Safety staff with sample disposal

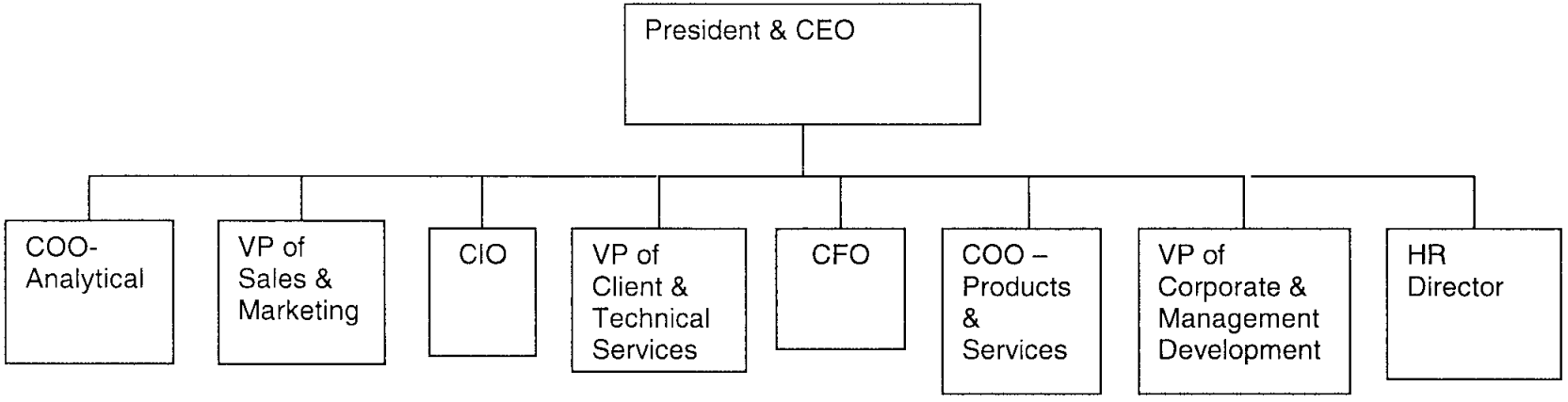
4.3 DEPUTIES

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

Key Personnel	Deputy
Laboratory Director	Erika Jordan
QA Manager	Rhonda Wagar
Radiochemistry Technical Director	Steve Wheland
Metals Technical Director	Diana Petty
EHS Coordinator	Tim Armstrong

Figure 4-1.

Corporate Organization Chart Structure



SECTION 5
QUALITY SYSTEM
(NELAC 5.4.2)

5.1 QUALITY POLICY STATEMENT

The management of TestAmerica and Richland are committed to providing data of known quality to its clients by adhering to approved methodologies, regulatory requirements and the QA/QC protocols described in this manual.

In all aspects of the laboratory and business operations, management is dedicated in maintaining the highest ethical standards. An Ethics Policy sign-off can be viewed in Appendix 1. Training on ethical and legal responsibilities is provided annually and each employee signs off annually on the policy as a condition of employment.

It is TestAmerica's Policy to continually improve systems and provide support to quality improvement efforts in laboratory, administrative and managerial activities. The company recognizes that the implementation of a quality assurance program requires management's commitment and support as well as the involvement of the entire staff.

Richland strives to provide clients with the highest level of professionalism and the best service practices in the industry.

Every staff member at Richland plays an integral part in quality assurance and is held responsible and accountable for the quality of their work. It is, therefore, required that all laboratory personnel are trained and agree to comply with applicable procedures and requirements established by this document.

5.2 ETHICS AND DATA INTEGRITY

TestAmerica is committed to ensuring the integrity of its data and meeting the quality needs of its clients. The 7 elements of TestAmerica's Ethics and Data Integrity Program include:

- An Ethics Policy (Policy No. CA-L-P-001) and employee ethics statements (Appendix 1).
- An Ethics and Compliance Officer (ECO).
- A training program.
- Self-governance through disciplinary action for violations.
- A confidential mechanism for anonymously reporting alleged misconduct and a means for conducting internal investigations of all alleged misconduct. (SOP No. CA-L-S-001)
- Procedures and guidance for recalling data if necessary (SOP No. CA-L-S-001).
- An effective external and internal monitoring system that includes procedures for internal audits (Section 16).

As an American Council of Independent Laboratories (ACIL) member, TestAmerica laboratories adhere to the following ACIL Code of Ethics:

- Produce results, which are accurate and include QA/QC information that meets client pre-defined Data Quality Objectives (DQOs).

- Present services in a confidential, honest and forthright manner.
- Provide employees with guidelines and an understanding of the ethical and quality standards of our industry.
- Operate our facilities in a manner that protects the environment and the health and safety of employees and the public.
- Obey all pertinent federal, state and local laws and regulations and encourage other members of our industry to do the same.
- Educate clients as the extent and kinds of services available.
- Assert competency only for work for which adequate personnel and equipment are available and for which adequate preparation has been made.
- Promote the status of environmental laboratories, their employees, and the value of services rendered by them.

5.3 QUALITY SYSTEM SUPPORTING DOCUMENTATION

The laboratory's Quality System is communicated through a variety of documents prepared by the laboratory and company management:

- Quality Assurance Manual (QAM) Template
- Quality Assurance Manual – Each laboratory has a lab specific quality assurance manual.
- Corporate SOPs and Policies - Corporate SOPs and Policies are developed for use by all relevant laboratories. They are incorporated into the laboratory's normal SOP distribution, training and tracking system. Corporate SOPs may be general or technical.
- Work Instructions - A subset of procedural steps, tasks or forms associated with an operation of a management system (e.g., checklists, preformatted bench sheets, forms).
- Laboratory SOPs – General, Technical and EH&S
- Corporate TestAmerica QA/QC Policy Memorandums (Refer to Section 3.4).
- Laboratory QA/QC Policy Memorandums (Refer to Section 3.4).
- Laboratory Chemical Hygiene Plan
- Laboratory Waste Management Plan (comprised of several SOPs)
- Laboratory Radiation Safety Program including Radioactive Material License.

The laboratory shall have SOPs in place for (but not limited to) the following areas:

- Sample Management
- Reagent/Standard Preparation
- General Laboratory Techniques
- Test Methods (for all procedures performed)
- Glassware Cleaning
- Equipment Calibration and Maintenance
- Quality Control
- Corrective Action
- Data Reduction and Validation

- Reporting
- Records Management (contained in this QAM)
- Radioactive and Hazardous Material Management

5.3.1 Order of Precedence

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

- TestAmerica QA/QC Policy Memorandum - Corporate
- Laboratory QA/QC Policy Memorandum
- Quality Assurance Manual
- Corporate SOPs and Policies
- Laboratory SOPs and Policies
- Other (Work Instructions (WI), Operator Aids, memos, flow charts, etc.)

5.4 QA/QC OBJECTIVES FOR THE MEASUREMENT OF DATA

Quality Assurance (QA) and Quality Control (QC) are activities undertaken to achieve the goal of producing data that accurately characterize the sites or materials that have been sampled. Quality Assurance is generally understood to be more comprehensive than Quality Control. Quality Assurance can be defined as the integrated system of activities that ensures that a product or service meets defined standards.

Quality Control is generally understood to be limited to the analyses of samples and to be synonymous with the term *"analytical quality control"*. QC refers to the routine application of statistically based procedures to evaluate and control the accuracy of results from analytical measurements. The QC program includes procedures for estimating and controlling precision and bias and for determining reporting limits.

Request for Proposals (RFPs) and Quality Assurance Project Plans (QAPP) provide a mechanism for the client and the laboratory to discuss the data quality objectives in order to ensure that analytical services closely correspond to client needs. The client is responsible for developing the QAPP. In order to ensure the ability of the laboratory to meet the Data Quality Objectives (DQOs) specified in the QAPP, clients are advised to allow time for the laboratory to review the QAPP before being finalized. Additionally, the laboratory will provide support to the client for developing the sections of the QAPP that concern laboratory activities.

Historically, laboratories have described their QC objectives in terms of precision, accuracy, representativeness, comparability, completeness, selectivity and sensitivity (PARCCSS).

5.4.1 Precision

The laboratory objective for precision is to meet the performance for precision demonstrated for the methods on similar samples and to meet data quality objectives of the EPA and/or other regulatory programs. Precision is defined as the degree of reproducibility of measurements under a given set of analytical conditions (exclusive of field sampling variability). Precision is documented on the basis of replicate analysis, usually duplicate or matrix spike (MS) duplicate samples.

5.4.2 Accuracy

The laboratory objective for accuracy is to meet the performance for accuracy demonstrated for the methods on similar samples and to meet data quality objectives of the EPA and/or other regulatory programs. Accuracy is defined as the degree of bias in a measurement system. Accuracy may be documented through the use of laboratory control samples (LCS) and/or MS. A statement of accuracy is expressed as an interval of acceptance recovery about the mean recovery.

5.4.3 Representativeness

The laboratory objective for representativeness is to provide data which is representative of the sampled medium. Representativeness is defined as the degree to which data represent a characteristic of a population or set of samples and is a measurement of both analytical and field sampling precision. The representativeness of the analytical data is a function of the procedures used in procuring and processing the samples. The representativeness can be documented by the relative percent difference between separately procured, but otherwise identical samples or sample aliquots.

The representativeness of the data from the sampling sites depends on both the sampling procedures and the analytical procedures. The laboratory may provide guidance to the client regarding proper sampling and handling methods in order to assure the integrity of the samples.

5.4.4 Comparability

The comparability objective is to provide analytical data for which the accuracy, precision, representativeness and reporting limit statistics are similar to these quality indicators generated by other laboratories for similar samples, and data generated by the laboratory over time.

The comparability objective is documented by inter-laboratory studies carried out by regulatory agencies or carried out for specific projects or contracts, by comparison of periodically generated statements of accuracy, precision and reporting limits with those of other laboratories, and by the degree to which approval from the US EPA or other pertinent regulatory agencies is obtained for any procedure for which significant modifications have been made.

5.4.5 Completeness

The completeness objective for data is 90% (or as specified by a particular project), expressed as the ratio of the valid data to the total data over the course of the project. Data will be considered valid if they are adequate for their intended use. Data usability will be defined in a QAPP, project scope or regulatory requirement. Data validation is the process for reviewing data to determine its usability and completeness. If the completeness objective is not met, actions will be taken internally and with the data user to improve performance. This may take the form of an audit to evaluate the methodology and procedures as possible sources for the difficulty or may result in a recommendation to use a different method.

5.4.6 Selectivity

Selectivity is defined as: The capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances. Target analytes are separated from non-target constituents and subsequently identified/detected through one or more of the following, depending on the analytical method: extractions (separation), digestions (separation), interelement corrections (separation), use of matrix modifiers (separation), specific retention times (separation and identification), confirmations with different detectors (separation and identification), specific wavelengths (identification), specific mass spectra (identification), etc..

5.4.7 Sensitivity

Sensitivity refers to the amount of analyte necessary to produce a detector response that can be reliably detected or quantified.

5.5 CRITERIA FOR QUALITY INDICATORS

The laboratory has SOPs that summarize the precision and accuracy acceptability limits for analyses performed at Richland. The SOPs include an effective date and are updated each time new limits are generated. Some acceptability limits are derived from US EPA methods when they are required.

5.5.1 QC Charts

Trend Analysis

Trend Analysis shall be performed by the QA Manager or designee(s) quarterly to identify significant problems within trends and evaluated for timely and appropriate corrective actions. Quality related information which can be included as part of the trend analysis are:

- Performance Data
- Audit reports
- Surveillance reports
- Nonconformance reports
- Failure rates
- Quality-related information from external sources

Trends determined to be adverse to quality shall be reported to the responsible supervisor for corrective action.

Counting instrument QC data are maintained electronically. Hard copies of control charts are prepared upon request. Trend analysis is performed on an as needed basis.

5.6 QUALITY SYSTEM METRICS

In addition to the QC parameters discussed above, the entire Quality System is evaluated on a monthly basis through the use of specific metrics (refer to Section 17). These metrics are used to drive continuous improvement in the laboratory's Quality System.

SECTION 6
DOCUMENT CONTROL
(NELAC 5.4.3)

6.1 OVERVIEW

The QA Department is responsible for the control of documents used in the laboratory to ensure that approved, up-to-date documents are in circulation and out-of-date (obsolete) documents are archived or destroyed. The following documents, at a minimum, must be controlled at each laboratory Facility:

- Laboratory Quality Assurance Manual
- Laboratory Standard Operating Procedures (SOP)
- Laboratory Policies
- Work Instructions, Operator Aids and Forms
- Corporate Policies and Procedures distributed outside the intranet

The Corporate staff posts Corporate Manuals, SOPs, Policies, Work Instructions, White Papers and Training Materials on the company intranet site. These are collectively termed "Official Documents" and encompass the Policies and Procedures that all facilities are required to employ. These official documents are only considered controlled when they are read on the company intranet site. Printed copies are considered uncontrolled unless the laboratory physically distributes them as controlled documents. A detailed description of the procedure for issuing, authorizing, controlling, distributing, and archiving official documents is found in Corporate SOP No. CW-Q-S-001, Corporate Document Control and Archiving.

The laboratory QA Department also maintains access to various references and document sources integral to the operation of the laboratory. This includes reference methods and regulations. Instrument manuals (hard or electronic copies) are also maintained by the laboratory.

The laboratory maintains control of records for raw analytical data and supporting records such as audit reports and responses, logbooks, standard logs, training files, MDL studies, Proficiency Testing (PT) studies, certifications and related correspondence, and corrective action reports. Raw analytical data consists of bound logbooks, instrument printouts, any other notes, magnetic media, electronic data and final reports. Discussion on records control is described in Section 15.

The maintenance of purchasing data is discussed in Section 9. The maintenance of sales and marketing contracts is discussed in Section 7.

6.2 DOCUMENT APPROVAL AND ISSUE

The pertinent elements of a control system for each document include a unique name and number, the number of pages of the item, the effective date, revision number and the laboratory's name. The QA Manager is responsible for the maintenance of the system and maintains the items in the QA files.

Controlled documents are authorized by the QA Department and other management. In order to develop a new document, a manager submits an electronic or hard copy draft to the QA Department for suggestions and approval before use. Upon approval, QA personnel add the identifying version information to the document and retains the official document on file. The official document is provided as needed to those using it. Controlled documents shall be available at all locations where the operational activity described in the document is performed (may include electronic access). Controlled documents are identified as such and records of their distribution are kept by the QA Department. Document control may be achieved by either electronic or hardcopy distribution. The QA Department maintains a list of the official versions of controlled documents.

Quality System Policies and Procedures will be reviewed at a minimum of every two years or more frequent when required and revised as appropriate. Changes to documents occur when a procedural change warrants a revision of the document.

6.3 PROCEDURES FOR DOCUMENT CONTROL POLICY

Uncontrolled copies of the QAM must not be used within the laboratory. A list of controlled manual holders is maintained in the SOP database. Previous revisions and back-up data are stored by the QA department.

For changes to SOPs
All SOPs and subsequent revisions shall be reviewed and approved by the Laboratory Director, a technical specialist, the QA Manager and Environmental Health and Safety Coordinator. Each reviewer is responsible for ensuring that the procedure is accurate and adequate based on their area of expertise.

Upon receipt of new procedures/revisions of controlled documents, the receiver shall remove the old version and insert the updated version of the document. The receiver will sign a document receipt form acknowledging the manual has been updated and will forward the signed form and old revision to the QA Department.

For clients who require approval of procedural change, a copy of the proposed revision shall be sent to the client for approval. The change shall not be implemented for that client until the client's requirements have been met.

Uncontrolled copies of manuals and SOPs will only be supplied to clients upon request. Uncontrolled copies will not be updated after distribution.

Forms, worksheets, work instructions and operator aids are organized by a QA assigned number. This number, date created, and revision number shall be placed on the bottom of the form. An original or copy of the form shall be maintained in the Quality files. Form revisions shall have the same requirements as the original form.

6.4 OBSOLETE DOCUMENTS

All invalid or obsolete documents are removed, or otherwise prevented from unintended use. The laboratory has specific procedures as described above to accomplish this. In general, obsolete documents are collected from employees according to distribution lists and are destroyed. At least one copy of the obsolete document is archived as described in Section 15.

SECTION 7
REVIEW OF WORK REQUEST

7.1 OVERVIEW

Richland has established procedures for the review of work requests, tender and contracts, oral or written. The procedures include evaluation of the laboratory's capability and resources to meet the contract's requirements within the requested time period. All requirements, including the methods to be used, must be adequately defined, documented and understood. For many environmental sampling and analysis programs, testing design is site or program specific and does not necessarily "fit" into a standard laboratory service or product. It is TestAmerica's intent to provide both standard and customized environmental laboratory services to our clients.

A thorough review of technical and QC requirements contained in contracts is performed to ensure project success. The appropriateness of requested methods, and the lab's capability to perform them must be established. Projects, proposals and contracts are reviewed for adequately defined requirements and TestAmerica's capability to meet those requirements. Alternate test methods that are capable of meeting the clients' requirements may be proposed by the lab. A review of the lab's capability to analyze non-routine analytes is also part of this review process.

All projects, proposals and contracts are reviewed for the client's requirements in terms of analyte lists, test methodology requested, sensitivity (detection and reporting levels), accuracy, and precision requirements (% Recovery and RPD). The reviewer ensures that the laboratory's test methods are suitable to achieve these regulatory and client requirements and that the laboratory holds the appropriate certifications and approvals to perform the work. The laboratory and any potential subcontract laboratories must be certified, as required, for all proposed tests.

The laboratory must determine if it has the necessary physical, personnel and information resources to meet the contract, and if the personnel have the expertise needed to perform the testing requested. Each proposal is checked for its impact on the capacity of the laboratory's equipment and personnel. As part of the review, the proposed turnaround time will be checked for feasibility.

Electronic or hard copy deliverable requirements are evaluated against the lab's capacity for production of the documentation.

If the laboratory cannot provide all services but intends to subcontract or workshare such services, whether to another TestAmerica facility or to an outside firm, this will be documented and discussed with the client prior to contract approval. (Refer to Section 8 for Subcontracting Procedures.)

The laboratory informs the client of the results of the review if it indicates any potential conflict, deficiency, lack of accreditation, or inability of the lab to complete the work satisfactorily. Any discrepancy between the client's requirements and TestAmerica's capability to meet those requirements is resolved in writing before acceptance of the contract. It is necessary that the contract be acceptable to both the laboratory and the client. Amendments initiated by the client and/or TestAmerica, are documented in writing.

All contracts, QAPPs, Sampling and Analysis Plans (SAPs), contract amendments, and documented communications become part of the project record.

The review process is repeated when there are amendments to the original contract by the client, and the participating personnel are informed of the changes.

7.2 REVIEW SEQUENCE AND KEY PERSONNEL

Appropriate personnel will review the work request at each stage of evaluation.

For routine projects and other simple tasks, a review by the Project Manager (PM) is considered adequate. The PM confirms that the laboratory has any required certifications, that it can meet the clients' data quality and reporting requirements and that the lab has the capacity to meet the clients turn around needs.

For new, complex or large projects, the proposed contract is given to the National Account Director, who will decide which lab will receive the work based on the scope of work and other requirements, including certification, testing methodology, and available capacity to perform the work. The contract review process is outlined in SOP No. CA-L-P-002, Contract Compliance Policy.

This review encompasses all facets of the operation. The scope of work is distributed to the appropriate personnel, as needed based on scope of contract, to evaluate all of the requirements shown above (not necessarily in the order below)

- Legal & Contracts Director
- General Manager
- The Laboratory Manager of Project Management
- The Laboratory Operations Manager
- Laboratory and/or Corporate Technical Directors
- Laboratory and/or Corporate Information Technology Managers/Directors
- Regional and/or National Account representatives
- Laboratory and/or Corporate Quality
- Laboratory and/or Corporate Environmental Health and Safety Managers/Directors
- The Laboratory Director reviews the formal laboratory quote and makes final acceptance for their facility.

The National Account Director, Legal Contracts Director, or local account representative then submits the final proposal to the client.

In the event that one of the above personnel is not available to review the contract, his or her back-up will fulfill the review requirements.

The Legal & Contracts Director maintains copies of all signed contracts. A copy also will be maintained by the project management group.

7.3 DOCUMENTATION

Appropriate records are maintained for every contract, tender or work request. All stages of the contract review process are documented and include records of any significant changes.

Records are maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract. The PM is responsible for maintaining all documentation including phone logs of conversations and email correspondence with the client.

7.3.1 Project-Specific Quality Planning

Communication of contract specific technical and QC criteria is an essential activity in ensuring the success of site specific testing programs. To achieve this goal, Richland assigns a PM to each client. The PM is the first point of contact for the client. It is the PM's responsibility to ensure that project specific technical and QC requirements are effectively evaluated and communicated to the laboratory personnel before and during the project. QA department involvement may be needed to assist in the evaluation of custom QA requirements.

PMs are the direct client contact and they ensure resources are available to meet project requirements. Although PMs do not have direct reports or staff in production, they coordinate opportunities and work with laboratory management and supervisory staff to ensure available resources are sufficient to perform work for the client's project. Project management is positioned between the client and laboratory resources.

Prior to work on a new project, the dissemination of project information and/or project opening meetings may occur to discuss schedules and unique aspects of the project. Items to be discussed may include the project technical profile, turnaround times, methods, analyte lists, reporting limits, deliverables, sample hazards, or other special requirements. The PM introduces new projects to the laboratory staff through project kick-off meetings or to the supervisory staff. These meetings provide direction to the laboratory staff in order to maximize production and client satisfaction, while maintaining quality. In addition, project notes may be associated with each sample batch as a reminder upon sample receipt and analytical processing.

During the project, any change that may occur within an active project is agreed upon between the client/regulatory agency and the PM/laboratory. These changes (e.g., use of a non-standard method or modification of a method) and approvals must be documented prior to implementation. Documentation pertains to any document, e.g., letter, e-mail, variance, contract addendum, which has been signed by both parties.

Such changes are updated to the project notes and are introduced to the managers at these meetings. The laboratory staff is then introduced to the modified requirements via the PM or the individual laboratory supervisor. After the modification is implemented into the laboratory process, documentation of the modification is made in the case narrative of the data report(s) or by communication with the client.

TestAmerica strongly encourages client visits to the laboratory and for formal/informal information sharing session with employees in order to effectively communicate ongoing client needs as well as project specific details for customized testing programs.

SECTION 8
SUBCONTRACTING OF TESTS
(NELAC 5.4.5)

8.1 OVERVIEW

For the purpose of this quality manual, the phrase subcontract laboratory refers to a laboratory external to the corporate network. The phrase "work sharing" refers to internal transfers of samples between company laboratories. The term outsourcing refers to the act of subcontracting tests.

When contracting with our clients, the laboratory makes commitments regarding the services to be performed and the data quality for the results to be generated. When we must outsource testing for our clients because project scope, changes in laboratory capabilities, capacity or unforeseen circumstances, we must be assured that the subcontractors or work sharing laboratories understand the requirements and will meet the same commitments we have made to the client. Refer to the SOP on Subcontracting Procedures (CA-L-S-002) and the Work Sharing Process SOP (CA-C-S-001).

When outsourcing analytical services, the laboratory will assure, to the extent necessary, that the subcontract or work sharing laboratory maintains a program consistent with the requirements of this document, the requirements specified in NELAC/ISO 17025 and/or the client's Quality Assurance Project Plan (QAPP). All QC guidelines specific to the client's analytical program are transmitted to the subcontractor and agreed upon before sending the samples to the subcontract facility. Additionally, work requiring accreditation will be placed with an appropriately accredited laboratory. The laboratory performing the subcontracted work will be identified in the final report, as will non-NELAC accredited work where required.

Project Managers (PMs), Customer Service Managers (CSM), or Regional Account Executives (RAE) for the Export Lab are responsible for obtaining client approval prior to outsourcing any samples. The laboratory will advise the client of a subcontract or work sharing arrangement in writing and when possible approval from the client shall be retained in the project folder.

Note: In addition to the client, some regulating agencies, such as the US Army Corps of Engineers and the USDA, require notification prior to placing such work.

For DOE projects, the laboratory shall not use any third party (sub-tier) laboratories, including other TestAmerica laboratories, for performance of work without written approval from the DOE Procurement Representative. Note that some DOE clients may not allow any subcontracting to a sub-tier laboratory. The laboratory using a sub-tier laboratory shall document and is responsible for ensuring that such sub-tier laboratory meets all of the requirements in this section, including being available for client inspections and audits.

8.2 QUALIFYING AND MONITORING SUBCONTRACTORS

Whenever a PM, Regional Account Executive (RAE) or Customer Service Manager (CSM) becomes aware of a client requirement or laboratory need where samples must be outsourced to another laboratory, the other laboratory(s) shall be selected based on the following:

- The first priority is to attempt to place the work in a qualified network laboratory;
- Firms specified by the client for the task (Documentation that a subcontractor was designated by the client must be maintained with the project file. This documentation can be as simple as placing a copy of an e-mail from the client in the project folder);
- Firms listed as pre-qualified and currently under a subcontract with the company;
- Firms identified in accordance with the company's Small Business Subcontracting program as small, women-owned, veteran-owned and/or minority-owned businesses;
- In addition, the firm must hold the appropriate certification to perform the work required.

With the exception of DOD and DOE programs noted in 8.1, all intra-company laboratories are pre-qualified for outsourcing provided they hold the appropriate accreditations, can adhere to the project/program requirements and the client approved sending samples to that laboratory. The client must provide acknowledgement that the samples can be sent to that facility (an e-mail is sufficient documentation or if acknowledgement is verbal, the date, time, and name of person providing acknowledgement must be documented). The originating laboratory is responsible for communicating all technical, quality, and deliverable requirements as well as other contract needs. Refer to SOP No. CA-C-S-001, Work Sharing Process.

When the potential sub-contract laboratory does not meet the above criteria, then to begin the process, Account Executives or PMs may nominate a laboratory as a subcontractor based on need. The decision to nominate a laboratory must be approved by the Laboratory Director. The Laboratory Director requests that the QA Manager begin the process of approving the subcontract laboratory. The client must provide acknowledgement that the samples can be sent to that facility (an e-mail is sufficient documentation or if acknowledgement is verbal, the date, time, and name of person providing acknowledgement must be documented).

8.2.1 The QA Manager must ensure that the Subcontracting Approval Form (Figure 8-2) has been completed and have supporting documentation on file prior to initiation of any work. In some cases a network laboratory or Corporate QA may have already completed an approval of a subcontracting laboratory. A listing of all approved subcontracting laboratories and supporting documentation is available on the TestAmerica intranet site. If this option is used, the laboratory must ensure that the subcontracting lab is capable of meeting the needs of the current project. A letter or e-mail is sent to the lab requesting the following information:

8.2.1.1 A copy of their Quality Assurance Manual (controlled if possible). Ensure data quality limits for relevant methods are acceptable and that training procedures are adequate. (Optional if Laboratory is NELAC accredited.)

8.2.1.2 Evidence of a current SOP per method. A copy of the first page and signature page of the SOP is acceptable. A table of contents including effective dates may also be acceptable. The SOP can be examined if an on-site audit is performed. (Optional if Laboratory is NELAC accredited.)

8.2.1.3 The most recent 2 sets of full proficiency testing (PT) results relevant to the analyses of interest and any associated corrective action. (Optional if Laboratory is NELAC accredited.)

8.2.1.4 Copy of necessary certifications verifying that the required approvals are current. Ensure that all needed analytes are included; some may not be accredit-able (if so, document). Certificate and scope of International Standard accreditation are required, when applicable. Project Management requests a copy of the current certification at the start-up phase of the client's project and each subsequent project and notification of any revocation of accreditation.

8.2.1.5 Example final report to confirm format is compliant and provides the necessary information. (Optional if Laboratory is NELAC accredited.)

8.2.1.6 Statement of Qualification (SOQ) or summary list of Technical Staff and Qualifications – position, education and years of experience. (Optional if Laboratory is NELAC accredited.)

8.2.1.7 USDA permit if soils less than three feet deep from New York, North Carolina, South Carolina, Georgia, Florida, Tennessee, Alabama, Mississippi, Louisiana, Arkansas, Texas, Oklahoma, New Mexico, Arizona, California, Hawaii, or outside the continental U. S. are to be analyzed. These samples require special shipping measures; check with the EHS Department. It may be necessary to heat-treat the samples before shipping if the subcontract laboratory does not have a USDA permit; however, some analytes/tests may be irrelevant after heat treatment.

8.2.1.8 Insurance Certificate. This is required by TestAmerica's Chief Financial Officer.

8.2.1.9 State Audit with Corrective Action Response. (Optional if Laboratory is NELAC accredited.)

8.2.1.10 Description of Ethics and Data Integrity Plan. (Optional if Laboratory is NELAC accredited.)

8.2.1.11 DoD work includes additional requirements as described in Section 8.1 above.

8.2.1.12 Copy of Raw Data Associated with first project sent to the Laboratory. The raw data is reviewed by the QA Manager and the PM to ensure that the results meet the client's needs. This requirement can be skipped if an on-site visit of the laboratory is planned. (Optional if Laboratory is NELAC accredited.) Laboratories worked with previously [minimum of 6 months] are grandfathered in.

Note: The lab does not need to complete the approval form (Figure 8-2) if information on the intranet site is sufficient to meet the needs of the project.

Note: There are some instances where a subcontracting laboratory accredited by a State or Agency program may not require all elements listed below. If the accreditation is NELAC, follow the guidelines below. If the accreditation is not NELAC, contact Corporate QA for approval.

8.2.2 The client will assume responsibility for the quality of the data generated from the use of a subcontractor they have requested the lab to use. The company does not certify laboratories. The subcontractor is on our approved list and can only be recommended to the extent that we would use them.

8.2.3 The status and performance of qualified subcontractors will be monitored periodically by the Laboratory who originally posts a subcontracting lab to the intranet site.

- Complaints shall be investigated. Documentation of the complaint, investigation and corrective action will be maintained in the subcontractor's file on the intranet site. Complaints must be posted using the Vendor Performance Report (Form No. CW-F-WI-009).
- Information must be updated on the intranet when new information is received from the subcontracted laboratories.
- Subcontractors in good standing will be retained on the intranet listing. The QA Manager will notify all network laboratories and Corporate QA if any laboratory is removed from the intranet site. This notification will be posted on the intranet site and e-mailed to all Lab Directors/Managers, QA Managers and Sales Directors.

8.3 OVERSIGHT AND REPORTING

The PM must request that the selected subcontractor be presented with a subcontract, if one is not already executed between the laboratory and the subcontractor. The subcontract must include terms which flow down the requirements of our clients, either in the subcontract itself or through the mechanism of work orders relating to individual projects. A standard subcontract and the Lab Subcontractor Vendor Package (posted on the intranet) can be used to accomplish this, and the Legal & Contracts Director can tailor the document or assist with negotiations, if needed. The PM (or RAE or CSM) responsible for the project must advise and obtain client consent to the subcontract as appropriate, and provide the scope of work to ensure that the proper requirements are made a part of the subcontract and are made known to the subcontractor.

Prior to sending samples to the subcontracted laboratory, the PM confirms their certification status to determine if it's current and scope-inclusive. The information is documented on a Subcontracted Sample Form (Figure 8-3) and the form is retained in the project folder. For network laboratories, certifications can be viewed on the company website.

The Sample Control department is responsible for ensuring compliance with QA requirements and applicable shipping regulations when shipping samples to a subcontracted laboratory.

All subcontracted samples must be accompanied by a Chain of Custody (COC). A copy of the original COC sent by the client must be included with all samples subbed within the network.

The PM will communicate with the subcontracted laboratory to monitor the status of the analyses, facilitate successful execution of the work and ensure the timeliness and completeness of the analytical report.

Non-NELAC accredited work must be identified in the subcontractor's report as appropriate. If NELAC accreditation is not required, the report does not need to include this information.

Reports submitted from subcontractor laboratories are not altered and are included in their original form in the final project report. This clearly identifies the data as being produced by a subcontractor facility. If subcontract laboratory data is incorporated into the laboratories EDD

(i.e., imported), the report must explicitly indicate which lab produced the data for which methods and samples.

Note: The results submitted by a network work sharing laboratory may be transferred electronically and the results reported by the network work sharing lab are identified on the final report. The report must explicitly indicate which lab produced the data for which methods and samples. The final report must include a copy of the completed COC for all work sharing reports.

8.4 CONTINGENCY PLANNING

With the exception of DOD and DOE programs noted in 8.1, the Laboratory Director may waive the full qualification of a subcontractor process temporarily to meet emergency needs. In the event this provision is utilized, Corporate QA must be informed, and the QA Manager will be required to verify adequacy of proficiency scores and certifications. The laboratory must also request a copy of the raw data to support the analytical results for the first project submitted to the subcontract laboratory unless the laboratory has NELAC accreditation. The raw data is reviewed by the QA Manager and the PM to ensure that the results meet the client's needs. The QA Manager will request full documentation and qualify the subcontractor under the provisions above. The approval process should be completed within 30 calendar days of subcontracting.

Figure 8-1.

Example - Client-Approved Subcontractor Form

Client Information:

Client Name & Account Number:_____

Client Contact: _____

Client Address: _____

_____

Project Information: (Please choose all applicable.)

- **Certification required: □ State □ NELAC □ A2LA □ Method____**

  □ Target compound_____ □ Other_____

- **Required Turn around time (method provisional)_____**

Subcontractor's Information:

Subcontractor's Name: _____

Subcontractor's Contact: _____

Subcontractor's Email: _____

Subcontractor's Address: _____

_____

Subcontractor's Phone Number: _____

Analytical Test/Compound/Method to be subcontracted: _____

Certification Statement:

I hereby give Richland permission to use the above noted subcontractor for the above noted testing procedures/methods. I realize that the above subcontractor will be held liable for the validity of the above mentioned testing procedures/methods. All subcontractors shall meet the requirements as spelled out in project information and will follow all analytical holding times and turn around times for analytical reports. The subcontract laboratory, and not TestAmerica, will be held liable for liquidated damages for delays in subcontracted analytical reports and/or electronic data deliverables.

_____

Client Signature **Date**

Figure 8-2.
Example - Subcontracting Laboratory Approval Form (Initial / Renewal)

SUBCONTRACTING LABORATORY APPROVAL

Reference: Section 8 – Quality Assurance Manual

Date: _____
Laboratory: _____

Address: _____
_____

Contact and e-mail address: _____
Phone: Direct _____ Fax _____

Requested Item[3]	Date Received	Reviewed/ Accepted	Date
1. QA Manual[3]			
2. Copy of State Certification[1]			
3. State Audit with Corrective Action Response (or NELAC or A2LA Audit)[3]			
4. Most Recent (and relevant) 2 Sets of WP/WS Reports with Corrective Action Response[1,3]			
5. SOQ or Summary list of Technical Staff and Qualifications [3]			
6. SOPs for Methods to Be Loadshifted[2,3]			
7. USDA Soil Permit			
8. Insurance Certificate			
9. Sample Report[3]			
10. For DoD Work: Statement that Lab quality system complies with QSM.			
11. For DoD Work: Approved by specific DoD Component laboratory approval process.			
11. Description of Ethics Program[3]			

1 - Required when emergency procedures are implemented.
2 - Some labs may not submit copies due to internal policies. In these cases, a copy of the first page and signature page of the SOP is acceptable. This requirement may also be fulfilled by supplying a table of SOPs with effective dates.
3 – If the laboratory has NELAC accreditation, Item #1,3,4, 5, 6, 9 and 10 are optional.

On Site Audit Planned: YES NO If yes, Date Completed: _____ By Whom: _____

Comments:

Lab Acceptable for Subcontracting Work: YES NO Limitations: _____

QA Manager: _____ Date: _____

Figure 8-3.

Example - Subcontracted Sample Form

Date/Time: _____

Subcontracted Laboratory Information:

- Subcontractor's Name: _____
- Subcontractor Point of Contact: _____
- Subcontractor's Address: _____
- Subcontractor's Phone: _____
- Analyte/Method: _____
- Certified for State of Origin: _____
- NELAC Certified: Yes_____No_____
- A2LA (or ISO 17025) Certified: Yes_____No_____
- CLP-like Required: Yes_____No_____
  (Full doc required)
- Requested Sample Due Date: _____
  (Must be put on COC)

Project Manager: _____

Laboratory Sample # Range: _____
(Only of Subcontracted Samples)

Laboratory Project Number (Billing Control #): _____

All subcontracted samples are to be sent via bonded carrier and Priority Overnight. Please attach tracking number below and maintain these records in the project files.

PM Signature_____**Date**_____

SECTION 9
PURCHASING SERVICES AND SUPPLIES
(NELAC 5.4.6)

9.1 OVERVIEW

Evaluation and selection of suppliers and vendors is performed, in part, on the basis of the quality of their products, their ability to meet the demand for their products on a continuous and short term basis, the overall quality of their services, their past history, and competitive pricing. This is achieved through evaluation of objective evidence of quality furnished by the supplier, which can include certificates of analysis, recommendations, and proof of historical compliance with similar programs for other clients. To ensure that quality critical consumables and equipment conform to specified requirements, all purchases from specific vendors are approved by a member of the supervisory or management staff.

Capital expenditures are made in accordance with the Controlled Purchases Procedure, CW-F-S-004. Only one quote is required where the item being purchased is a sole source product. Examples of sole source capital expenditures are laboratory test equipment, client specified purchases and building leases. A minimum of two quotes is required where the opportunity exists to source from more than one vendor. All documentation related to the purchase of capital items will be maintained in the individual CapEx files located in Corporate Purchasing. Data will be held in accordance with the record retention policy.

TestAmerica will enter into formal contracts with vendors when it is advantageous to do so. Contracts will be signed in accordance with the Authorization Matrix Policy, CW-F-P-002. Examples of items that are purchased through vendor contracts are laboratory instruments, consumables, copiers and office supplies. Request for Proposals (RFP's) will be issued where more information is required from the potential vendors than just price. RFP's allow TestAmerica to determine if a vendor is capable of meeting requirements such as supplying all of the TestAmerica facilities, meeting required quality standards and adhering to necessary ethical and environmental standards. The RFP process also allows potential vendors to outline any additional capabilities they may offer.

Non-capital expenditure items are purchased through the requisition and approval process in JD Edwards or through other TestAmerica authorized methods (approved web-sites, purchasing cards). Labs have the ability to select from the approved vendors in JD Edwards.

9.2 GLASSWARE

Glassware used for volumetric measurements must be Class A or verified for accuracy according to laboratory procedure. Pyrex (or equivalent) glass should be used where possible. For safety purposes, thick-wall glassware should be used where available.

9.3 REAGENTS, STANDARDS & SUPPLIES

Chemical reagents, solvents, glassware, and general supplies are ordered as needed to maintain sufficient quantities on hand. Purchasing guidelines for equipment and reagents must meet with the requirements of the specific method and testing procedures for which they are being purchased.

9.3.1 Purchasing

The nature of the analytical laboratory demands that all material used in any of the procedures is of a known quality. The wide variety of materials and reagents available makes it advisable to specify recommendations for the name, brand, and grade of materials to be used in any determination. This information is contained in the method SOP.

Procurement of Quality-Related Items/Services

The quality of instruments, equipment, standards, reagents and laboratory containers used in analyses must be known so that their effect upon analytical results can be defined. These items must meet a minimum quality requirement. Laboratory staff responsible for selection and purchasing shall be trained to this detailed procurement process. The training documentation is encompassed in the QAM training. Quality related items (QRIs) shall be evaluated to ensure that they meet the requirements and specifications established by Richland. These requirements and specifications can be obtained from project-specific QA requirements, data quality objectives, analytical method requirements and defined technical specifications. Verification that such requirements are met can be performed by one of the following:

- Source evaluation and selection (i.e. historical performance)
- Source verification
- Audit
- Examination of items or services before use

Quality specifications shall be included or referenced in the purchasing documents for the procurement of the applicable items/services. Reference to an approved model, lot number, catalog line item or chemical grade is sufficient. Procurement records shall be maintained, including evidence of conformance.

If applicable, the procurement process shall ensure that the supplier, designer and end-user requirements are met during the production phase.

When the QRI is received it shall be verified that the specified requirements have been met, such as material certificates are included and delivered on time. If the QRI meets the requirements, it is released for use, maintained until use and documentation (i.e. packing slips) is filed by the purchasing department.

If the QRI does not meet specifications, a Nonconformance Memo shall be generated. Corrective actions for failure of an item/service to meet required specifications are as follows:

- Review current supplies and segregate the affected items.
- Return item(s) to vendor or destroy
- Evaluate a new lot or alternate supplier
- Evaluate the impact on product or process
- Notification to the appropriate management

For items that are used regularly by Richland where no unique requirements or specifications are required, the items may be purchased off-the-shelf. These items are ordered from the supplier on the basis of specifications set forth in the supplier's published product description.

Off-the-shelf items include general laboratory supplies such as glassware, filter paper and pipettes.

Evaluation of instruments purchased shall be conducted according to acceptance testing (i.e. initial calibration). Acceptance criteria may include instrument reliability, sensitivity, stability, accuracy and ability to interface with existing computer systems and networks.

9.3.2 Receiving

It is the responsibility of the office manager to receive the shipment. Once the ordered reagents or materials are received, the analyst compares the information on the label or packaging to the original order to ensure that the purchase meets the quality level specified. Material Safety Data Sheets (MSDSs) are kept in the specific laboratories and online through the Company's intranet website. Anyone may review these for relevant information on the safe handling and emergency precautions of on-site chemicals.

9.3.3 Specifications

There are many different grades of analytical reagents available to the analyst. All methods in use in the laboratory specify the grade of reagent that must be used in the procedure. If the quality of the reagent is not specified, it may be assumed that it is not significant in that procedure and, therefore, any grade reagent may be used. It is the responsibility of the analyst to check the procedure carefully for the suitability of grade of reagent.

Chemicals must not be used past the manufacturer's expiration date and must not be used past the expiration time noted in a method SOP. If dates are not provided, the laboratory may contact the manufacturer to determine an expiration date.

The laboratory assumes a five year expiration date on inorganic dry chemicals unless noted otherwise by the manufacturer or by the reference source method.

- An expiration date can not be extended if the dry chemical is discolored or appears otherwise physically degraded, the dry chemical must be discarded.

Compressed gases in use are checked for pressure and secure positioning daily. The minimum total pressure must be approximately 500 psig or the tank should be replaced. The quality of the gases must meet method or manufacturer specification or be of a grade that does not cause any analytical interference.

Water used in the preparation of standards or reagents must have a conductivity of less than 1mmho/cm (or resistivity of greater than 1.0 megaohm-cm) at 25°C. The resistivity is checked and recorded for each use. If the water's resistivity is less than the specified limit, the Reagent Preparation Laboratory supervisor must be notified immediately in order to make arrangements for correction.

The laboratory may purchase reagent grade (or other similar quality) for use in the laboratory. This water must be certified "clean" by the supplier for all target analytes or otherwise verified by the laboratory prior to use. This verification is documented.

9.3.4 Storage

Reagent and chemical storage is important from the aspects of both integrity and safety. Light-sensitive reagents may be stored in brown-glass containers. Specific storage instructions for reagents and chemicals can be found in the laboratory analytical SOPs. Section 22 discusses conditions for standard storage. Standards must be stored separately from samples.

9.4 PURCHASE OF EQUIPMENT/INSTRUMENTS/SOFTWARE

When a new piece of equipment is needed, either for additional capacity or for replacing inoperable equipment, the analyst or supervisor makes a supply request to the Operations Manager and/or the Laboratory Director. If they agree with the request the procedures outlined in Policy No. CA-T-P-001, Qualified Products List, are followed. A decision is made as to which piece of equipment can best satisfy the requirements. The appropriate written requests are completed and purchasing places the capital request.

Upon receipt of a new or used piece of equipment, it is given a short name, such as ALP200, added to the equipment list described in Section 21 that is maintained by the Lab Support Department Its capability is assessed to determine if it is adequate or not for the specific application. Instruments shall be set up according to the manufacturer's instructions. Any deviations shall be documented in the Instrument Database (IDB).

For software, its operation must be deemed reliable and evidence of instrument verification must be retained by the Lab Support Department. Software certificates supplied by the vendors are filed with the Lab Support Department. The manufacturer's operation manual is retained by the appropriate supervisor.

9.5 SERVICES

Service to analytical instruments (except analytical balances) is performed on an as needed basis. Routine preventative maintenance is discussed in Section 21. The need for service is determined by analysts and/or supervisors. The service providers that perform the services are approved by the QA Manager.

9.6 SUPPLIERS

TestAmerica selects vendors through a competitive proposal/bid process, strategic business alliances or negotiated vendor partnerships (contracts). The level of control used in the selection process is dependent on the anticipated dollar amount and the potential impact on TestAmerica business. Vendors that provide test and measuring equipment, standards, certified containers, instrument related service contracts or subcontract laboratory services shall be subject to more rigorous controls than vendors that provide off-the-shelf items of defined quality that meet the end use requirements. The JD Edwards purchasing system includes all suppliers /vendors that have been approved for use.

Evaluation of suppliers is accomplished by ensuring the supplier ships the product or material ordered and that the material is of the appropriate quality. This is documented by signing off on packing slips or other supply receipt documents. The purchasing documents contain the data that adequately describe the services and supplies ordered.

Any issues of vendor performance are to be reported immediately by the laboratory staff to the Corporate Purchasing Group by completing a Vendor Performance Report (CW-F-WI-009).

The Corporate Purchasing Group will work through the appropriate channels to gather the information required to clearly identify the problem and will contact the vendor to report the problem and to make any necessary arrangements for exchange, return authorization, credit, etc.

As deemed appropriate, the Vendor Performance Reports will be summarized and reviewed to determine corrective action necessary, or service improvements required by vendors

When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information shall be forwarded to appropriate management for action and notification sent to the affected clients.

The laboratory has access to a listing of all approved suppliers of critical consumables, supplies and services. This information is provided through the JD Edwards purchasing system.

9.6.1 New Vendor Procedure

TestAmerica employees who wish to request the addition of a new vendor must complete a J.D. Edwards Vendor Add Request Form (CW-F-WI-007 – refer to Figure 9-1).

New vendors are evaluated based upon criteria appropriate to the products or services provided as well as their ability to provide those products and services at a competitive cost. Vendors are also evaluated to determine if there are ethical reasons or potential conflicts of interest with TestAmerica employees that would make it prohibitive to do business with them as well as their financial stability. The QA Department and/or the Technology Director are consulted with vendor and product selection that have an impact on quality.

Figure 9-1

Example – JD Edwards Vendor Add Request Form

TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING

JD Edwards Vendor Add Request Form

Vendor name:	Lab location and individual making request:
Vendor address (remit to):	Vendor phone:
Vendor address (remit to):	Vendor fax:
Contact name:	Product / service provided:

Reason for Vendor Addition: Check all reasons that apply

☐ Cost Reduction	Estimated Annual Savings $
☐ Replace Current Vendor	Reason?
	Vendor being Replaced?
☐ New Product / Service	Describe:
☐ ISO Approved (Required for Aerotech / P&K only)	

Small Business:

Does this vendor help us to meet our small business objectives: _____

If yes, which category: _____

Personal and Ethical Considerations:

Is there any personal conflict of interest with a TestAmerica employee and the vendor listed above? _____

Have ethical considerations been taken into account in your evaluation of this vendor? _____

Can this product be sourced from another TestAmerica facility? _____

Please complete form and email to NCPurchasing@testamericainc.com or fax to (330) 966-9275.

I approve the addition of this vendor:

_____ Purchasing Manager - Patrick Eckman

_____ Corporate Controller - Leslie Bowers

Form No. CW-F-WI-007

SECTION 10
SERVICE TO THE CLIENT
(NELAC 5.4.7)

10.1 OVERVIEW

Richland cooperates with clients and their representatives to monitor the laboratory's performance in relation to work performed for the client. It is the laboratory's goal to meet all client requirements in addition to statutory and regulatory requirements discussed in Section 5. The laboratory has procedures to ensure confidentiality to clients (Section 16 and 26). The laboratory will afford clients or their representatives cooperation to clarify the client's request.

10.2 SPECIAL SERVICES

The laboratory's standard procedures for reporting data are described in Section 26. When requested the following special services are provided:

- The laboratory will provide the client or the client's representative reasonable access to the relevant areas of the laboratory for the witnessing of tests performed for the client.
- The laboratory will work with client-specified third party data validators as specified in the client's contract.
- The laboratory will provide the client with requested information pertaining to the analysis of their samples. An additional charge may apply for additional data/information that was not previously agreed upon.

10.3 CLIENT COMMUNICATION

Project managers are an important communication link to the clients. The lab shall inform its clients of any delays in project completion as well as any non-conformances in either sample receipt (refer to Section 24) or sample analysis. Project management will maintain ongoing client communication throughout the entire client project. Technical Directors are available to discuss any technical questions or concerns that the client may have.

10.4 REPORTING

The laboratory will work with the client to produce any special communication reports required by the contract.

10.5 CLIENT SURVEYS

The laboratory assesses both positive and negative client feedback. The results are used to improve overall laboratory quality and client service.

Richland participates in the American Council of Independent Laboratories (ACIL) Seal of Excellence program. This program includes the submission of a survey to laboratory clients. The clients send their responses directly to ACIL.

TestAmerica's Sales and Marketing teams periodically develops lab and client specific surveys to assess client satisfaction.

SECTION 11
COMPLAINTS
(NELAC 5.4.8)

11.1 OVERVIEW

Richland believes that effective client complaint handling processes have important business and strategic value. Listening to and documenting client concerns captures 'client knowledge' that helps to continually improve processes and improving client satisfaction. An effective client complaint handling process also provides assurance to the data user that the laboratory will stand behind its data, service obligations and products.

A client complaint is any expression of dissatisfaction with any aspect of our business services, communications, responsiveness, data, reports, invoicing and other functions expressed by any party, whether received verbally or in written form. Client inquiries, complaints or noted discrepancies are documented, communicated to management, and addressed promptly and thoroughly.

The laboratory has procedures for dealing with both external and internal complaints. The nature of the complaint is identified, documented and investigated, and an appropriate action is determined and taken. In cases where a client complaint indicates that an established policy or procedure was not followed, the QA Department must evaluate whether a special audit must be conducted to assist in resolving the issue. A written confirmation or letter to the client, outlining the issue and response taken is recommended as part of the overall action taken.

The process of complaint resolution and documentation utilizes the procedures outlined in Section 13 (Corrective Actions) and is documented following the client complaint/compliment tracking form. It is the laboratory's goal to provide a satisfactory resolution to complaints in a timely and professional manner.

11.2 EXTERNAL COMPLAINTS

An employee that receives a complaint initiates the complaint resolution process and the documentation of the complaint.

The general steps in the complaint handling process are:

- Receiving Complaints
- Complaint Investigation and Service Recovery
- Process Improvement

The laboratory shall inform the initiator of the complaint of the results of the investigation and the corrective action taken, if any.

11.3 INTERNAL COMPLAINTS

Internal complaints include, but are not limited to: errors and non-conformances, training issues, internal audit findings, and deviations from methods. Corrective actions may be initiated by any staff member who observes a nonconformance and shall follow the procedures outlined in

Section 13. In addition, Corporate management, Sales and Marketing and Information Technology (IT) may initiate a complaint by contacting the laboratory or through the corrective action system described in Section 13.

11.4 MANAGEMENT REVIEW

The number and nature of client complaints is reported by the QA Manager to the laboratory and QA Director in the QA Monthly report. Monitoring and addressing the overall level and nature of client complaints and the effectiveness of the solutions is part of the Annual Management Review (Section 17)

SECTION 12
CONTROL OF NON-CONFORMING WORK
(NELAC 5.4.9)

12.1 OVERVIEW

In the context of environmental testing, a non-conformance is any situation in which some aspect of the work does not conform to the laboratory's own procedures or agreed client requirements. A non-conformance does not necessarily invalidate the reported data, but it does initiate the requirements of this section.

When data discrepancies are discovered or deviations and departures from laboratory standard procedures, policies and/or client requests have occurred, corrective action is taken immediately. First, the laboratory evaluates the significance of the nonconforming work. Then, a corrective action plan is initiated based on the outcome of the evaluation. If it is determined that the nonconforming work is an isolated incident, the plan could be as simple as adding a qualifier to the final results and/or making a notation in the case narrative. If it is determined that the nonconforming work is a systematic or improper practices issue, the corrective action plan could include a more in depth investigation and a possible suspension of an analytical method. In all cases, the actions taken are documented using the laboratory's corrective action system (refer to Section 13).

Due to the frequently unique nature of environmental samples, sometimes departures from documented policies and procedures are needed. Any policy or procedure deviation shall be documented and applicable client notification taken as described in the nonconformance SOP.

12.2 RESPONSIBILITIES AND AUTHORITIES

SOP No. CA-L-S-001, Internal Investigation of Potential Data Discrepancies and Determination for Data Recall, outlines the general procedures for the reporting and investigation of data discrepancies and alleged incidents of misconduct or violations of the company's data integrity policies as well as the policies and procedures related to the determination of the potential need to recall data.

Under certain circumstances the Laboratory Director or QA Manager may exceptionally authorize departures from documented procedures or policies. The departures may be a result of procedural changes due to the nature of the sample; a one-time procedure for a client; QC failures with insufficient sample to reanalyze, etc.. Where required, the client will be informed of the departure prior to initiating the change. Any departures must be well documented using the laboratory's corrective action procedures described in Section 13. Any impacted data must be referenced in a case narrative and/or flagged with an appropriate data qualifier.

Any nonconforming work or data discrepancy discovered by any laboratory staff member must be reported to facility senior laboratory management within 24-hours. The Senior Management staff is compromised of the Laboratory Director, the QA Manager, and the Technical Manager. The reporting of issues involving alleged violations of the company's Data Integrity or Manual Integration procedures must be conveyed to an Ethics and Compliance Officer (ECO) and Quality Director within 24 hours.

Whether an inaccurate result was reported due to calculation or quantitation errors, data entry errors, improper practices, or failure to follow SOPs, the data must be evaluated to determine the possible effect.

The Laboratory Director/Manager, QA Manager, ECOs, COO's – East and West, General Managers and the Quality Directors – East and West have the authority and responsibility to halt work, withhold final reports, or suspend an analysis for due cause as well as authorize the resumption of work.

All lab employees have the authority to stop work for reasons of unresolved safety or quality issues. Employees are encouraged to work through their chain of command to resolve such problems, but TestAmerica also presents other lines of communication in ethics and safety training that are available to all employees.

12.3 EVALUATION OF SIGNIFICANCE AND ACTIONS TAKEN

For each nonconforming issue reported, an evaluation of its significance and the level of management involvement needed is made. This includes reviewing its impact on the final data, whether or not it is an isolated or systematic issue, and how it relates to any special client requirements.

SOP No. CA-L-S-001 distinguishes between situations when it would be appropriate for the laboratory QA Manager and Laboratory Director (or his/her designee) to make the decision on the need for client notification (written or verbal) and data recall (report revision) and when the decision must be made with the assistance of the ECO's and Corporate Management. Laboratory level decisions are documented and approved using the laboratory's standard nonconformance/corrective action reporting (Section 13) in lieu of the data recall determination form contained in SOP No. CA-L-S-001.

When applicable (i.e. for all affected DOE clients), the laboratory shall immediately notify the affected clients of potential data quality issues. Corrective actions taken to resolve the issue shall be submitted to the client in a timely and responsive manner.

12.4 PREVENTION OF NONCONFORMING WORK

If it is determined that the nonconforming work could recur, further corrective actions must be made following the laboratory's corrective action system (Section 13).

On a monthly basis, the QA Department evaluates non-conformances to determine if any nonconforming work has been repeated multiple times. If so, the laboratory's corrective action process may be followed.

12.5 METHOD SUSPENSION/RESTRICTION (STOP WORK PROCEDURES)

In some cases it may be necessary to suspend/restrict the use of a method or target compound which constitutes significant risk and/or liability to the laboratory. Suspension/restriction procedures can be initiated by any of the person in the laboratory.

Prior to suspension/restriction, confidentiality will be respected, and the problem and the required corrective and preventive action will be stated in writing and presented to the Laboratory Director.

The Laboratory Director shall arrange for the appropriate personnel to meet with the QA Manager as needed. This meeting shall be held to confirm that there is a problem, that suspension/restriction of the method is required and will be concluded with a discussion of the steps necessary to bring the test fully back on line. In some cases that may not be necessary if all appropriate personnel have already agreed there is a problem and there is agreement on the steps needed to bring the test fully back on line.

The QA Manager will also initiate a corrective action report as described in Section 13 if one has not already been started. A copy of any meeting notes and agreed upon steps should be faxed or e-mailed by the laboratory to the appropriate General Manager and member of Corporate QA. This fax/e-mail acts as notification of the incident.

After suspension/restriction, the lab will hold all reports to clients pending review. No faxing, mailing or distributing through electronic means may occur. The report must not be posted for viewing on the internet. It is the responsibility of the Laboratory Director to hold all reporting and to notify all relevant laboratory personnel regarding the suspension/restriction (i.e., Project Management, Log-in, etc...). Analysis may proceed in some instances depending on the non-conformance issue.

Within 72 hours, the QA Manager will determine if compliance is now met and reports can be released, OR determine the plan of action to bring work into compliance, and release work. A team, with all principals involved (Laboratory Director, Technical Director, QA Manager, Supervisors) can devise a start-up plan to cover all steps from client notification through compliance and release of reports. Project Management, the Director of Client Services and Sales and Marketing should be notified if clients must be notified or if the suspension/restriction affects the laboratory's ability to accept work. The QA Manager must approve start-up or elimination of any restrictions after all corrective action is complete. This approval is given by final signature on the completed corrective action report as described in Section 13.

If the nonconformance involves 10CFR21 "Reporting of Defects and Noncompliance" requirements for an NRC licensee, the Laboratory Director or designee shall be informed and the project manager shall verbally inform the customer of the nonconformance, followed by a written report to the customer within five days.

A complete copy of 10CFR21 shall be posted in a conspicuous location. The following notification shall also be posted:

> ANY EMPLOYEE WHO HAS REASON TO BELIEVE THAT GOODS OR SERVICES SUBJECT TO REGULATION BY THE NUCLEAR REGULATORY COMMISSION HAVE BEEN DELIVERED FROM THIS FACILITY WHICH ARE NONCOMPLIANT OR DEFECTIVE, AS DEFINED IN 10CFR21 SHALL IMMEDIATELY INFORM HIS SUPERVISOR.

SECTION 13
CORRECTIVE ACTION
(NELAC 5.4.10)

13.1 OVERVIEW

A major component of TestAmerica's Quality Assurance (QA) Program is the problem investigation and feedback mechanism designed to keep the laboratory staff informed on quality related issues and to provide insight to problem resolution. When nonconforming work or departures from policies and procedures in the quality system or technical operations are identified, the corrective action procedure provides a systematic approach to assess the issues, restore the laboratory's system integrity, and prevent reoccurrence. Corrective actions are documented using Non-Conformance Memos (NCM) and Corrective Action Reports (CAR).

The DOE requires that prior to implementation of corrective actions where client data is affected, the laboratory shall notify the client of the proposed corrective action.

13.2 DEFINITIONS

- **Correction**: Actions necessary to correct or repair analysis specific non-conformances. The acceptance criteria for method specific QC and protocols as well as the associated corrective actions are contained in Data Review SOP. The analyst will most frequently be the one to identify the need for this action as a result of QC sample analysis. No significant action is taken to change behavior, process or procedure.

- **Corrective Action**: The action taken is not only a correction made to the immediate event, but a change in process, procedure or behavior that is required to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.

13.3 GENERAL

Problems within the quality system or within analytical operations may be discovered in a variety of ways, such as QC sample failures, internal or external audits, proficiency testing (PT) performance, client complaints, staff observation, etc.. SOP RICH-QA-0029 provides further detail of Richland's nonconformance system.

The purpose of a corrective action system is to:

- Identify non-conformance events and assign responsibility for investigation.
- Resolve non-conformance events and assign responsibility for any required corrective action.
- Identify Systematic Problems before they become serious.
- Identify and track Client complaints and provide resolution (see more on client complaints in Section 11).

13.3.1 Non-Conformance Memo (NCM) - is used to document the following types of corrective actions:

- Deviations from an established procedure or SOP
- QC outside of limits (non matrix related)
- Isolated Reporting / Calculation Errors
- Client Complaints

13.3.2 Corrective Action Report (CAR) - is used to document the following types of corrective actions:

- Questionable trends that are found in the monthly review of NCMs.
- Issues found while reviewing NCMs that warrant further investigation.
- Internal and External Audit Findings, if further investigations are warranted.
- Failed or Unacceptable PT results.
- Corrective actions that cross multiple departments in the laboratory.
- Systematic Reporting / Calculation Errors

13.4 CLOSED LOOP CORRECTIVE ACTION PROCESS

Any employee in the company can initiate a corrective action. There are four main components to a closed-loop corrective action process once an issue has been identified: Cause Analysis, Selection and Implementation of Corrective Actions (both short and long term), Monitoring of the Corrective Actions, and Follow-up.

13.4.1 Cause Analysis

- Upon discovery of a non-conformance event, the event must be defined and documented. An NCM or CAR must be initiated, someone is assigned to investigate the issue and the event is investigated for cause. Table 13-1 provides some general guidelines on determining responsibility for assessment.
- The cause analysis step is the key to the process as a long term corrective action cannot be determined until the cause is determined.
- If the cause is not readily obvious, the Supervisor, the Technical Director, Lab Director, and/or QA Manager is consulted.

13.4.2 Selection and Implementation of Corrective Actions

- Where corrective action is needed, the laboratory shall identify potential corrective actions. The action(s) most likely to eliminate the problem and prevent recurrence are selected and implemented. Responsibility for implementation is assigned.
- Corrective actions shall be to a degree appropriate to the magnitude of the problem identified through the cause analysis.
- Whatever corrective action is determined to be appropriate, the laboratory shall document and implement the changes. The NCM or CAR is used for this documentation.

13.4.3 Monitoring of the Corrective Actions

- The Supervisor and QA Manager is responsible to ensure that the corrective action taken was effective.

- Ineffective actions will be documented and re-evaluated until acceptable resolution is achieved. Supervisors are accountable to the Laboratory Director to ensure final acceptable resolution is achieved and documented appropriately.
- Each NCM and CAR are tracked and a monthly summary of all corrective actions is printed out for review to aid in ensuring that the corrective actions have taken effect.
- The QA Manager reviews monthly NCMs and CARs for trends. Highlights are included in the QA monthly report (refer to Section 17). If a significant trend develops that adversely affects quality, an audit of the area is performed and corrective action implemented.
- Any out-of-control situations that are not addressed acceptably at the laboratory level may be reported to the Corporate Quality Director by the QA Manager, indicating the nature of the out-of-control situation and problems encountered in solving the situation.

13.4.4 Follow-up Audits

- Follow-up audits may be initiated by the QA Manager and shall be performed as soon as possible when the identification of a nonconformance casts doubt on the laboratory's compliance with its own policies and procedures, or on its compliance with state or federal requirements. (Section 16 includes additional information regarding internal audit procedures.)
- These audits often follow the implementation of the corrective actions to verify effectiveness. An additional audit would only be necessary when a critical issue or risk to business is discovered.

13.5 TECHNICAL CORRECTIVE ACTIONS

In addition to providing acceptance criteria and specific protocols for technical corrective actions in the method SOPs, the laboratory has general procedures to be followed to determine when departures from the documented policies and procedures and quality control have occurred (refer to Section 12 for information regarding the control of non-conforming work). The documentation of these procedures is through the use of an NCM.

Table 13-1 provides some general guidelines for identifying the individual(s) responsible for assessing each QC type and initiating corrective action. The table also provides general guidance on how a data set should be treated if associated QC measurements are unacceptable. Specific procedures are included in Method SOPs, QAM Sections 20 and 21, and SOP CA-L-S-001 (Internal Investigation of Potential Data Discrepancies and Determination for Data Recall). All corrective actions are reviewed at a minimum monthly by the QA Manager and highlights are included in the QA monthly report.

To the extent possible, samples shall be reported only if all quality control measures are acceptable. If the deficiency does not impair the usability of the results, data will be reported with an appropriate data qualifier and/or the deficiency will be noted in the case narrative. Where sample results may be impaired, the Project Manager is notified by a written NCM and appropriate corrective action (e.g., reanalysis) is taken and documented.

Table 13-1. Example – General Corrective Action Procedures

QC Activity ***(Individual Responsible for Initiation/Assessment)***	**Acceptance Criteria**	**Recommended Corrective Action**
Matrix Spike / Matrix Spike Duplicate (MS/MSD) *(Analyst, Data Reviewer)*	- % Recovery within limits documented in Data Review SOP	- If the acceptance criteria for duplicates or matrix spikes are not met because of matrix interferences, the acceptance of the analytical batch is determined by the validity of the LCS. - If the LCS is within acceptable limits the batch is acceptable. - The results of the duplicates, matrix spikes and the LCS are reported with the data set.
Laboratory Control Sample (LCS) *(Analyst, Data Reviewer)*	- % Recovery within limits specified in Data Review SOP.	-Recount/Reanalyze, if still not acceptable, Batch must be re-prepared and re-analyzed. **Note:** If there is insufficient sample or the holding time cannot be met, contact client and note in case narrative
Method Blank (MB) *(Analyst, Data Reviewer)*	< Reporting Limit	- Reanalyze/Recount blank. - If still positive, determine source of contamination. If necessary, reprocess (i.e. digest or extract) entire sample batch. Report blank results.
Proficiency Testing (PT) Samples *(QA Manager, Supervisor)*	- Criteria supplied by PT Supplier.	- Any failures must be investigated for cause. Failures may result in the need to repeat a PT sample to show the problem is corrected.
Internal / External Audits *(QA Manager, Supervisor, Laboratory Director)*	- Defined in Quality System documentation such as SOPs, QAM, etc..	- Non-conformances must be investigated through CAR system and necessary corrections must be made.
Reporting / Calculation Errors (Depends on issue -- possible individuals include: Analysts, Data Reviewers, Project Managers, Supervisor, QA Manager, Corporate QA, Corporate Management)	- SOP CA-L-S-001, Internal Investigation of Potential Data Discrepancies and Determination for Data Recall.	- Corrective action is determined by type of error. Follow the procedures in SOP CA-L-S-001.

QC Activity ***(Individual Responsible for Initiation/Assessment)***	**Acceptance Criteria**	**Recommended Corrective Action**
Client Complaints *(Project Managers, Lab Director, QA Manager, Sales and Marketing)*	-	- Corrective action is determined by the type of complaint. For example, a complaint regarding an incorrect address on a report will result in the report being corrected and then follow-up must be performed on the reasons the address was incorrect (e.g., database needs to be updated).
QA Monthly Report (Refer to Section 17 for an example) (QA Manager, Lab Director,Supervisors)	- QAM, SOPs.	- Corrective action is determined by the type of issue. For example, CARs for the month are reviewed and possible trends are investigated.
Spilled reagent or sample (analyst and/or EH&S)	N/A	Note on analytical worksheet or Incident Report

SECTION 14.0
PREVENTIVE ACTION
(NELAC 5.4.11)

14.1 OVERVIEW

The laboratory's preventive action programs improve, or eliminate potential causes of nonconforming product and/or nonconformance to the quality system. This preventive action process is a proactive continuous process improvement activity that can be initiated through feedback from clients, employees, business providers, and affiliates. The QA Department has the overall responsibility to ensure that the preventive action process is in place, and that relevant information on actions is documented and submitted for management review.

Dedicating resources to an effective preventive action system emphasizes Richland's commitment to its Quality Assurance (QA) program. It is beneficial to identify and address negative trends before they develop into complaints, problems and corrective actions. Additionally, customer service and satisfaction can be improved through continuous improvements to laboratory systems.

Opportunities for improvement may be discovered during management reviews, the QA Metrics Report, internal or external audits, proficiency testing performance, client complaints, staff observation, etc..

The monthly Quality Assurance Metrics Report shows performance indicators in all areas of the quality system. These areas include revised reports, corrective actions, audit findings, internal auditing and data authenticity audits, client complaints, PT samples, holding time violations, SOPs, ethics training, etc. These metrics are used to help evaluate quality system performance on an ongoing basis and provide a tool for identifying areas for improvement.

The laboratory's Corrective Action process (Section 13) is integral to implementation of preventive actions. A critical piece of the corrective action process is the implementation of actions to prevent further occurrence of a non-compliance event. Historical review of corrective action provides a valuable mechanism for identifying preventive action opportunities.

14.1.1 The following elements are part of a preventive action system:

- Identification of an opportunity for preventive action.
- Process for the preventive action.
- Define the measurements of the effectiveness of the process once undertaken.
- Execution of the preventive action.
- Evaluation of the plan using the defined measurements.
- Verification of the effectiveness of the preventive action.
- Close-Out by documenting any permanent changes to the Quality System as a result of the Preventive Action. Documentation of Preventive Action is incorporated into the monthly QA reports, corrective action process, management review.

14.1.2 Any Preventive Actions undertaken or attempted shall be taken into account during the Annual Management Review (Section 17). A highly detailed recap is not required; a simple

recount of success and failure within the preventive action program will provide management a measure for evaluation.

14.2 MANAGEMENT OF CHANGE

The Management of Change process is designed to manage significant events and changes that occur within the laboratory. Through these procedures, the potential risks inherent with a new event or change are identified and evaluated. The risks are minimized or eliminated through pre-planning and the development of preventive measures. The types of changes covered under this system include: Facility Changes, Major Accreditation Changes, Addition or Deletion to Division's Capabilities or Instrumentation, Key Personnel Changes, Laboratory Information Management System (LIMS) changes. This process is discussed in further detail in SOP CA-Q-S-003, Management of Change.

SECTION 15.0
CONTROL OF RECORDS
(NELAC 5.4.12)

Richland maintains a record system appropriate to its needs and that complies with applicable standards or regulations as required. The system produces unequivocal, accurate records that document all laboratory activities. The laboratory retains all original observations, calculations and derived data, calibration records and a copy of the analytical report for a minimum of five years after it has been issued.

15.1 OVERVIEW

The laboratory has established procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. A record index is listed in Table 15-1. Quality records are maintained by the Quality Assurance (QA) Manager in a database, which is backed up as part of the regular network backup. Records are of two types; either electronic or hard copy paper formats depending on whether the record is computer or hand generated (some records may be in both formats).

Technical records are maintained by the project management group.

Table 15-1. Record Index[1]

Technical Records	Official Documents	QA Records	Project Records	Administrative Records
Retention: 5 Years from analytical report issue*	5 Years from document retirement date*	5 Years from archival* **Data Investigation:** 5years or the life of the affected raw data storage whichever is greater (beyond 5 years if ongoing project or pending investigation)	5 Years from analytical report issue*	**Personnel:** 7 Years (HR Records must be maintained as per Policy CW-L-P-001) **Finance:** See Accounting and Control Procedures Manual
Raw Data Logbooks[2] Standards Certificates Analytical Records Lab Reports	Quality Assurance Manual (QAM)	Internal and External Audits/ Responses	Sample receipt and COC Documentation	Finance and Accounting
	Work Instructions	Certifications	Contracts and Amendments	EH&S Manual, Permits, Disposal Records
	SOPs Manuals	Corrective/Preventive Action	Correspondence	Employee Handbook
		Management Reviews	QAPP	Personnel files, Employee Signature & Initials, Administrative Training Records (e.g., Ethics)
		Method & Software Validation, Verification data	SAP	
		Data Investigation	Telephone Logbooks	Administrative Policies
	Policies		Lab Reports	Technical Training Records

[1] Record Types encompass hardcopy and electronic records.
[2] Examples of Logbook types: Maintenance, Instrument Run, Preparation (standard and samples), Standard and Reagent Receipt, Archiving, Balance Calibration, Temperature (hardcopy or electronic records).
* Exceptions listed in Table 15-2.

For raw data and project records, record retention shall be calculated from the date the project report is issued. For other records, such as Controlled Documents, QA, or Administrative Records, the retention time is calculated from the date the record is formally retired. Records related to the programs listed in Table 15-2 have lengthier retention requirements. Policy CW-L-P-001 (Record Retention) provides additional information on record retention requirements.

15.1.1 Programs with Longer Retention Requirements

Some regulatory programs have longer record retention requirements than the standard record retention time. These are detailed in Table 15-2 with their retention requirements. In these cases, the longer retention requirement is enacted. If special instructions exist such that client data cannot be destroyed prior to notification of the client, the PM is contacted for authorization prior to destroying the data.

Table 15-2. Special Record Retention Requirements

Program	Retention Requirement
Drinking Water – All States	10 years (project records)
Housing and Urban Development (HUD) Environmental Lead Testing	10 years
Alaska	10 years
Louisiana – All	10 years
Michigan Department of Environmental Quality – all environmental data	10 years
Navy Facilities Engineering Service Center (NFESC)	10 years
NY Potable Water NYCRR Part 55-2	10 years

15.1.2 All records are held secure and in confidence. Records maintained at the laboratory are located in secure rooms.

15.1.3 The laboratory has procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records. All analytical data is maintained as hard copy or in a secure readable electronic format. For analytical reports that are maintained as copies in PDF format, see section 20 for 'Computer and Electronic Data Related Requirements' for more information.

15.1.4 The record keeping system allows for historical reconstruction of all laboratory activities that produced the analytical data, as well as rapid recovery of historical data. The history of the sample from when the laboratory took possession of the samples must be readily understood through the documentation. This shall include inter-laboratory transfers of samples and/or extracts.

- The records include the identity of personnel involved in sampling, sample receipt, preparation, or testing. All analytical work contains the initials (at least) of the personnel involved. The chain of custody would indicate the name of the sampler. If any sampling notes are provided with a work order, they are kept with this package.

- All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification are documented.

- The record keeping system facilitates the retrieval of all working files and archived records for inspection and verification purposes (e.g., set format for naming electronic files, set format for what is included with a given analytical data set).

- Changes to hardcopy records shall follow the procedures outlined in Section 13 and 20. Changes to electronic records in LIMS or instrument data are recorded in audit trails.

- The reason for a signature or initials on a document is clearly indicated in the records such as "sampled by," "prepared by," "reviewed by", or "Analyzed by".

- All generated data except those that are generated by automated data collection systems, are recorded directly, promptly and legibly in permanent dark ink.

- Hard copy data may be scanned into PDF format for record storage as long as the scanning process can be verified in order to ensure that no data is lost and the data files and storage media must be tested to verify the laboratory's ability to retrieve the information prior to the destruction of the hard copy that was scanned.

- Also refer to Section 20 for 'Computer and Electronic Data Related Requirements.

15.1.5 BASIC CORRECTIONS

When mistakes occur in records, each mistake shall be crossed-out, and not erased, deleted, made illegible, or otherwise obliterated (e.g. no white-out), and the correct value entered alongside. All such corrections shall be initialed (or signed) and dated by the person making the correction. In the case of records stored electronically, the original "uncorrected" file must be maintained intact and a second "corrected" file is created.

This same process applies to adding additional information to a record. All additions made later than the initial must also be initialed (or signed) and dated.

When corrections are due to reasons other than obvious transcription errors, the reason for the corrections (or additions) shall also be documented.

The record keeping system shall fulfill the following requirements:

a) The records shall include the identity of personnel involved in preparation, calibration or testing.

b) All information relating to the laboratory facilities, equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation or data verification shall be documented.
c) All documentation entries shall be signed or initialed by responsible personnel.
d) All generated data except those that are generated by automated data collection systems, shall be recorded directly, promptly and legibly in permanent ink.
e) Entries in records shall not be obliterated by methods such as erasures, overwritten files or markings. All corrections to record-keeping errors shall be made by one line marked through the error. The individual making the correction shall sign (or initial) and date the correction (this is the person who authorized the change).
f) Units shall accompany all numbers that are not dimensionless.
g) Use leading zeros for numbers less than one.
h) If a data correction is not self-explanatory, a written justification is required.

The term "logbook" may be defined as a hardcopy record or as an electronic record. Electronic logbooks shall be maintained and archived as required for all electronic records as described in the quality manuals and software SOPs.

A log of names, initials and signatures for all individuals signing or initialing any laboratory record shall be maintained.

Should a record become lost or damaged, efforts will be made to regenerate the record by electronic means or transcription. It is the responsibility of the area supervisor where the record was originally generated to recapture the information and attempt to regenerate the record as much as possible. The regenerated record shall be reviewed and approved by the QA Manager or designee. Each page of the regenerated record shall be labeled "Regenerated Record". In cases where regeneration is not possible, an NCM shall be filed with the appropriate records.

15.2 TECHNICAL AND ANALYTICAL RECORDS

15.2.1 The laboratory retains records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each analytical report issued, for a minimum of five years unless otherwise specified by a client or regulatory requirement (refer to Section 15.1). The records for each analysis shall contain sufficient information to enable the analysis to be repeated under conditions as close as possible to the original. The records shall include the identity of laboratory personnel responsible for performance of each analysis and checking of results.

15.2.2 Observations, data and calculations are recorded at the time they are made and are identifiable to the specific task.

15.2.3 Changes to hardcopy records shall follow the procedures outlined in Section 13 and 20. Changes to electronic records in LIMS or instrument data are recorded in audit trails.
The essential information to be associated with analysis, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs, include:

- laboratory sample ID code;
- Date of analysis and time of analysis is required if the holding time is seventy-two (72) hours or less, or when time critical steps are included in the analysis (e.g., drying times,

incubations, etc.); instrumental analyses have the date and time of analysis recorded as part of their general operations. Where a time critical step exists in an analysis, location for such a time is included as part of the documentation in a specific logbook or on a benchsheet

- Instrumentation identification and instrument operating conditions/parameters. Operating conditions/parameters are typically recorded in instrument maintenance logs where available.
- analysis type;
- all manual calculations and manual integrations;
- analyst's or operator's initials/signature;
- sample preparation including cleanup, separation protocols, incubation/ingrowth periods, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;
- test results;
- standard and reagent origin, receipt, preparation, and use;
- calibration criteria, frequency and acceptance criteria;
- data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;
- quality control protocols and assessment;
- electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries; and
- Method performance criteria including expected quality control requirements. These are indicated both in the LIMS and on specific analytical report formats.

15.3 LABORATORY SUPPORT ACTIVITIES

In addition to documenting all the above-mentioned activities, the following are retained QA records and project records (previous discussions in this section relate where and how these data are stored):

- all original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts' work sheets and data output records (chromatograms and other instrument response readout records);
- a written description or reference to the specific test method used which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value;
- copies of final reports;
- archived SOPs;
- correspondence relating to laboratory activities for a specific project;
- all corrective action reports, audits and audit responses;
- proficiency test results and raw data; and
- results of data review, verification, and crosschecking procedures

15.3.1 Sample Handling Records

Sample handling and tracking is discussed in Section 24. Records of all procedures to which a sample is subjected while in the possession of the laboratory are maintained. These include but are not limited to records pertaining to:

- sample preservation including appropriateness of sample container and compliance with holding time requirement;
- sample identification, receipt, acceptance or rejection and login;
- sample storage and tracking including shipping receipts, sample transmittal / COC forms;
- procedures for the receipt and retention of samples, including all provisions necessary to protect the integrity of samples.

15.4 ADMINISTRATIVE RECORDS

The laboratory also maintains the administrative records in either electronic or hard copy form. See Table 15-1.

15.5 RECORDS MANAGEMENT, STORAGE AND DISPOSAL

15.5.1 All records (including those pertaining to test equipment), certificates and reports are safely stored, held secure and in confidence to the client. Certification related records are available to the accrediting body upon request.

15.5.2 All information necessary for the historical reconstruction of data is maintained by the laboratory. Records that are stored only on electronic media must be supported by the hardware and software necessary for their retrieval.

15.5.3 Records that are stored or generated by computers or personal computers have hard copy, write-protected backup copies, or an electronic audit trail controlling access.

The individual preparing records for submittal shall place all documents in a designated container for transfer to the storage area. The project files, data and data package identification information shall be entered into the archive database. This information is printed and included in the archive box.

All records, other than project records, shall be submitted using a record transmittal form. Hard copy records may be transferred to an electronic media for storage. The transmittal forms and information sheets shall accompany the records to the storage area. The archive custodian shall verify the contents of the document container to the transmittal form. If there are any discrepancies, the document container is returned to the submitter.

When the document container and forms are approved by the custodian, a box and location number shall be placed on the side of the container. The custodian shall complete the records transmittal forms by supplying the container and location number.

If amendments or supplemental information/data is generated, it shall be filed with the original records. The original version shall be kept intact and the supplemental data will be clearly identified if it is a correction to previously generated records.

The original forms shall remain in the container and a copy will be maintained in the archive file. The custodian will also enter the appropriate information into the archive database.

15.5.4 All records shall be protected against fire, theft, loss, environmental deterioration, and vermin. In the case of electronic records, electronic or magnetic sources, storage media are protected from deterioration caused by magnetic fields and/or electronic deterioration. Dual storage in a separate building or location can also satisfy this requirement.

Access to the data is limited to laboratory and company employees. When there is a need to retrieve a document for review in the record storage area, a request is given to the archive custodian or designee. The custodian will determine the location of the document container via the database and retrieve the container. An outcard listing the appropriate information shall replace the file(s) removed.

When removal from the storage area is necessary, a records request form shall be filled out. This form shall include the name of the person receiving the records, description of the records, the date removed and the signature of the person requesting the file. This form shall be filed in the archive file. A outcard listing the appropriate information shall replace the file(s) removed.

When the records are returned to the storage area, the custodian shall place them in the original location and remove the outcard. The custodian signs and dates the records request form and returns the form to the archive files.

Richland shall maintain a complete system to retrieve all electronically stored records. This system shall be tested every six months to ensure proper operation. This is accomplished by loading a file and obtaining a hard copy printout.

15.5.5 In the event that the laboratory transfers ownership or goes out of business, Richland shall ensure that the records are maintained or transferred according to client's instructions. Upon ownership transfer, record retention requirements shall be addressed in the ownership transfer agreement and the responsibility for maintaining archives is clearly established. In addition, in cases of bankruptcy, appropriate regulatory and state legal requirements concerning laboratory records must be followed. In the event of the closure of the laboratory, all records will revert to the control of the corporate headquarters. Should the entire company cease to exist, as much notice as possible will be given to clients and the accrediting bodies who have worked with the laboratory during the previous 5 years of such action.

15.5.6 Records Disposal

15.5.6.1 Records are removed from the archive and disposed after 5 years unless otherwise specified by a client or regulatory requirement. On a project specific or program basis, clients may need to be notified prior to record destruction. Records are destroyed in a manner that ensures their confidentiality such as shredding, mutilation or incineration.

15.5.6.2 Electronic copies of records must be destroyed by erasure or physically damaging off-line storage media so no records can be read.

15.5.6.3 If a third party records management company is hired to dispose of records, a "Certificate of Destruction" is required. [Refer to Policy No. CW-L-P-001 (Records Retention).]

15.5.6.4 When records are returned to the client, the custodian shall transfer records to the custody of the client when requested. An external records release form shall be completed relinquishing Richland's custody of the records. The custodian will update the database accordingly.

15.5.6.5 Written approval must be received from all affected clients prior to disposal of any records associated with DOE analytical data.

SECTION 16
AUDITS
(NELAC 5.4.13)

16.1 OVERVIEW

Audits measure laboratory performance and insure compliance with accreditation/certification and project requirements. Audits specifically provide management with an on-going assessment of the quality of results produced by the laboratory, including how well the policies and procedures of the QA system and the Ethics and Data Integrity Program are being executed. They are also instrumental in identifying areas where improvement in the QA system will increase the reliability of data. There are two principle types of audits: Internal and External. Internal audits are performed by laboratory or corporate personnel. External audits are conducted by regulators, clients or third-party auditing firms. In either case, the assessment to program requirements is the focus.

Table 16-1. Audit Types and Frequency

Internal Audits	Description	Performed by	Frequency
	Analyst & Method Compliance	QA Department or Designee	- 100% of all methods over a two year period. - 100% of all analysts annually.
	Instrument	QA Department or Designee	100% of all organic instruments and any inorganic chromatography instruments. Annually.
	Work Order/ Final Report	QA Department or Designee	- 1 complete report each month.
	Support Systems	QA Department or Designee	- Annual for entire labs support departments & equipment (e.g., thermometers, balances), can be divided into sub-sections over the course of the year.
	Performance Audits (Double-Blind PTs)	Corporate QA, Laboratory QA Department or Designee	- As needed.
	Special	QA Department or Designee	- As Needed
External Audits	**Description**	**Performed by**	**Frequency**
	Program / Method Compliance	Regulatory Agencies, Clients, accreditation organizations	- As required by program and/or clients needs
	Performance Audits	Provided by a third party.	- As required by a client or regulatory agency. Generally provided semi-annually through the analysis of PT samples.

16.2 INTERNAL AUDITS

Annually, the laboratory prepares a schedule of internal audits to be performed throughout the year. As previously stated, these audits verify and monitor that operations continue to comply with the requirements of the laboratory's QA Manual and the Corporate Ethics Program. A schedule of the internal audits is maintained by the QA Manager.

It is the responsibility of the QA Manager to plan and organize audits in consideration of the laboratory work load and the department personnel schedules so that all pertinent personnel and operations are thoroughly reviewed. When designees (other than QA department personnel & approved by the QA Manager), perform audits, the QA Manager shall insure that these persons do not audit their own activities except when it can be demonstrated that an effective audit will be carried out. In general, the auditor:

- is neither the person responsible for the process being audited nor the immediate supervisor of the person responsible for the project/process.
- Is free of any conflicts of interest.
- Is free from bias and influences that could affect objectivity.

Laboratory personnel (e.g., supervisors and analysts) may assist with both method and support system audits as long as the items listed in the above paragraph are observed. These audits are conducted according to defined criteria listed in the checklists. These personnel must be approved by the QA Manager; and must complete the audit checklists in their entirety. This process introduces analyst experience and insight into the laboratory's auditing program.

The auditors shall have sufficient authority, access to work areas, and organizational freedom necessary to observe all activities affecting quality and to report the results of such assessments to laboratory management.

The auditor must review the previous audit report and identify all items for verification of corrective actions. A primary focus will be dedicated to the ability of the laboratory to correct root-cause deficiencies and that the corrective action has been implemented and sustained as documented.

If a potential data quality issue should arise, the affected clients shall be notified immediately. Corrective actions taken to resolve the issue, including a summary of the investigation, shall be submitted to the client in a timely and responsive manner.

16.2.1 Systems

An annual systems audit is required to ensure compliance to analytical methods and SOPs, the laboratory's Data Integrity and Ethics Policies, NELAC quality systems, client and State requirements. This audit can be performed in portions throughout the year through method, analyst, instrument, work order/final report and support system audits. Audits are documented and reported to management within 1 week of their performance. Systems audits cover all departments of the facility, both operational and support. The multiple audits are compiled into one systems audit package at the end of the year.

The auditor is responsible for obtaining or developing the audit checklist. The auditor shall verify by examination and evaluation of objective evidence whether each item on the checklist is being met. The auditor shall use their judgment to determine if there is a need to audit to a greater depth than the checklist indicatives. The checklist shall be modified accordingly. The auditors shall have the freedom to deviate from the checklist if items of importance are discovered.

16.2.1.1 Method, Analyst, Instrument and Work Order/Final Report Audits

Procedures for the method compliance, analyst, instrument and work order/final report audits are incorporated by reference to SOP No. CA-Q-S-004, Method Compliance and Data Authenticity Audits. These audits are not mutually exclusive. For example, the performance of a method audit will also cover multiple analysts and instruments. The laboratory's goal is to annually review all analysts and instruments as described in SOP No. CA-Q-S-004 (i.e., each instrument with multiple detectors or a bank of detectors is audited, not each detector). The laboratory will also audit all methods within a two year time period and audit a minimum of one Work Order/Final Report from receiving through reporting on a monthly basis.

16.2.1.2 Support Systems

Support system audits are performed to ensure that all departments & ancillary equipment are operating according to prescribed criteria. Support system audits include the review of both non-analytical and operational departments. Support equipment audits (e.g., metrology items) include the review of balance calibrations, weight calibrations; water quality testing, etc.. Non-analytical may include sample receiving and bottle preparation. These types of support audits ensure that the operations are being performed to support ethical data as well as ensuring the accuracy & precision of the utilized equipment.

These audits can be performed in portions throughout the year or in one scheduled session. However, the audit schedule must document that these aspects are reviewed annually. Many of the metrology systems are considered to be surveillance activities that can be monitored by QA personnel or delegated to specified department personnel. These surveillance activities are performed on a semi-annual basis unless issues warrant a greater frequency or previous audits continually showing no deficiencies allow the frequency to be reduced to once a year.

An example audit checklist can be found in Attachment 2. Instructions for reporting findings are included in the *Internal Audit Workbook.* In general, findings are reported to management within one week of the audit and a response is due from management within 30 days.

16.2.2 Performance Audits

Corporate QA may arrange for double blind PT studies to be performed in the laboratories. Results are given to Management and Corrective actions of any findings are coordinated at each facility by the QA Manager and Laboratory Director. These studies are performed on an as needed basis. They may be performed when concerns are raised regarding the performance of a particular method in specific laboratories, periodically to evaluate methods that may not normally be covered in the external PT program or may be used in the process of developing best practices. The local QA Manager may also arrange for PT studies on an as needed basis. (Refer to Section 16.3.2 for additional information on Performance Audits.)

16.2.3 Special Audits

Special audits are conducted on an as needed basis, generally as a follow up to specific issues such as client complaints, corrective actions, PT results, data audits, system audits, validation comments, regulatory audits or suspected ethical improprieties. Special audits are focused on a specific issue, and report format, distribution, and timeframes are designed to address the nature of the issue.

16.2.4 Safety Inspections

Safety inspections are conducted by the EH&S Specialist or designee. The inspection includes thorough examination of each laboratory and work area to note any safety concerns.

Radiological contamination smears shall be taken at the required frequencies. Should contamination be detected, actions shall be taken as described in the Radiation Protection Plan. Also, impact to samples shall be evaluated.

16.3 EXTERNAL AUDITS

TestAmerica facilities are routinely audited by clients and external regulatory authorities. External audits are performed when certifying agencies or clients conduct on-site inspections or submit performance testing samples for analysis. It is TestAmerica's policy to cooperate fully with regulatory authorities and clients. The laboratory makes every effort to provide the auditors with access to personnel, documentation and assistance. The laboratory supervisors are responsible for providing corrective actions to the QA Manager who coordinates the response for any deficiencies discovered during an external audit. Audit responses are due in the time allotted by the client or agency performing the audit. This time frame is generally 30 days.

Richland cooperates with clients and their representatives to monitor the laboratory's performance in relation to work performed for the client. The client may only view data and systems related directly to the client's work. All efforts are made to keep other client information confidential.

16.3.1 Confidential Business Information (CBI) Considerations

During on-site audits, auditors may come into possession of information claimed as business confidential. A business confidentiality claim is defined as "a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality or a request for a determination that such information is entitled to such treatment." When information is claimed as business confidential, the laboratory must place on (or attach to) the information at the time it is submitted to the auditor, a cover sheet, stamped or typed legend or other suitable form of notice, employing language such as "trade secret", "proprietary" or "company confidential". Confidential portions of documents otherwise non-confidential must be clearly identified. CBI may be purged of references to client identity by the responsible laboratory official at the time of removal from the laboratory. However, sample identifiers may not be obscured from the information. Additional information regarding CBI can be found in within the 2003 NELAC standards.

16.3.2 Performance Audits

The laboratory is involved in performance audits conducted at least semi-annually through the analysis of PT samples provided by a third party. The laboratory participates in the following types of PT studies:

Performance Evaluation Sample Program Description	Analysis Performed	Frequency of Participation
Environmental Resource Associates	Gamma, Iodine, Gross Alpha, Gross Beta, Tritium, Radium-226, Radium-228, Strontium-89 & 90, Natural Uranium	Semi-Annually for each study
DOELAP	Natural Uranium, Americium, Gamma, Plutonium, Strontium, Isotopic Uranium, Th-iso, Tc-99, Np-237	Every 3 years
Mixed Analyte Performance Evaluation Program	Americium, Gamma, Plutonium, H-3, Strontium, Isotopic Uranium, Ni-63, Fe-55	Semi-Annual
AIHA	Asbestos (PCM & PLM), metals	Semi-Annual

- It is TestAmerica's policy that PT samples be treated as typical samples in the production process. Further, where PT samples present special or unique problems in the regular production process they may need to be treated differently, as would any special or unique request submitted by any client. The QA Manager must be consulted and in agreement with any decisions made to treat a PT sample differently due to some special circumstance.

- PTs generally do not have holding times associated with them. In the absence of any holding time requirement, it is recommended that the holding time begin when the PT sample is prepared according to the manufacturers instructions. Holding times should apply to full volume PT samples only if the provider gives a meaningful "sampling date". If this is not provided, it is recommended that the date/time of opening of the full volume sample be considered the beginning of holding time.

- Login will obtain the COC information from the documentation provided with the PTs with review by QA or other designated staff.

- Vials will be prepared as required in the instruction set provided with the samples. After preparation to full volume the sample may be spiked, digested, concentrated, etc., as would be done for any normal sample requiring similar analysis.

- PT samples will not undergo multiple preps, multiple runs, multiple methods (unless being used to evaluate multiple methods), multiple dilutions, UNLESS this is what would be done to a normal client sample, or specified by the PT provider.

- The type, composition, concentration and frequency of quality control samples analyzed with the PT samples shall be the same as with routine environmental samples.

- No special reviews shall be performed by operation and QA, UNLESS this is what would be done to a normal client sample. To the degree that special report forms or login procedures are required by the PT supplier, it is reasonable that the laboratory WOULD apply special

review procedures, as would be done for any client requesting unusual reporting or login processes.

- Written responses to unacceptable PT results are required. In some cases it may be necessary for blind QC samples to be submitted to the laboratory to show a return to control.

16.4 AUDIT FINDINGS

Internal or External Audit findings should be documented using the corrective action process and database (refer to Section 13). The laboratory is expected to prepare a response to audit findings within 30 days of receipt of an audit report unless the report specifies a different time frame. The response may include action plans that could not be completed within the 30 day timeframe. In these instances, a completion date must set and agreed to by operations management and the QA Manager.

Responsibility for developing and implementing corrective actions to findings is the responsibility of the supervisor where the finding originated. Findings that are not corrected by specified due dates are reported monthly to management in the QA monthly report.

If any audit finding casts doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test results, the laboratory shall take timely corrective action, and shall notify clients in writing if the investigations show that the laboratory results have been affected. Once corrective action is implemented, a follow-up audit is scheduled to ensure that the problem has been corrected.

The procedures must be in accordance to SOP No. CA-L-S-001, Internal Investigations of Data Discrepancies and Determination of Data Recall.

Clients must be notified promptly in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any test report or amendment to a test report. The investigation must begin within 24-hours of discovery of the problem and all efforts are made to notify the client within two weeks after the completion of the investigation.

For DOE and other programs where required, the client will be informed of the proposed corrective action prior to initiating the change.

Figure 16-1.

Example – Internal Audit System Checklist: Corrective Actions

TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING

(Summary Page)

TestAmerica <Location>

INTERNAL AUDIT - Corrective Actions

[Printed Name(s) or Date(s)]

Area Audited:	
Auditor:	
Date:	
Persons Contacted During Audit:	
Date Reported to Department Manager:	
Reported To:	
Date Reported to Lab Director/Manager:	
Reported To:	
Date Response Due:	
Response Received and Accepted by QA Manager:	
Associated Corrective Action Report Number(s):	
Scheduled Follow-up:	

Item	Requirement	Ref.	Y	N	NA	Evidence/Comments	Follow Up
1	Does the laboratory have a corrective action program in place?	5.4.10.1					
2	Does the laboratory have a current corrective action SOP or is this information in the QA Manual?	5.4.10.1					
3	Do all laboratory personnel have documented training and access to initiate corrective actions?	5.4.10.1					
4	Are causes clearly identified by department, staff name, scope of issue (how many reports affected)?	5.4.10.6					
5	Is a root cause for the issue identified?	5.4.10.2					
6	Is a corrective action (plan) clearly described?						
7	Was the corrective action fully implemented?						
8	Is documentation (if applicable) completed as specifed by the corrective action (training, revised SOP, etc)						
9	Has a follow-up assessment been conducted to verify the corrective action was successful?						
10	Are corrective actions reviewed on a regular basis by management?	5.4.10.6a 5					
11	Is there a defined distribution flow for corrective action notification, review, closure, and follow-up?	5.4.10.6a					
12	Are non-conformances reviewed on a regular basis and used, if necessary, to initiate root cause corrective actions?						
13	Does the lab have a documented procedure for QC corrective action (i.e., documented within each method / parameter SOP or in the QA Manual)?	4.10.1					
14	***Verify Corrective Actions from previous systems audits. List Items:***						
15							
16							
17							

Auditor Signature: _____

Primary Reference(s): Corporate SOP CA-Q-S-002, Acceptable Manual Integration Practices
NELAC Standard, June 2003
DoD Quality Systems Manual, Version 3, January 2006
EPA Manual for the Certification of Laboratories Analyzing Drinking Water

SECTION 17
MANAGEMENT REVIEWS
(NELAC 5.4.14)

17.1 QUALITY ASSURANCE REPORT

A comprehensive QA Report shall be prepared each month by the laboratory's QA Department and forwarded to the Laboratory Director for review and comments. The final report shall be submitted to the Operation Manager as well as the appropriate Quality Director and General Manager. All aspects of the QA system are reviewed to evaluate the suitability of policies and procedures. At a minimum, the report content will contain the items listed below. During the course of the year, the Laboratory Director, General Manager or Corporate QA may request that additional information be added to the report.

The TestAmerica QA Report template is comprised of a discussion of three key QA issues facing the laboratory and ten specific sections (Figure 17-1):

- **Metrics:** Describe actions or improvement activities underway to address any outlying quality metrics that have been reported in the monthly Quality System Metrics Table.
- **SOPs:** Report SOPs that have been finalized and report status of any outstanding SOP reviews.
- **Corrective Actions:** Describe highlights and the most frequent cause for report revisions and corrective/preventive action measures underway. Include a discussion of any recalls handled at the lab level as per the Investigation/Recall SOP (SOP: CA-L-S-001). Include a section for client feedback and complaints. Include both positive and negative feedback. Describe the most serious client complaints and resolutions in progress.
- **MDLs and Control Limits:** Report which MDL verifications are due. Report the same for Control Limits.
- **Audits:** Report Internal and External Audits that were conducted. Include all relevant information such as which methods, by whom, corrective actions needed by when and discuss unresolved audit findings.
- **Performance Testing (PT) Samples:** Report the PT tests that are currently being tested with their due dates, report recent PT results by study, acceptable, total reported and the month and year.
- **Certifications:** Report on any certification programs being worked on by due date and packages completed. Describe any issues, lapses, or potential revocations.
- **Regulatory Updates:** Include information on new state or federal regulations that may impact the laboratory. Report new methods that require new instrumentation, deletion of methods, changes in sampling requirements and frequencies etc.
- **Miscellaneous:** Include any issues that may impact quality within the laboratory.
- **Next Month:** Report on plans for the upcoming month.
- **Lab Director Comments Section:** This section gives the Laboratory Director the opportunity to comment on issues discussed in the report and to document plans to resolve

these issues. Unresolved issues that reappear in subsequent monthly reports must be commented on by the Laboratory Director.

- **Quality System Metrics Table:** The report also includes statistical results that are used to assess the effectiveness of the quality system. Effective quality systems are the responsibility of the entire laboratory staff. Each laboratory provides their results in a template provided by Corporate QA (Figure 17-2).

On a monthly basis, Corporate QA compiles information from all the monthly laboratory reports. The VP-QA/EHS prepares a report that includes a compilation of all metrics and notable information and concerns regarding the QA programs within the laboratories. The report also includes a listing of new regulations that may potentially impact the laboratories. This report is presented to the Analytical Division Senior Management Team and General Managers.

17.2 ANNUAL MANAGEMENT REVIEW

The senior lab management team (Laboratory Director, Technical Director, QA Manager, Operations Manager, Manager of Project Management) conducts an annual review of its quality systems and LIMS to ensure its continuing suitability and effectiveness in meeting client and regulatory requirements and to introduce any necessary changes or improvements. Corporate Operations and Corporate QA personnel may be included in this meeting at the discretion of the Laboratory Director. The LIMS review consists of examining any audits, complaints or concerns that have been raised through the year that are related to the LIMS. The laboratory will summarize any critical findings that cannot be solved by the lab and report them to Corporate IT.

This review uses information generated during the preceding year to assess the "big picture" by ensuring that routine quality actions taken and reviewed on a monthly basis are not components of larger systematic concerns. The monthly review (refer to Section 17.1) should keep the quality systems current and effective, therefore, the annual review is a formal senior management process to review specific existing documentation. This review shall not be considered an internal audit. Significant issues from the following documentation are compiled or summarized by the QA Manager prior to the review meeting:

- Matters arising from the previous annual review.
- Prior Monthly QA Reports issues.
- Laboratory QA Metrics.
- Review of report reissue requests.
- Review of client feedback and complaints.
- Issues arising from any prior management or staff meetings.
- Issues that may be raised from prior Senior Management team meetings including:
  - Adequacy of staff, equipment and facility resources.
  - Adequacy of policies and procedures.
  - Future plans for resources and testing capability and capacity.
- The annual internal double blind PT program sample performance (if performed),

- Compliance to the Ethics Policy and Data Integrity Plan. Including any evidence/incidents of inappropriate actions or vulnerabilities related to data Integrity.
- Compliance to the health and safety program including hazardous and radioactive materials management functions.

The annual review includes the previous 12 months. Based on the annual review, a report is generated by the QA Manager and management. The report is distributed to the appropriate General Manager and the Quality Director. The report includes, but is not limited to:

- The date of the review and the names and titles of participants.
- A reference to the existing data quality related documents and topics that were reviewed.
- Quality system or operational changes or improvements that will be made as a result of the review (e.g., an implementation schedule including assigned responsibilities for the changes).

The QA Manual is also reviewed at this time and revised to reflect any significant changes made to the quality systems.

17.3 POTENTIAL INTEGRITY RELATED MANAGERIAL REVIEWS

Potential integrity issues (data or business related) must be handled and reviewed in a confidential manner until such time as a follow-up evaluation, full investigation, or other appropriate actions have been completed and issues clarified. The Corporate Data Investigation/ Recall SOP shall be followed (SOP No. CA-L-S-001). All investigations that result in finding of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients.

The Chairman/CEO, President/CEO, COOs and Quality Directors receive a monthly report from the VP of Quality and EHS summarizing any current data integrity or data recall investigations as described in SOP No. CA-L-S-001. The General Manager's are also made aware of progress on these issues for their specific labs.

Figure 17-1.

Example - QA Monthly Report to Management

LABORATORY: x
PERIOD COVERED: Month/Year
PREPARED BY: x DATE: Month Day, Year
DISTRIBUTED TO: xx (Include LD, GM, QA Director, etc...)

THREE KEY ISSUES FOR MONTH:
Include a discussion of three key issues that were focused in on this month.
1. x
2. x
3. x

---

1. METRICS
Describe actions or improvement activities underway to address any outlying quality metrics.

2. SOPs

See Tab for SOP specifics.

The following SOPs were finalized (or reviewed for accuracy): (See Tab)

The following SOPs are due to QA: xx

In QA to complete: xx

3. CORRECTIVE ACTION

Highlights: xx

Revised Reports:
Describe the most frequent cause for report revisions and corrective/preventive action measures underway.

Data Investigations/Recalls (Corporate Data Investigation/Recall SOP) :
Include a discussion of any recalls handled at the lab level as Corp SOP.

Client Feedback and Complaints:
Include both positive and negative feedback.

Describe the most serious client complaints) and resolutions in progress.

4. MDLs AND CONTROL LIMITS

MDLs Due:

Control Limits Due:

5. AUDITS

INTERNAL AUDITS

Discuss Any Outstanding Issues (or Attach Summary):

EXTERNAL AUDITS
Discuss Any Outstanding Issues (or Attach Summary):

6. PT SAMPLES

The following PT samples are now in house (Due Dates):
xx

7. CERTIFICATIONS

Certification Packages Being Worked On (Include Due Date):
x

Describe any issues, lapses, or potential revocations.

8. REGULATORY UPDATE
Include information on new state or federal regulations that may impact the laboratory – new methods that require new instrumentation, deletion of methods, changes in sampling requirements or frequencies, …

9. MISCELLANEOUS
Include any issues that may impact quality within the laboratory.

10. NEXT MONTH
Items planned for next month.

LAB DIRECTOR COMMENTS AND PLANNED CORRECTIVE ACTIONS:	
LAB DIRECTOR REVIEW:	DATE:

Figure 17-2.

Example - Laboratory Metrics Categories

Reports for month
Reports revised due to lab error
% Revised Reports
# of Data Recall Investigations
# of Reports Actually Recalled
Corrective Action Reports
Corrective Action Reports still open
Total Number of Unresolved Open Corrective Action Reports
% of Unresolved Open Corrective Action Reports
# Reports independent QA reviewed
% QA Data Review: Reports
# Technical staff (Analysts/technicians, including Temps)
# of Analyst work product reviewed year-to-date
# of Analytical instruments w/electronic data file storage capability
# of Analytical instruments reviewed for data authenticity year-to-date
% Analyst/Instrument Data Authenticity Audits
 # Client Complaints
 # Client Compliments
# of planned internal audits
# of planned internal method audits performed year-to-date
% Annual Internal Audits Complete
# of Open Internal Audit Findings Past Due
Total Number of External Audit Findings
# of Open External Audit Findings Past Due
% External Audit Findings Past Due
# of PT analytes participated and received scores
# of PT analytes not acceptable
% PT Cumulative Score
 # PT Repeat Analyte Failures Cumulative (analyte failed more than once in 4 consecutive studies by PT Type) (only applies to failed analytes)
SOPs

SOPs Reviewed/revised within 24 months
Methods **or Administrative procedures** without approved SOPs
SOP Status
Method certification Losses due to performance/audit issues
Hold Time Violations due to lab error
Date of Last Comprehensive Ethics Training Session
 # Staff that haven't Received Comprehensive Ethics Training (>30 Days From Employment Date)
MDL Status (Good, Fair, or Poor) >90%, >70%, <70%
Training Documentation Records (Good, Fair, or Poor)
LQM Revision/review Date
QAM Updated to New Integrated Template
Last Annual Internal Audit Date (Opened, Closed)
Last Management QS Review Date
#SOPs required for 12 month review cycle (DOD *or drinking water)*
#SOPs for 12 month cycle/revised within 12 months *(Includes QS and Methods Listed in QSM)*
12 month % SOP Status *(Includes QS and Methods Listed in QSM)*

SECTION 18
PERSONNEL
(NELAC 5.5.2)

18.1 OVERVIEW

TestAmerica's management believes that its highly qualified and professional staff is the single most important aspect in assuring a high level of data quality and service. The staff consists of professionals and support personnel as outlined in the organization chart. A current organization chart is maintained in the QA records.

All personnel must demonstrate competence in the areas where they have responsibility. Any staff that is undergoing training shall have appropriate supervision until they have demonstrated their ability to perform their job function on their own. Staff shall be qualified for their tasks based on appropriate education, training, experience and/or demonstrated skills as required.

The laboratory employs sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned responsibilities.

All personnel are responsible for complying with all QA/QC requirements that pertain to the laboratory and their area of responsibility. Each staff member must have a combination of experience and education to adequately demonstrate a specific knowledge of their particular area of responsibility. Technical staff must also have a general knowledge of lab operations, test methods, QA/QC procedures and records management.

Laboratory management is responsible for formulating goals for lab staff with respect to education, training and skills and ensuring that the laboratory has a policy and procedures for identifying training needs and providing training of personnel. The training shall be relevant to the present and anticipated responsibilities of the lab staff.

The laboratory only uses personnel that are employed by or under contract to, the laboratory. Contracted personnel, when used, must meet competency standards of the laboratory and work in accordance to the laboratory's quality system.

Personnel dealing with sample receipt, radioactive waste management and materials shipping shall be trained in waste management, shipping (49CFR172) and handling, and radioactive material control, as appropriate.

18.2 EDUCATION AND EXPERIENCE REQUIREMENTS FOR TECHNICAL PERSONNEL

Selection of qualified candidates for laboratory employment begins with documentation of minimum education, training, and experience prerequisites needed to perform the prescribed task. Minimum education and training guidelines for TestAmerica employees are outlined in job descriptions and are generally summarized for analytical staff in the table below.

The laboratory maintains job descriptions for all personnel who manage, perform or verify work affecting the quality of the environmental testing the laboratory performs. Job Descriptions are

located on the TestAmerica intranet site's Human Resources web-page (Also see Section 4 for position descriptions/responsibilities).

Experience and specialized training are accepted in lieu of a college degree (basic lab skills such as using a balance, quantitation techniques, etc. are also considered).

18.3 TRAINING

TestAmerica is committed to furthering the professional and technical development of employees at all levels.

Orientation to the laboratory's policies and procedures, in-house method training, and employee attendance at outside training courses and conferences all contribute toward employee proficiency. Below are examples of various areas of required employee training for all personnel including full-time, part-time, temporary, contracted and administrative:

Required Training	Time Frame*	Employee Type
Environmental Health & Safety	Refer to EH&S Manual	All
Ethics – New Hires	1 week of hire	All
Ethics - Comprehensive	90 days of hire	All
Data Integrity	30 days of hire	Technical and PMs
Quality Assurance	90 days of hire	All
Ethics – Comprehensive Refresher	Annually	All
Initial Demonstration of Capability (DOC)	Prior to unsupervised method performance	Technical

The laboratory maintains records of relevant authorization/competence, education, professional qualifications, training, skills and experience of technical personnel (including contracted personnel) as well as the date that approval/authorization was given. These records are kept on file at the laboratory. Also refer to "Demonstration of Capability" in Section 20.

The training of technical staff is kept up to date by:

- Each employee must have documentation in their training file that they have read, understood and agreed to follow the most recent version of the laboratory QA Manual and SOPs in their area of responsibility. This documentation is updated as SOPs are updated.
- Documentation from any training courses or workshops on specific equipment, analytical techniques or other relevant topics are maintained in their training file.
- Documentation of proficiency (refer to Section 20).
- An Ethics Agreement signed by each staff member (renewed each year) and evidence of annual ethics training.
- A Confidentiality Agreement signed by each staff member signed at the time of employment.

- Human Resources maintains documentation and attestation forms on employment status & records; benefit programs; timekeeping/payroll; and employee conduct (e.g., ethics). This information is maintained in the employee's secured personnel file.

Within the first quarter of initial employment, an associate shall receive training on the Quality Assurance Program. In order to demonstrate qualification, each associate shall be required to take a QA examination. A score of 70% correct is considered acceptable. If an associate's test does not meet the 70% criteria, they shall receive further instruction or be allowed to retake the exam. An associate is not considered qualified to perform independently until they have received a passing score.

For non-analytical procedures, the trainee is assigned to a qualified associate and will work under their direction until such time that in the trainer's and supervisor's judgment the associate is qualified to work independently. In some cases this may require only reading and understanding the requirements described in the SOP.

For analytical procedures, the trainee shall observe and work under the direction of a qualified analyst. During this training period, the trainer shall enter their initials along with the trainee's signature/initials on the ICOC documentation. When the trainee has successfully completed the Demonstration of Capability study, they may work independently on client samples.

When training sessions are given, each associate shall sign an attendance sheet as evidence of their attendance. A brief description of the topics covered will be on or attached to the attendance sheet. The attendance sheet shall be kept in the Quality files.

When an associate completes a course, class or seminar given by an external agency, the associate shall provide proof of attendance to place in the training files.

After the analyst has been trained, a copy of the first PT results for each applicable test shall be included in the individual's training record.

All training forms and attendance sheets shall have the time duration of the training.

Retraining or reassignment of an associate may be required if determined by the supervisor, QA Manager, Technical Director or Laboratory Director. Examples of instance where this is warranted are:

a) QC results are outside expected limits for that individual's data exclusively.
b) The individual omits a step or performs the step incorrectly.

If the associate is reassigned for the reasons listed above, the associate will be disqualified for that SOP. The supervisor may choose to disqualify the associate for related SOPs depending on the circumstances. If at a later date the associate has gained the experience to requalify, as determined by the supervisor, the DOC process shall be followed.

5.1.2.1 Annual Requalification

Annual continued proficiency will be documented by at least one of the following:

a) Acceptable performance of a blind sample (single blind to the analyst)

b) Another demonstration of capability
c) Successful analysis of a blind performance sample on a similar test method using the same technology would only require documentation for one of the test methods
d) At least four laboratory control samples with acceptable levels of precision and accuracy
e) If a-d cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically indistinguishable results.

18.4 DATA INTEGRITY AND ETHICS TRAINING PROGRAM

Establishing and maintaining a high ethical standard is an important element of a Quality System. Ethics and data integrity training is integral to the success of TestAmerica and is provided for each employee at TestAmerica. It is a formal part of the initial employee orientation within 1 week of hire, comprehensive training within 90 days, and an annual refresher for all employees. Senior management at each facility performs the ethics training for their staff.

In order to ensure that all personnel understand the importance TestAmerica places on maintaining high ethical standards at all times; TestAmerica has established an Ethics Policy No. CA-L-P-001 and an Ethics Statement/Agreement (Appendix 1). All initial and annual training is documented by signature on the signed Ethics Policy and Code of Ethical Conduct demonstrating that the employee has participated in the training and understands their obligations related to ethical behavior and data integrity.

Violations of this Ethics Policy will not be tolerated. Employees who violate this policy will be subject to disciplinary actions up to and including termination. Criminal violations may also be referred to the Government for prosecution. In addition, such actions could jeopardize TestAmerica's ability to do work on Government contracts, and for that reason, TestAmerica has a Zero Tolerance approach to such violations.

Employees are trained as to the legal and environmental repercussions that result from data misrepresentation. Key topics covered in the presentation include:

- Organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting.
- Ethics Policy (Appendix 1)
- How and when to report ethical/data integrity issues. Confidential reporting.
- Record keeping.
- Discussion regarding data integrity procedures.
- Specific examples of breaches of ethical behavior (e.g. peak shaving, altering data or computer clocks, improper macros, etc., accepting/offering kickbacks, illegal accounting practices, unfair competition/collusion)
- Internal monitoring. Investigations and data recalls.
- Consequences for infractions including potential for immediate termination, debarment, or criminal prosecution.

- Importance of proper written narration / data qualification by the analyst and project manager with respect to those cases where the data may still be usable but are in one sense or another partially deficient.

Additionally, a data integrity hotline (1-800-736-9407) is maintained by TestAmerica and administered by the Corporate Quality Department.

SECTION 19
ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS
(NELAC 5.5.3)

19.1 OVERVIEW

Richland is a 33,000 ft^2 secure laboratory facility with controlled access and designed to accommodate an efficient workflow and to provide a safe and comfortable work environment for employees. Access is controlled by various measures.

The laboratory is equipped with structural safety features. Each employee is familiar with the location, use, and capabilities of general and specialized safety features associated with their workplace. The laboratory provides and requires the use of protective equipment including safety glasses, protective clothing, gloves, etc.. OSHA and other regulatory agency guidelines regarding required amounts of bench and fume hood space, lighting, ventilation (temperature and humidity controlled), access, and safety equipment are met or exceeded.

Traffic flow through sample preparation and analysis areas is minimized to reduce the likelihood of contamination. Adequate floor space and bench top area is provided to allow unencumbered sample preparation and analysis space. Sufficient space is also provided for storage of reagents glassware, and portable equipment. Ample space is also provided for sample storage before analysis and archival storage of samples after analysis. Laboratory HVAC and deionized water systems are designed to minimize potential trace contaminants.

The laboratory is separated into specific areas for sample receiving, sample preparation, sample separation, sample analysis, inorganic sample analysis and administrative functions.

19.2 ENVIRONMENT

Laboratory accommodation, test areas, energy sources, lighting are adequate to facilitate proper performance of tests. The facility is equipped with heating, ventilation, and air conditioning (HVAC) systems appropriate to the needs of environmental testing performed at this laboratory.

The environment in which these activities are undertaken does not invalidate the results or adversely affect the required accuracy of any measurements.

The laboratory provides for the effective monitoring, control and recording of environmental conditions that may affect the results of environmental tests as required by the relevant specifications, methods, and procedures.

When any of the method or regulatory required environmental conditions change to a point where they may adversely affect test results, analytical testing will be discontinued until the environmental conditions are returned to the required levels (refer to Section 12).

Environmental conditions of the facility housing the computer network and LIMS are regulated to protect against raw data loss.

19.3 WORK AREAS

There is effective separation between laboratory activities when warranted. Examples include:

Bioassay and Environmental sample processing areas.

Urine and Fecal processing

Low level and Intermediate level processing

Segregation of alpha spectrometry detectors

Access to and use of all areas affecting the quality of analytical testing is defined and controlled by secure access to the laboratory building as described below in the Building Security section.

Adequate measures are taken to ensure good housekeeping in the laboratory and to ensure that any contamination does not adversely affect data quality. These measures include regular cleaning to control dirt and dust within the laboratory.

Work areas are available to ensure an unencumbered work area. Work areas include:

- Access and entryways to the laboratory.
- Sample receipt areas.
- Sample storage areas.
- Chemical and waste storage areas.
- Data handling and storage areas.
- Sample processing areas.
- Sample analysis areas.

19.4 FLOOR PLAN

A floor plan can be found in Appendix 3.

19.5 BUILDING SECURITY

All visitors to the laboratory facility shall enter through the main entrance and register at the reception desk. Visitors will be issued a visitor's badge, and be escorted by an associate at all times. Associates shall not admit visitors through any door except the main entrance. Upon completion of the visit, visitors shall return the visitors badge to the receptionist or their escort. It is the responsibility of the escort to see that the badge is returned.

Persons delivering samples and supplies to Richland may be admitted through the receiving door or other entrance that facilitates delivery. Delivery personnel are not required to obtain a badge.

Contractors and service personnel shall obtain a contractors badge with a key card. The contractors and service personnel may move about the building unescorted.

Associates shall be issued a key card on their first day of work. All associates shall use this key card upon entering the facilities. Key cards shall not be lent or borrowed from other associates.

If a key card is lost, the associate shall immediately notify the Administrative Assistant who is responsible for assuring that the lost card is invalidated and a replacement issued. If a key card is forgotten, a temporary card may be issued. The associate shall return the temporary card upon the completion of work for that day.

Any associate who discovers a visitor who is unbadged or unescorted shall escort that person to the reception desk. The person shall be badged or the proper escort located.

Facility breeches of security after business hours are identified with an audible alarm and a dialout alarm. The contracted security firm will call the laboratory facility to ascertain if the building is occupied. If there is no answer, the security firm shall use the call out list provided to them by the HR Coordinator.

Upon notification of an alarm, if evidence of criminal activity is discovered appropriate law enforcement shall be notified. If an associate suspects that samples have been tampered with, they shall report that information immediately to supervision. The appropriate manager shall determine if samples have actually been affected and an evaluation as to the possible impact to data.

SECTION 20.0
TEST METHODS AND METHOD VALIDATION
(NELAC 5.5.4)

20.1 OVERVIEW

Richland uses methods that are appropriate to meet our clients' requirements and that are within the scope of the laboratory's capabilities. These include sampling, handling, transport, storage and preparation of samples, and, where appropriate, an estimation of the measurement of uncertainty as well as statistical techniques for analysis of environmental data.

Instructions are available in the laboratory for the operation of equipment as well as for the handling and preparation of samples. All instructions, Standard Operating Procedures (SOPs), reference methods and manuals relevant to the working of the laboratory are readily available to all staff. Deviations from published methods are documented (with justification) in the laboratory's approved SOPs. SOPs are submitted to clients for review at their request. Significant deviations from published methods require client approval and regulatory approval where applicable.

20.2 STANDARD OPERATING PROCEDURES (SOPs)

Richland maintains SOPs that accurately reflect all phases of the laboratory such as assessing data integrity, corrective actions, handling customer complaints as well as all analytical methods and sampling procedures. The method SOPs are derived from the most recently promulgated/approved, published methods and are specifically adapted to the laboratory facility, where applicable. Modifications or clarifications to published methods are clearly noted in the SOPs. All SOPs are controlled in the laboratory (refer to Section 6 on Document Control):

- All SOPs contain a revision number, effective date, and appropriate approval signatures. Controlled copies are available to all staff.
- Procedures for preparation, review, revision and control are incorporated by reference to SOPs: CW-Q-S-002 (Writing a Standard Operating Procedure (SOP)
- SOPs are reviewed at a minimum of every 2 years (annually for Drinking Water and DoD SOPs), and where necessary, revised to ensure continuing suitability and compliance with applicable requirements.

20.3 LABORATORY METHODS MANUAL

For each test method, the laboratory shall have available the published referenced method as well as the laboratory developed SOP. Refer to the corporate SOP CW-Q-S-002 "Writing a Standard Operating Procedure" for content and requirements of technical and non-technical SOPs.

Note: If more stringent standards or requirements are included in a mandated test method or regulation than those specified in this manual, the laboratory shall demonstrate that such requirements are met. If it is not clear which requirements are more stringent, the standard from the method or regulation is to be followed. Any exceptions or deviations from the referenced methods or regulations are noted in the specific analytical SOP.

20.4 SELECTION OF METHODS

Since numerous methods and analytical techniques are available, continued communication between the client and laboratory is imperative to assure the correct methods are utilized. Once client methodology requirements are established, this and other pertinent information is summarized by the Project Manager. These mechanisms ensure that the proper analytical methods are applied when the samples arrive for log-in. For non-routine analytical services (e.g., special matrices, non-routine compound lists, etc.), the method of choice is selected based on client needs and available technology. The methods selected should be capable of measuring the specific parameter of interest, in the concentration range of interest, and with the required precision and accuracy.

20.4.1 Sources of Methods

Routine analytical services are performed using standard EPA-approved methodology. In some cases, modification of standard approved methods may be necessary to provide accurate analyses of particularly complex matrices. When the use of specific methods for sample analysis is mandated through project or regulatory requirements, only those methods shall be used.

When clients do not specify the method to be used or methods are not required, the methods used will be clearly validated and documented in an SOP and available to clients and/or the end user of the data.

20.4.1.1 The analytical methods used by the laboratory are those currently accepted and approved by the U. S. EPA and the state or territory from which the samples were collected. Reference methods include:

- *Prescribed Procedures for Measurement of Radioactivity in Drinking Water, EPA-600/4-80-032, August 1980.*
- *Eastern Environmental Radiation Facility Radiochemistry Procedures Manual, EPA, PB84-215581, June 1984.*
- *HASL-300 28th Edition, Environmental Measurements Laboratory (EML), 1997.*
- *Analytical Method for Determination of Asbestos Fibers in Water, EPA-600/4-83, September 1983.*
- *Determination of Asbestos Structures Over 10-mm in Length in Drinking Water, EPA-600/R-94-134, June 1994.*
- *Technical Notes on Drinking Water Methods, EPA-600/R94-173, October 1994*
- *NIOSH Manual of Analytical Methods, 4th ed., August 1994.*
- *Standard Methods for the Examination of Water and Wastewater, 18th/19th/20th edition; Eaton, A.D. Clesceri, L.S. Greenberg, A.E. Eds; American Water Works Association, Water Pollution Control Federation, American Public Health Association: Washington, D.C.*
- *Annual Book of ASTM Standards, American Society for Testing & Materials (ASTM), Philadelphia, PA.*
- *Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-R-05-004, January 2005)*
- *Code of Federal Regulations (CFR) 40, Parts 136, 141, 172, 173, 178, 179 and 261*

The laboratory reviews updated versions to all the aforementioned references for adaptation based upon capabilities, instrumentation, etc., and implements them as appropriate. As such,

the laboratory strives to perform only the latest versions of each approved method as regulations allow or require.

Other reference procedures for non-routine analyses may include methods established by specific states, ASTM or equipment manufacturers. Sample type, source, and the governing regulatory agency requiring the analysis will determine the method utilized.

The laboratory shall inform the client when a method proposed by the client may be inappropriate or out of date. After the client has been informed, and they wish to proceed contrary to the laboratory's recommendation, it will be documented.

20.4.2 Demonstration of Capability

Before the laboratory may institute a new method and begin reporting results, the laboratory shall confirm that it can properly operate the method. In general, this demonstration does not test the performance of the method in real world samples, but in an applicable and available clean matrix sample. If the method is for the testing of analytes that are not conducive to spiking, demonstration of capability may be performed on quality control samples. If required, a demonstration of capability shall be performed on representative matrix samples.

20.4.2.1 A demonstration of capability is performed whenever there is a change in instrument type, method or personnel.

20.4.2.2 The initial demonstration of capability must be thoroughly documented and approved by the Technical Director and QA Manager prior to independently analyzing client samples. All associated documentation must be retained in accordance with the laboratories archiving procedures (refer to Section 15, Control of Records).

20.4.3 Initial Demonstration of Capability (IDOC) Procedures

20.4.3.1 The spiking standard used must be prepared independently from those used in instrument calibration.

20.4.3.2 The analyte(s) shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified by a method or the laboratory SOP.

20.4.3.3 At least four aliquots shall be prepared and analyzed according to the test method (either concurrently or over a period of days).

20.4.3.4 Using all of the results, calculate the mean recovery in the appropriate reporting units and the standard deviations for each parameter of interest.

20.4.3.5 When it is not possible to determine the mean and standard deviations, such as for presence, absence and logarithmic values, the laboratory will assess performance against criteria described in the Method SOP.

20.4.3.6 Compare the information obtained above to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory generated acceptance criteria (LCS or interim criteria) if there is no mandatory criteria

established. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.

20.4.3.7 When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst must proceed according to either option listed below:

- Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with 20.4.3.3 above.
- Beginning with 20.4.3.3 above, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, will confirm a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all analytes of interest beginning with 20.4.3.1 above.

A certification statement (see Figure 20-1 as an example) shall be used to document the completion of each initial demonstration of capability. A copy of the certification is archived in the procedure file.

20.5 LABORATORY DEVELOPED METHODS AND NON-STANDARD METHODS

Any new method developed by the laboratory must be fully defined in an SOP/Methods Manual (Section 20.2) and validated by qualified personnel with adequate resources to perform the method. Method specifications and the relation to client requirements must be clearly conveyed to the client. The information included in the checklist below (Figure 20-2) is needed before samples are accepted for analysis by a new method.

20.6 VALIDATION OF METHODS

Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. (From 2003 NELAC Standard)

All non-standard methods, laboratory designed/developed methods, standard methods used outside of their scope, and major modifications to published methods must be validated to confirm they are fit for their intended use. The validation will be as extensive as necessary to meet the needs of the given application. The results are documented with the validation procedure used and contain a statement as to the fitness for use.

20.6.1 Method Validation and Verification Activities for All New Methods

While method validation can take various courses, the following activities can be required as part of method validation. Method validation records are designated QC records and are archived accordingly.

20.6.1.1 Determination of Method Selectivity

Method selectivity is the demonstrated ability to discriminate the analyte(s) of interest from other analytes or interferences in the specific matrix or matrices. In some cases to achieve the required selectivity for an analyte, a confirmation or separation analysis is required as part of the method.

20.6.1.2 Determination of Method Sensitivity

Sensitivity can be both estimated and demonstrated. Whether a study is required to estimate sensitivity depends on the level of method development required when applying a particular measurement system to a specific set of samples. Where estimations and/or demonstrations of sensitivity are required by regulation or client agreement, such as the procedure in 40 CFR Part 136 Appendix B, under the Clean Water Act, these shall be followed.

The Minimum Detectable Concentration (MDC) for a radionuclide by radiochemical measurement is determined from the blank/background variability associated with the appropriate detector, the detector efficiency, sample aliquot size and chemical yield. The background variability is proportional to the sample count time.

NOTE: The background variability is based on the analytical test and derived by: 1) using sample specific parameters, or 2) process blank specific parameters, or 3) by averaging the multiple MDCs derived in 1 or 2.

The MDC is calculated for individual samples (depending on counting technique) using the Environmental Protection Agency's definition as found in the Health Physics Society Committee Report – HPSR-1 "Upgrading Environmental Radiation Data", EPA 520/1-80-012 published in 1980. The MDC is expected to be less than the client required detection limit. Cesium-137 is the MDC analyte of interest for gamma evaluation.

The MDC is calculated periodically for each group of blank quality control samples containing a similar analyte and matrix which has been analyzed using equivalent procedures. Reagent blanks are more frequently analyzed to obtain the group MDC, but wherever possible, matrix blanks are analyzed. The specific parameters are defined for Radiobioassay, in HPS Standard N13.30, 1996, Performance Criteria for Radiobioassay and for Environmental measurements in ANSI standard N42.23, 1996, Measurement and Associated Instrumentation Quality Assurance for Radioassay Laboratories. The MDC is expected to be less than the client required detection limit for the analyte.

If the sample MDC is greater than the client required detection limit (CRDL) or reporting limit (RL), the Data Reviewer shall examine the sample volume/weight, counting time, tracer yield and/or other relevant factors. The Data Reviewer shall decide the corrective action which may include reanalysis, recounting or data acceptance and document per laboratory procedure.

20.6.1.3 Relationship of Limit of Detection (LOD) to the Quantitation Limit (QL)

An important characteristic of expression of sensitivity is the difference in the LOD and the QL. The LOD is the minimum level at which the presence of an analyte can be reliably concluded. The QL is the minimum level at which both the presence of an analyte and its concentration can be reliably determined. For most instrumental measurement systems, there is a region where semi-quantitative data is generated around the LOD (both above and below the estimated MDL or LOD) and below the QL. In this region, detection of an analyte may be confirmed but quantification of the analyte is unreliable within the accuracy and precision guidelines of the measurement system. When an analyte is detected below the QL, and the presence of the analyte is confirmed by meeting the qualitative identification criteria for the analyte, the analyte can be reliably reported, but the amount of the analyte can only be estimated. If data is to be reported in this region, it must be done so with a qualification that denotes the semi-quantitative nature of the result.

20.6.1.4 Determination of Interferences
A determination that the method is free from interferences in a blank matrix is performed.

20.6.1.5 Determination of Range
Where appropriate, a determination of the applicable range of the method may be performed. In most cases, range is determined and demonstrated by comparison of the response of an analyte in a curve to established or targeted criteria. The curve is used to establish the range of quantitation and the lower and upper values of the curve represent upper and lower quantitation limits. Curves are not limited to linear relationships.

20.6.1.6 Determination of Accuracy and Precision
Accuracy and precision studies are generally performed using replicate analyses, with a resulting percent recovery and measure of reproducibility (standard deviation, relative standard deviation) calculated and measured against a set of target criteria.

20.6.1.7 Documentation of Method
The method is formally documented in an SOP. If the method is a minor modification of a standard laboratory method that is already documented in an SOP, an SOP Attachment describing the specific differences in the new method is acceptable in place of a separate SOP.

20.6.1.8 Continued Demonstration of Method Performance
Continued demonstration of Method Performance is addressed in the SOP. Continued demonstration of method performance is generally accomplished by batch specific QC samples such as LCS, method blanks or PT samples.

20.7 ESTIMATION OF UNCERTAINTY OF MEASUREMENT

20.7.1 Uncertainty is "a parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand" (as defined by the International Vocabulary of Basic and General Terms in Metrology, ISO Geneva, 1993, ISBN 92-67-10175-1). Knowledge of the uncertainty of a measurement provides additional confidence in a result's validity. Its value accounts for all the factors which could possibly affect the result, such as adequacy of analyte definition, sampling, matrix effects and interferences, climatic conditions, variances in weights, volumes, and standards, analytical procedure, and random variation. Some national accreditation organizations require the use of an "expanded uncertainty": the range within which the value of the measurand is believed to lie within at least a 95% confidence level with the coverage factor k=2.

20.7.2 Uncertainty is not error. Error is a single value, the difference between the true result and the measured result. On environmental samples, the true result is never known. The measurement is the sum of the unknown true value and the unknown error. Unknown error is a combination of systematic error, or bias, and random error. Bias varies predictably, constantly, and independently from the number of measurements. Random error is unpredictable, assumed to be Gaussian in distribution, and reducible by increasing the number of measurements.

20.8 CONTROL OF DATA

The laboratory has policies and procedures in place to ensure the authenticity, integrity, and accuracy of the analytical data generated by the laboratory.

20.8.1 Computer and Electronic Data Related Requirements

The three basic objectives of our computer security procedures and policies are shown below. More detail is outlined in SOP RICH-IS-0001. The laboratory is currently running the RadCalc which is a custom in-house developed LIMS system that has been highly customized to meet the needs of the laboratory. All users shall be trained in computer security awareness. It is referred to as LIMS for the remainder of this section.

20.8.1.1 Maintain the Database Integrity:

Assurance that data is reliable and accurate through data verification (review) procedures, password-protecting access, anti-virus protection, data change requirements, as well as an internal LIMS permissions procedure.

- LIMS Database Integrity is achieved through data input validation, internal user controls, and data change requirements.
- Spreadsheets and other software developed in-house must be verified with documentation through hand calculations prior to use.

Note: "Commercial off-the-shelf software in use within the designed application range is considered to be sufficiently validated." *From NELAC 2003 Standard.* However, laboratory specific configurations or modifications are validated prior to use.

- In order to assure accuracy, all data entered or transferred into the LIMS data system goes through a minimum of two levels of review.
- The QA department performs random data audits to ensure the correct information has been reported.
- Changes to reports are documented as part of the audit trail.
- Analytical data file security is provided through three policies.

- The first policy forbids unauthorized personnel from using laboratory data acquisition computers.
- The second policy is the implementation of network passwords and login names that restrict directory access.
- The third layer is maintained through the LIMS and includes the use of username/password combinations to gain access to the LIMS system, the fact that all data in the LIMS is associated with the user to added/reviewed the data, and the restriction of review authority of data.

- All software installations will be in accordance with any relevant copyright licensing regulations.
- All software installed on any computer within the laboratory must be approved by the Information Technology Department regional support technician assigned to the laboratory Shrink-wrapped or otherwise sealed OEM software that is directly related to instrument usage does not need approval but the Information Technology department must be notified of the installation.
- Anti-virus software shall be installed on all servers and workstations. The anti-virus software shall be configured to check for virus signature file and program updates on a

daily basis and these updates will be pushed to all servers and workstations. The anti-virus software will be configured to clean any virus-infected file if possible, otherwise the file will be deleted. Disks and CDs brought from any outside source that are not OEM software must be scanned for viruses before being accessed.

- **Interlab LIMS Permissions Policy**

- PURPOSE - The purpose of this policy is to provide a mechanism for maintaining the integrity of information contained in each laboratory's LIMS while providing the necessary access for information sharing to staff at other laboratory facilities.
- DEFINITIONS - Host Laboratory: The laboratory facility that 'owns' the LIMS system or 'hosts' a project/job.
- POLICIES

(a) All permissions for the laboratory's LIMS system must only be granted by a representative of that laboratory.
- If someone outside of the host lab needs permissions for Project Management or other uses, they must go through the Lab Director or his/her designated representative.
- Permissions must never be granted without the knowledge of the host laboratory.

(b) Only laboratory analytical or QA staff from the home laboratory may have edit permissions for laboratory analysis data.

(c) Any changes made in laboratory's LIMS system:
- Must be documented and traceable.
- If made by staff of an affiliate lab, written permission from the home lab to make the changes (email approval is sufficient) is required.
- No corrections may be made in another laboratories system without their knowledge.

(d) Data qualifiers in laboratory reports must only be corrected, edited, etc. by the staff at the host laboratory.

(e) Full analytical data "View" only permissions may be granted to outside Project Management and Sales staff. Search permissions may also be granted so status may be checked.

(f) All qualifiers must be approved by QA staff before adding to standard reference tables.

(g) Please contact Corporate QA or IT staff if you have any questions regarding implementation or interpretation of this policy.

20.8.1.2 **Ensure Information Availability:** Protection against loss of information or service through scheduled back-ups, secure storage of media, line filter, Uninterruptible Power Supply (UPS), and maintaining older versions of software as revisions are implemented.

- Insured by timely backup procedures on reliable backup media, stable file server network architecture, and UPS protection
- UPS Protection:
- Each fileserver is protected by an appropriate power protection/backup unit. In the event of a power outage, there is approximately 15-30 minutes of up-time for the servers prior to shutdown. This allows for proper shutdown procedures to be followed with the fileservers.
- Fire extinguishers designed to avoid damage to computer equipment are available and mounted in visible, accessible areas.
- File Server Architecture

- All files are maintained on multiple Windows 2000 or newer servers which are secured physically in the Information Technology office. Access to these servers is limited to members of the Information Technology staff.
- All supporting software is maintained for at least 5 years from the last raw data generated using that software. [Length of time is dependent on local regulations or client requirements (e.g., OVAP requires 10 years)]

• System Back-up Overview and Procedures
- Data from both servers and instrument attached PC's are backed up and purged in compliance with the corporate back-up policy.
- A Maintenance Plan has been defined to create a daily archive of all data within the LIMS database to a backup location. This backup is initiated automatically by either the database or back-up system.
- Backup tapes will be stored in compliance with the corporate Data Backup Policy. Backup verifications are carried out in accordance with the corporate Data Backup Policy.
- Instrument data back-ups are verified on a periodic basis by the QA department when performing electronic data audits. The audit takes place on data that has been moved to a back-up location ensuring that it has been moved.

20.8.1.3 Maintain Confidentiality: Ensure data confidentiality through physical access controls, and encryption of when electronically transmitting data.

- All servers are located in a secure area of the IT department offices. Access to the servers is limited to IT staff members, lab directors, the President and Vice President of Operations.
- The company website contains SSL (Secure Socket Layer) encryption for secure website sessions and data transfers.
- The reporting portion of the LIMS system requires a project manager to enter their unique password anytime they create a report that displays a signature on it (.PDF).
- Electronic documents such as PDF files and electronic data deliverables will be made available to clients via the secure web site. The logon page for this web site contains an agreement that the customer must accept before they will be logged on which states that the customer agrees not to alter any electronic data made available to them.
- If electronic documents are made available outside of the web site, the customer must sign an agreement in advance that states they will not alter the data in any way.

20.8.2 Data Reduction

The complexity of the data reduction depends on the analytical method and the number of discrete operations involved (e.g., extractions, dilutions, instrument readings and concentrations). The analyst calculates the final results from the raw data or uses appropriate computer programs to assist in the calculation of final reportable values.

For manual data entry, the data is reduced by the analyst and then verified by a technical data reviewer or alternate analyst prior to updating the data in LIMS. The spreadsheets, or any other type of applicable documents, are signed by both the analyst and alternate reviewer to confirm the accuracy of the manual entry(s).

Manual integration of peaks will be documented and reviewed and the raw data will be flagged in accordance with the TestAmerica Corporate SOP CA-Q-S-002, *Acceptable Manual Integration Practices or RICH-RD-0016.*

Analytical results are reduced to appropriate concentration units specified by the analytical method, taking into account factors such as dilution, sample weight or volume, etc. Blank correction will be applied only when required by the method or per client requirements; otherwise, it should not be performed. Calculations are independently verified by appropriate laboratory staff. Calculations and data reduction steps for various methods are summarized in the respective analytical SOPs or program requirements.

20.8.2.1 All raw data must be retained in the worklist folder, computer file (if appropriate), and/or runlog. All criteria pertinent to the method must be recorded. The documentation is recorded at the time observations or calculations are made and must be signed or initialed/dated (month/day/year). It must be easily identifiable who performed which tasks if multiple people were involved.

20.8.2.2 In reporting, the analyst or the instrument output records the raw data result using values of known certainty plus one uncertain digit. If final calculations are performed external to LIMS, the results should be entered in LIMS with at least three significant figures.

20.8.2.3 For those methods that do not have an instrument printout or an instrumental output compatible with the LIMS System, the raw results and dilution factors are entered directly into LIMS by the analyst, and the software calculates the final result for the analytical report. LIMS has a defined significant figure criterion for each analyte.

The laboratory strives to import data directly from instruments or calculation spreadsheets to ensure that the reported data are free from transcription and calculation errors. For those analyses with an instrumental output compatible with the LIMS, the raw results and dilution factors are transferred into LIMS electronically.. The analyst prints a copy of what has been entered to check for errors. This printout and the instrument's printout of calibrations, concentrations/activities, if applicable, are retained with the data file.

20.8.3 Logbook / Worksheet Use Guidelines

Logbooks and worksheets are filled out 'real time' and have enough information on them to trace the events of the applicable analysis/task. (e.g. calibrations, standards, analyst, sample ID, date, time on short holding time tests, temperatures when applicable, calculations are traceable, etc.)

- Logbooks shall have sequentially numbered pages.
- The persons responsible for the activity will sign or initial and date the entry. Whenever possible, the entries shall be in chronological order.
- Corrections are made following the procedures outlined in Section 13.
- Logbooks are controlled by the QA department. A record is maintained of all logbooks in the lab.
- Unused portions of pages must be "Z"'d out, signed and dated.

- Worksheets are created with the approval of the Operations Manager at the facility. The QA Manager controls all worksheets following the procedures in Section 6.

20.8.4 Review / Verification Procedures

Review procedures are outlined in several SOPs to ensure that reported data are free from calculation and transcription errors, that QC parameters have been reviewed and evaluated before data is reported. The general review concepts are discussed below, more specific information can be found in the SOPs.

20.8.4.1 The data review process at Richland starts at the Sample Control level. Sample Control personnel review chain-of-custody forms and input the sample information and required analyses into a computer LIMS. The Project Managers perform final review of the chain-of-custody forms and inputted information.

20.8.4.2 First level review is accomplished by checking reported results against raw data and evaluating the results for accuracy. During the first level review, blanks, laboratory control samples, sample data, qualifiers and spike information are evaluated. Issues that deem further review include the following:

- QC data are outside the specified control limits for accuracy and precision
- Reviewed sample data does not match with reported results
- Unusual detection limit changes are observed
- Samples having unusually high results
- Samples exceeding a known regulatory limit
- Raw data indicating some type of contamination or poor technique
- Transcription errors

20.8.4.3 Unacceptable analytical results may require reanalysis of the samples. Corrective action is initiated whenever necessary.

20.8.4.4 The results are then entered or directly transferred into the computer database.

20.8.4.5 As a second level review, the Project Manager reviews the results for appropriateness and completeness. This review and approval ensures that client requirements have been met and that the final report has been properly completed. The process includes, but is not limited to, verifying that chemical relationships are evaluated, COC is followed, cover letters/ narratives are present, flags are appropriate, and project specific requirements are met. The following are some examples of chemical relationships that are reviewed (if data is available):

- Comparing gross alpha results to alpha emitters
- Comparing gross beta results to beta emitters

20.8.5 Manual Integrations

Computerized data systems provide the analyst with the ability to re-integrate raw instrument data in order to optimize the interpretation of the data. Though manual integration of data is an invaluable tool for resolving variations in instrument performance and some sample matrix problems, when used improperly, this technique would make unacceptable data appear to meet quality control acceptance limits. Improper re-integrations lead to legally indefensible data, a poor reputation, or possible laboratory decertification. Because guidelines for re-integration of data are not provided in the methods and most methods were written prior to widespread implementation of computerized data systems, the laboratory trains all analytical staff on proper manual integration techniques using SOP CA-Q-S-002 and RICH-RD-0016 as the guidelines.

20.8.5.1 The analyst must use professional judgment and common sense to determine when manual integrating is required. Analysts are encouraged to ask for assistance from a senior analyst or manager when in doubt.

20.8.5.2 Analysts shall not increase or decrease peak areas to for the sole purpose of achieving acceptable QC recoveries that would have otherwise been unacceptable. The intentional recording or reporting of incorrect information (or the intentional omission of correct information) is against company principals and policy and is grounds for immediate termination.

20.8.5.3 Client samples, performance evaluation samples, and quality control samples are all treated equally.

20.8.5.4 All manual integrations receive a second level review.

Figure 20-1.
Example - Demonstration of Capability Documentation

DEMONSTRATION OF CAPABILITY (DOC)

Laboratory Name:_____

Laboratory Address:_____

Method:_____ Matrix:_____

Date:_____ Analyst(s):_____

Source of Analyte(s):_____

Analytical Results

Analyte	Conc. (units)	Rep 1	Rep 2	Rep 3	Rep 4	Average % Recovery	%RSD

% RSD = Percent relative standard deviation = standard deviation divided by average % Recovery

Raw data reference: _____

Certification Statement:

We, the undersigned, certify that:

1. The cited test method has met Demonstration of Capability requirements.
2. The test method was performed by the analyst(s) identified on this certification.
3. A copy of the test method and the laboratory-specific SOPs are available for all personnel on site.
4. The data associated with the method demonstration of capability are true, accurate, complete, and self-explanatory.
5. All raw data necessary to reconstruct and validate these analyses have been retained at the facility, and the associated information is well organized and available for review.

_____ _____
Analyst Signature Date

_____ _____
Technical Director Signature Date

_____ _____
Quality Assurance Coordinator Signature Date

Figure 20-2.

Example - New Method / Additional Analyte Checklist

New Method / Additional Analyte Checklist

The following items are **required** to be completed prior to the acceptance of client samples. Fill in any blanks that do not apply with "NA". Provide associated instrument QC when samples or QC samples are analyzed (includes run log).

New Method _____ Added Analytes _____

1_____ Standard Operating Procedure

- Note: For additional analytes, a **ROMD [or whatever an internal communication memo is named in your lab]** can be used to add the analytes, include RL and matrix.
  - _____ Analysis SOP
  - _____ Preparation SOP
  - _____ SOP for any other relevant process
  - _____ Pages from any applicable logbooks (instrument, standards, etc)

2_____Evaluation of Selectivity. As applicable: e.g. Retention Time Window Study, second column confirmation, Interelement correction checks, spectral or fluorescence profiles, etc.

3_____ Initial Calibration Curve (Include Tune verification or similar (e.g. degradation checks) if applicable)

4_____ Method Detection Limit (MDL) Study (summary and raw data)

- _____ Water
- _____ Soil
- _____ Other

5_____ Real Sample and MS, MSD ***(CA ELAP Requirement)***

- Tap Water for water only methods
- Local Soil sample for SW-846 methods (if applying for soil or soil/water)
- Local water sample may be used in lieu of tap water if it is a non- drinking water method
- Does not have to contain the target analytes

6_____ Reporting Limit Verification standard

- Spike a blank matrix at the RL and process through the entire method. MDL study should be able to be used if recovery is good. Note the spike level(s) and recovery(ies)

7_____ Demonstration of Capability (DOC) per analyst (Precision and Accuracy (P&A) verification)

- 4 LCS for each matrix – most acceptance criteria are in the methods. The MDL study may be used if DOC criteria are met.
- Non-Standard methods – 3 x (1 LCS at LOQ-25%, 50%, 75% of the calibration range + Blank) prepared each day. (see NELAC Chpt 5, appendix C.3.3 (b))

8_____ Acceptable PT sample(s) if available

Notes: PT sample required for all new methods
PT sample required for all new analytes under NELAP

Submitted by _____ Date _____

9_____ Certification/Approval from Regulatory Agency where available.

QA Review / Acceptance _____ **Date** _____

SECTION 21
EQUIPMENT (AND CALIBRATIONS)
(NELAC 5.5.5)

21.1 OVERVIEW

TestAmerica purchases the most technically advanced analytical instrumentation for sample analyses. Instrumentation is purchased on the basis of accuracy, dependability, efficiency and sensitivity. Each laboratory is furnished with all items of sampling, preparation, analytical testing and measurement equipment necessary to correctly perform the tests for which the laboratory has capabilities. Each piece of equipment is capable of achieving the required accuracy and complies with specifications relevant to the method being performed. Before being placed into use, the equipment (including sampling equipment) is calibrated and checked to establish that it meets its intended specification. The calibration routines for analytical instruments establish the range of quantitation. Calibration procedures are specified in laboratory SOPs. A list of laboratory equipment and instrumentation is presented in Table 21-1.

Equipment is only operated by authorized and trained personnel. Manufacturers instructions for equipment use are readily accessible to all appropriate laboratory personnel.

21.2 PREVENTIVE MAINTENANCE

21.2.1 Richland follows a well-defined program to ensure proper equipment operation and to prevent the failure of laboratory equipment or instrumentation during use. This program of preventive maintenance helps to avoid delays due to instrument failure.

Routine preventive maintenance procedures and frequency, such as lubrication, cleaning, and replacements, should be performed according to the procedures outlined in the manufacturer's manual.

21.2.1.1 Calibrations, routine maintenance, and adjustments are part of the analysts' and laboratory supervisors' responsibilities. However, service contracts may be in place for some instruments to cover any major repairs.

21.2.1.2 TestAmerica Richland maintains redundant instrument capacity so that a spare part inventory is not necessary.

21.2.2 Table 21-2 summarizes the schedule for routine maintenance. It is the responsibility of each department supervisor to ensure that instrument maintenance logs are kept for all equipment in his/her department. Preventative maintenance procedures may also be outlined in analytical SOPs or instrument manuals. (Note: for some equipment, the log used to monitor performance is also the maintenance log. Multiple pieces of equipment may share the same log as long as it is clear as to which instrument is associated with an entry.)

21.2.3 Instrument maintenance logs are controlled and are used to document instrument problems, instrument repair and maintenance activities. Maintenance logs shall be kept for all major pieces of equipment. Instrument maintenance logs may also be used to specify instrument parameters.

21.2.3.1 Documentation must include all major maintenance activities such as contracted preventive maintenance and service and in-house activities such as the replacement of electrical components, tubing, valves, detectors, cleaning and adjustments.

21.2.3.2 Each entry in the instrument log includes the analyst's initials, the date, a detailed description of the problem (or maintenance needed/scheduled), a detailed explanation of the solution or maintenance performed, and a verification that the equipment is functioning properly (state what was used to determine a return to control. e.g. instrument recalibrated on 'date' with acceptable verification, etc.).

21.2.3.3 When maintenance or repair is performed by an outside agency, service receipts detailing the service performed will be maintained and entries will be made into the appropriate logs.

21.2.4 In addition, the maintenance records contain:

- The identification of the instrument/equipment (instrument's Serial Number and Model Number)
- The date the instrument/equipment was put into use.
- If available, the condition when the instrument was received (e.g. new, used, reconditioned).

21.2.5 If an instrument requires repair (subjected to overloading or mishandling, gives suspect results, or otherwise has shown to be defective or outside of specified limits) it shall be taken out of operation and tagged as out of service or otherwise isolated until such a time as the repairs have been made and the instrument can be demonstrated as operational by calibration and/or verification or other test to demonstrate acceptable performance. The laboratory shall examine the effect of this defect on previous data (refer to Sections 12 and 13).

21.2.6 In the event of equipment malfunction that cannot be resolved, service shall be obtained from the instrument vendor manufacturer, or qualified service technician, if such a service can be tendered. If on-site service is unavailable, arrangements shall be made to have the instrument shipped back to the manufacturer for repair. Back up instruments, which have been approved, for the analysis shall perform the analysis normally carried out by the malfunctioning instrument. If the back up is not available and the analysis cannot be carried out within the needed timeframe, the samples shall be subcontracted using the procedures outlined in Section 8, when applicable.

If an instrument is sent out for service or transferred to another facility, it must be recalibrated and verified prior to return to lab operations.

21.3 SUPPORT EQUIPMENT

This section applies to all devices that may not be the actual test instrument, but are necessary to support laboratory operations providing critical/precise measurement information. These include but are not limited to: balances, ovens, refrigerators, freezers, incubators, temperature measuring devices and volumetric dispensing devices if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume. All support equipment shall be uniquely identified and raw data records associated with the support equipment are retained to document equipment performance. Whenever practicable, any

support equipment requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and date or expiration criteria when recalibration is due.

21.3.1 Weights and Balances

The accuracy of the balances used in the laboratory is checked every working day, before use. All balances are placed on stable counter tops.

Each balance is checked at three weights prior to use with at least two certified ASTM type 1 weights spanning its range of use (weights that have been calibrated to ASTM type 1 weights may also be used for daily verification). These weights shall bracket the range of expected use for the day. ASTM type 1 weights used only for calibration of other weights (and no other purpose) are inspected for corrosion, damage or nicks at least annually and if no damage is observed, they are calibrated at least every 5 years by an outside calibration laboratory. Any weights (including ASTM Type 1) used for daily balance checks or other purposes are recalibrated/recertified annually to NIST standards (this may be done internally if laboratory maintains "calibration only" ASTM type 1 weights).

An external certified service engineer services laboratory balances on an annual basis. This service is documented on each balance with a signed and dated certification sticker that identifies traceability of the calibration to the NIST standards. Balance calibrations are checked each day of use.

All of this information is recorded in logs, and the recalibration/recertification certificates are kept on file.

21.3.2 Thermometers

All thermometers are calibrated on an annual basis with a NIST-traceable thermometer.

The NIST thermometer is recalibrated every five years (unless thermometer has been exposed to temperature extremes or apparent separation of internal liquid) by an approved outside service and the provided certificate of traceability is kept on file. The NIST thermometer has increments of 0.2 °C, and has a range applicable to all method and certification requirements. The NIST traceable thermometer is used for no other purpose than to calibrate other thermometers.

All of this information is documented in logbooks. Monitoring method-specific temperatures, including incubators, heating blocks, water baths, and ovens, is documented in method-specific logbooks.

21.3.3 Refrigerators/Freezer Units, Waterbaths, Ovens and Incubators

The temperatures of all refrigerator units and freezers used for sample storage are monitored daily, when in use.

Incubators are monitored on days of use.

All of this equipment has a unique identification number, and is assigned a unique thermometer for monitoring.

Sample storage refrigerator temperatures are kept between > 0°C and ≤ 6 °C. Should a refrigerator temperature be out of limits, actions shall be taken as described in SOP RICH-RC-0007.

Specific temperature settings/ranges for other refrigerators, ovens waterbaths, and incubators can be found in method specific SOPs.

All of this information is documented in Daily Temperature Logbooks and method-specific logbooks.

21.3.4 Autopipettors

Mechanical volumetric dispensing devices are checked for accuracy at least quarterly. "Critical" pipets, as described in SOP RICH-QA-0002, are verified daily before each use.

The laboratory maintains a sufficient inventory of autopipettors, and dilutors of differing capacities that fulfill all method requirements.

These devices are given unique identification numbers, and the delivery volumes are verified gravimetrically, at a minimum, on a quarterly basis.

21.3.5 Microwave Bomb Digestors

Documentation shall be maintained for the calibration activities required for microwave bomb digestion as prescribed in the analytical method.

21.4 INSTRUMENT CALIBRATIONS

Calibration of analytical instrumentation is essential to the production of quality data. Strict calibration procedures are followed for each method. These procedures are designed to determine and document the method detection limits, the working range of the analytical instrumentation and any fluctuations that may occur from day to day.

Sufficient raw data records are retained to allow an outside party to reconstruct all facets of the initial calibration. Records contain, but are not limited to, the following: calibration date, method, instrument, analyst(s) initials or signatures, analysis date, analytes, concentration/activity,

Sample results must be quantitated from the initial calibration and may not be quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method or program.

If the initial calibration or continuing calibration verification results are outside of the acceptance criteria, corrective action is performed and any affected samples are reanalyzed if possible. If the reanalysis is not possible, any data associated with an unacceptable initial calibration will be reported with appropriate data qualifiers.

21.4.1 RADIOCHEMICAL CALIBRATIONS

Radiochemical calibrations shall be performed as prescribed in ASTM method D7282. Frequency of calibrations shall also follow this method.

21.4.2 CALIBRATION STANDARDS

- Shelf life for stock radioactive standards shall not exceed 5 half lives. Shelf life for stock solutions prepared in the laboratory from salts, metals or dilution from a mother solution shall be no greater than one year, unless stated otherwise on the calibration certificate from the manufacturer. Standards in the form of a soil, sealed sources, filter, plated sources and sealed epoxy Marinelli beakers do not always have an expiration date. After the1 year shelf life of the stock solution has expired, it must be re-certified.

- If the standard is not re-verified, the standard shall be removed or clearly designated as acceptable for qualitative purposes only.

- The expiration date of the secondary standard shall not exceed the expiration date of the primary standard.

The accuracy of calibration standards is checked by comparison with a calibration verification standard from a second source. In cases where a second standard source is not available, a source from a different vendor is acceptable. All cases where this requirement cannot be met shall be documented with a nonconformance memo.

When a traceable standard is not available to use for calibration or verification activities, a nontraceable standard may be used if written client approval is obtained (when required).

Calibration standards are prepared using the appropriate procedures. However, the general procedures are described below.

21.4.2.1 For each analyte of interest, prepare calibration standards at the minimum number of concentrations as stated in the analytical methods.

21.4.2.2 Standards for instrument calibration are obtained from a variety of sources. All radioactive standards are traceable to NIST whenever possible. Dilution standards are prepared from stock standards purchased from commercial suppliers. A standard log is maintained, containing concentration/activity, date of receipt, date of standard preparation, any dilutions made, lot number, supplier, type of solvent and a unique code number to identify the standard.

21.4.3 RADIOCHEMICAL CONTINUING INSTRUMENT CALIBRATION VERIFICATION

21.4.3.1 Check sources shall be used only to verify that efficiencies have not changed. They shall not be used to determine efficiencies.

21.4.3.2 Performance checks shall be performed using appropriate check sources and monitored with control charts or tolerance charts to ensure that the instrument is operating properly and that the detector response has not significantly changed and therefore the instrument calibration has not changed. The same check source used in the preparation of the tolerance chart or control chart at the time of calibration shall be used in the calibration verification.

21.4.3.2.1 GAMMA - For gamma spectroscopy systems, the performance checks for efficiency and energy calibration shall be performed on a day of use basis along with performance checks on peak resolution.

21.4.3.2.2 For systems using sample changers and/or long count times that run more than a day, the energy calibration shall be checked before each analytical batch.

21.4.3.2.3 The Full-Width-Half-Maximum (FWHM) resolution of the detector shall be evaluated daily or prior to instrument use. The measure FWHM resolution shall be trended. Corrective actions shall be taken when an intolerable condition becomes evident or when gross changes are identified in the resolution of the detector at the energies that bound the applicable energy range.

21.4.3.2.4 ALPHA SPECTROSCOPY – For alpha spectroscopy systems, the performance check for energy calibration shall be performed on a weekly basis and the performance check for counting efficiency shall be performed on a monthly basis.

21.4.3.2.5 Detector response (counting efficiency) determinations shall be performed when the check source count is outside the acceptable limits of the control chart.

21.4.3.2.6 Calibration or QC sources that will not cause detector contamination from recoil atoms shall be used whenever possible.

21.4.3.2.7 GAS-PROPORTIONAL AND LIQUID SCINTILLATION COUNTERS – The performance check for counting efficiency shall be performed on a day-of-use basis. For batches of sample that uninterruptedly count for more than a day, a performance check can be performed at the beginning and end of the batch as long as this time interval is no greater than one week.

21.4.3.2.7.1 For scintillation counters, the calibration verification for counting efficiency shall be performed on a day of use basis. Radon scintillation detector efficiencies shall be verified at least on a monthly basis when the system is in use.

21.4.4 RADIOCHEMICAL BACKGROUND MEASUREMENT

21.4.4.1 Background measurements shall be made on a day-of-use basis (except for alpha spectroscopy) and monitored using control charts or tolerance charts to ensure that the laboratory maintains its capability to meet required data quality objectives. The duration of the background check shall be of sufficient duration (i.e., at least as long as the sample count time). When applicable, these values are subtracted from the toal measured activity in the determination of the sample activity.

21.4.4.2 Successive long background measurements may be evaluated as background check measurements. The background check frequency may be extended to accommodate long sample count times.

21.4.4.3 A background shall also be collected before and after any counting chamber changes are made, i.e. cleaning, liner replacement, or instrument modification.

21.4.4.4 GAMMA – The long background measurements, used for background corrections, shall be performed on at least a monthly basis.

21.4.4.5 ALPHA SPECTROSCOPY – Background measurements shall be performed on at least a monthly basis. The monthly background shall be performed for each Region of Interest (ROI). A detector background shall be rechecked after counting a high-activity sample.

21.4.4.6 GAS PROPORTIONAL – Background measurements shall be performed on at least a weekly basis. Long background measurements (to be used for background corrections) shall be performed on a quarterly basis, at a minimum. A detector background shall be rechecked after counting a high-activity sample.

21.4.4.7 SCINTILLATION COUNTERS – Background measurements shall be performed each day of use. The daily instrument check shall include a check with an unquenched, sealed background vial, which is never used to correct sample results for background.

21.4.5 RADIOCHEMICAL INSTRUMENT CONTAMINATION MONITORING

21.4.5.1 SOP RICH-HS-0006 specifies the requirements for monitoring radiochemical instrumentation. The SOP specifies the monitoring frequencies and criteria for initiating corrective action.

Table 21-1. Example - Laboratory Instrumentation

Manufacturer	Model	Number of Detectors	Purchase Date	Auto-sampler	Method Performed
Randam	Randam SC-5	81	1990	No	Alpha Scintillation
LudLum	LudLum200, USGS	55	1990	No	Alpha Scintillation
Canberra	Canberra 7401	44	1990	No	Alpha Spectroscopy
Ortec	Ortec 576A	149	1990	No	Alpha Spectroscopy
Ortec	Ortec 576	43	1990	No	Alpha Spectroscopy
Tennelec	Tennelec TC256	28	1990	No	Alpha Spectroscopy
Canberra	CanberraGC2518 5	1	1990	No	Gamma Spectroscopy
Canberra	Canberra GL20208	1	1990	No	Gamma Spectroscopy
Ortec	Ortec LoAx51370	1	1990	No	Gamma Spectroscopy
Ortec	LO-AX-51370/20	2	2003	No	Gamma Spectroscopy
Ortec	Ortec GEM-25185	1	1990	No	Gamma Spectroscopy
Ortec	GEM-40	4	2003	No	Gamma Spectroscopy
Ortec	Ortec GEM-25195	3	1990	No	Gamma Spectroscopy
Ortec	Ortec GMX-40195	1	1990	No	Gamma Spectroscopy
PGT	PGT NIGC-2519	2	1990	No	Gamma Spectroscopy
PGT	PGT NIGC-2519	3	1990	No	Gamma Spectroscopy
PGT	PGT IGP-2007	1	1990	No	Gamma Spectroscopy
Spectrum Sciences	QA-230	2	1990	No	Gas Proportional Counter
Tennelec	Tennelec LB5100	1	1990	No	Gas Proportional Counter
Tennelec	Tennelec LB4000	3	1990	No	Gas Proportional Counter
UST	UST Quad	8	1990	No	Gas Proportional Counter
Packard	Packard 4530	1	1990	No	Liquid Scintillation
Packard	Packard 2000	1	1990	No	Liquid Scintillation
Packard	Packard 2200CA	2	1990	No	Liquid Scintillation
Packard	Packard 2550TRL	1	1990	No	Liquid Scintillation
Packard	Packard 2500TR	1	1990	No	Liquid Scintillation
Packard	3100 TR	1	2004	No	Liquid Scintillation
Quantalus	Quantalus	1	1990	No	Liquid Scintillation
UST	KPA 2	1	1990	No	Kenetic Phosphorimeter Analyzer
CHEMCHEK	KPA 3	1	1990	No	Kenetic Phosphorimeter Analyzer
Thermo Jarrell Ash 61E ICAP	12621100	1	1995	No	6010B
Perkin Elmer Elan DRC II	AI12010609	1	2007	Yes	ICP/MS

Table 21-2.

Example: Schedule of Routine Maintenance

Instrument	Items Checked/Service	Minimum Frequency
Alpha Proportional	Check gas flow/bubbler oil level	Each day of use
	Clean sample tray	Weekly
Beta Proportional	Check gas flow	Each day of use
	Clean sample holders	Weekly
Liquid Scintillation	Clean sample changer	Monthly
	Check condensate trays	Monthly
	Check air filters	Monthly
Quad αβ Proportional	Check gas flow	Each day of use
	Clean sample holders	Weekly
Gamma Spectroscopy	Check LN_2 level	Bi-weekly
	Check plastic liner, replace if needed	Weekly
Alpha Spectroscopy	Clean sample holder	As needed
	Change vacuum pump oil	Every six months
KPA	Clean mirror surfaces	As needed
	Change dye cell contents	At least quarterly
	Clean reference cell	Every two months
	Change reference cell contents	As needed
	Replace Plasma cartridge	Every 2E+07 pulses or as needed
Alpha Scintillation	Vacuum detector chambers	Monthly
ICP - ICP/MS	Check torch tip	Each day of use
	Clean torch tip	As needed
	Check pump and capillary tubing	Weekly
	Check coolant level	Weekly
	Clean intelligence controller filters	Monthly
	Clean cooling inlet filters	Monthly
	Clean and oil guiding rods	Monthly
	Oil RFPT coolant fan	Semi-annually

SECTION 22
MEASUREMENT TRACEABILITY
(NELAC 5.5.6)

22.1 OVERVIEW

Traceability of measurements shall be assured using a system of documentation, calibration, and analysis of reference standards. Laboratory equipment that are peripheral to analysis and whose calibration is not necessarily documented in a test method analysis or by analysis of a reference standard shall be subject to ongoing certifications of accuracy. At a minimum, these must include procedures for checking specifications of ancillary equipment: balances, thermometers, temperature, Deionized (DI) and Reverse Osmosis (RO) water systems, automatic pipettes and other volumetric measuring devices. With the exception of Class A Glassware (including glass microliter syringes that have a certificate of accuracy), quarterly accuracy checks are performed for all mechanical volumetric devices. Wherever possible, subsidiary or peripheral equipment is checked against standard equipment or standards that are traceable to national or international standards. The following definitions are provided by the American Association for Laboratory Accreditation (A2LA):

"Traceability is the property of a measurement result whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, each step in the chain having stated uncertainties." There are six essential elements:

- An unbroken chain of comparison
- A calculated measurement uncertainty for each step in the chain to allow for an overall uncertainty calculation
- Documentation of each step in each calibration report
- All steps in the chain are performed by individuals with evidence of technical competence and accredited by a recognized accreditation body
- Reference to International Standard (SI) units
- Recalibration at appropriate intervals to preserve traceability

Calibration is defined as "determining and documenting the deviation of the indication of a measuring instrument (or the stated value of a material measure) from the conventional 'true' value of the measurand."

Uncertainty is defined as "a parameter associated with the result of a measurement that characterizes the dispersion of the value that could reasonably be attributed to the measurand." Measurement of Uncertainty is discussed is Section 20 of this QA Manual.

22.2 NIST-TRACEABLE WEIGHTS AND THERMOMETERS

Reference standards of measurement shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.

For NIST-traceable weights and thermometers, the laboratory requires that all calibrations be conducted by a calibration laboratory accredited by A2LA, NVLAP (National Voluntary Laboratory Accreditation Program), APLAC (Asia-Pacific Laboratory Accreditation Cooperation), or EA (European Cooperation for Accreditation). A certificate and scope of accreditation is kept on file at the laboratory. Refer to Section 21 for calibration of weights and thermometers.

22.3 REFERENCE STANDARDS / MATERIALS

Reference standards/materials, where commercially available, are traceable to certified reference materials with an accompanying Certificate of Analysis. If a standard cannot be purchased from a vendor that supplies a Certificate of Analysis, the purity of the standard is documented by analysis. (Refer to Section 9 for additional information on purchasing). All radioactive standards are traceable to NIST whenever possible. Other international traceable radioactive standards may be used when NIST traceable standards are not available. When a traceable standard is not available, written approval for use of a non-traceable standard must be obtained from the DOE clients.

The receipt of all reference standards must be documented. Reference standards are labeled with a unique Standard Identification Number and expiration date. All documentation received with the reference standard is retained as a QC record and references the Standard Identification Number.

All reference, primary and working standards/materials, whether commercially purchased or laboratory prepared, must be checked to ensure that the variability of the standard or material from the 'true' value does not exceed method requirements. The accuracy of calibration standards is checked by comparison with a standard from a second source. In cases where a second standard manufacturer is not available, a vendor certified different lot is acceptable for use as a second source. The appropriate Quality Control (QC) criteria for specific standards are defined in laboratory SOPs.

All radioactive standards shall be verified prior to initial use and annually. At least three verification measurements of a standard shall be used to determine the mean value and standard deviation of the verification results. The mean value shall be within 5% of the decay corrected certified value. The two sigma value used for the 95% confidence interval of the mean shall not exceed 10% of the mean value of the three verification measurements. If all criteria are met, the certified value shall be used.

Corrections for radioactive decay and/or ingrowth of progeny shall be performed for radionuclide standards.

All standards and materials must be stored and handled according to method or manufacturer's requirements in order to prevent contamination or deterioration. For safety requirements, please refer to method SOPs and the laboratory Environmental Health and Safety Manual.

22.4 DOCUMENTATION AND LABELING OF STANDARDS, REAGENTS, AND REFERENCE MATERIALS

Reagents must be at a minimum the purity required in the test method. The date of reagent receipt and the expiration date are documented.

All manufacturer or vendor supplied Certificate of Analysis or Purity must be retained, stored appropriately, and readily available for use and inspection. These records are maintained in the QA files when applicable. Records must be kept of the date of receipt and date of expiration of standards, reagents and reference materials. In addition, records of preparation of laboratory standards, reagents, and reference materials must be retained, stored appropriately, and be readily available for use and inspection. For detailed information on documentation and labeling, please refer to method specific SOPs.

22.4.1 All standards, reagents, and reference materials must be labeled in an unambiguous manner. Standards are logged into the laboratory's LIMS system *according to the RadCalc user guide* and are assigned a unique identification number. Reagents are labeled according to SOP RICH-QA-5002. The following information is typically recorded in the electronic database:

- Standard ID
- Description of Standard
- Preparer's name
- Final volume and number of vials prepared
- Preparation Date
- Expiration Date
- Standard source type (stock or daughter)
- Parent standard ID (if applicable)
- Parent Standard Analyte Concentration (if applicable)
- Parent Standard Amount used (if applicable)
- Final concentration of each analyte
- Comment box (text field)

Records are maintained electronically for standard and reference material preparation. These records show the traceability to purchased stocks or neat compounds. Preparation procedures are provided in the Method SOPs.

22.4.2 All standards, reagents, and reference materials must be clearly labeled with a minimum of the following information:

- Expiration Date
- Standard ID
- Special Health/Safety warnings if applicable

All secondary containers of prepared reagents must include a preparation date and an ID number to trace back to preparation. Procedures for preparation of reagents can be found in the Method SOPs. Standard ID numbers must be traceable through associated logbooks, worksheets and raw data.

All reagents and standards must be stored in accordance to the following priority: 1)with the manufacturer's recommendations; 2) with requirements in the specific analytical methods

SECTION 23.0
SAMPLING
(NELAC 5.5.7)

23.1 OVERVIEW

Richland does not provide sampling services. The laboratory's responsibility in the sample collection process lies in supplying the sampler with the necessary coolers, sample containers, preservatives, sample labels, custody seals, COC forms required to properly preserve and ship samples to the laboratory.

23.2 SAMPLING CONTAINERS

The laboratory offers clean sampling containers for use by clients. These containers are obtained from reputable container manufacturers and meet EPA specifications as required.

23.2.1 Preservatives

Upon request, preservatives are provided to the client in pre-cleaned sampling containers. In some cases containers may be purchased pre-preserved from the container supplier. Whether prepared by the laboratory or bought pre-preserved, the grades of the preservatives are at a minimum:

- Hydrochloric Acid – Reagent grade or equivalent
- Nitric Acid – Reagent grade or equivalent
- Sodium Hydroxide – Reagent grade or equivalent

23.3 SAMPLING CONTAINERS, PRESERVATION REQUIREMENTS, HOLDING TIMES

The preservation and holding time criteria specified in the following tables are derived from the source documents for the methods. If method required holding times (refer to Table 23-1) or preservation requirements are not met, the reports will be qualified using a flag, footnote or case narrative. As soon as possible or "ASAP" is an EPA designation for tests for which rapid analysis is advised, but for which neither EPA nor the laboratory have a basis for a holding time.

23.4 SAMPLE ALIQUOTS / SUBSAMPLING

Taking a representative sub-sample from a container is necessary to ensure that the analytical results are representative of the sample collected in the field. The size of the sample container, the quantity of sample fitted within the container, and the homogeneity of the sample need consideration when sub-sampling for sample preparation. It is the laboratory's responsibility to take a representative subsample or aliquot of the sample provided for analysis. In that regard the following guidelines apply to analysts:

Analysts should handle each sample as if it is potentially dangerous. At a minimum, safety glasses, gloves, and lab coats must be worn when preparing aliquots for analysis.

23.4.1 For water samples, before taking each aliquot for analysis, invert the sample container end-over-end at least three times and immediately pour off the aliquot. Especially when suspended solids are present, adequate mixing of the sample is extremely important.

23.4.2 For solid samples, if the solid can be mixed, stir before removing the aliquot. Mix more than is needed for the analysis to be performed (e.g. if 30 g are needed, mix 50-100 g, if 1 g is needed, mix 20 g, etc.).

- For soil samples, avoid debris in the subsample aliquot as much as possible (e.g. gravel, sticks, roots and grass); note this information in the sample preparation record.

If the solid is extremely heterogeneous, and the client has given no instructions, utilize the following technique: take portions of masses from each group, proportional to their contribution to the original sample to make a composite. Record in detail how the composite was created. For very unusual samples, consult with the QA department or Supervisor

23.4.3 For multiphasic samples, the client should instruct the laboratory as to the intent of the testing and how to handle the sample. If the entire sample is to be accounted for, and the phases do not mix easily with inversion/stirring, such that a representative aliquot can be taken, the analyst should record the percent by volume of each phase. The analysis must be conducted on each phase separately.

***Please note**: the holding times are program specific and different programs may have different holding times for equivalent methods.*

Table 23-1.
Holding Times, Preservation and Container Requirements

ANALYSIS	MATIX	SUGGESTED CONTAINER TYPE	PRESERVATION	HOLDING TIME
All radiochemical analyses, except H-3, C-14, I-129, I-131 and Rn-222	Water	Plastic	HNO_3 - pH<2	180 days
	Soil	Glass	None	180 days
H-3, I-129, I-131	Water	Glass	None	180 days for H-3 and I-129. 8 days for I-131
	Soil	Glass	None	180 days
Rn-222	Water	Amber glass	None	72 hours upon receipt
C-14	Water	Glass	None	180 days
	Soil	Glass	None	180 days
CrVI	Water	Plastic	4°C	24 hours
	Soil	Glass	4°C	30 days
ICP Metals	Water	Plastic	HNO_3 - pH<2	180 days
	Soil	Glass	None	180 days
Total Coliform	Water	Plastic	4°C	2 hours after receipt

SECTION 24
HANDLING OF SAMPLES
(NELAC 5.5.8)

Sample management procedures at Richland ensure that sample integrity and custody are maintained and documented from sampling/receipt through disposal.

24.1 CHAIN OF CUSTODY (COC)

The COC form is the written documented history of any sample and can be initiated when bottles are sent to the field, or at the time of sampling. This form is completed by the sampling personnel and accompanies the samples to the laboratory where it is received and stored under the laboratory's custody. The purpose of the COC form is to provide a legal written record of the handling of samples from the time of collection until they are received at the laboratory. It also serves as the primary written request for analyses from the client to the laboratory. The COC form acts as a purchase order for analytical services when no other contractual agreement is in effect. An example of a COC form may be found in Figure 24-1.

24.1.1 Field Documentation

The information the sampler needs to provide at the time of sampling on the container label is:

- Sample identification
- Date and time
- Preservative

During the sampling process, the COC form is completed and must be legible (see Figure 24-1). This form includes information such as:

- Client name, address, phone number and fax number (if available)
- Project name and/or number
- The sample identification
- Date, time and location of sampling
- Sample collectors name
- The matrix description
- The container description
- The total number of each type of container
- Preservatives used
- Analysis requested
- Requested turnaround time (TAT)
- Any special instructions
- Purchase Order number or billing information (e.g. quote number) if available
- The date and time that each person received or relinquished the sample(s), including their signed name.

If the matrix description is not available on the COC, the laboratory shall contact the client prior to proceeding.

The samples are stored in a cooler with ice, as applicable, and remain solely in the possession of the client's field technician until the samples are delivered to the laboratory. The sample collector must assure that each container is in his/her physical possession or in his/her view at all times, or stored in such a place and manner to preclude tampering. The field technician relinquishes the samples in writing on the COC form to the sample control personnel at the laboratory or to a TestAmerica courier. Samples are only considered to be received by lab when personnel at the laboratory have physical contact with the samples.

Note: Independent couriers are not required to sign the COC form.

24.1.2 Legal / Evidentiary Chain-of-Custody

If samples are identified for legal/evidentiary purposes on the COC, login will complete the custody seal (Figure 24-2), retain the shipping record with the COC, and initiate an internal COC form for laboratory use by analysts and a sample disposal record

The legal COC records shall establish an intact, continuous record of the physical possession, storage and disposal of sample containers, collected samples, sample aliquots, and sample extracts or digestates. The COC records shall account for all time periods associated with the samples. For ease of discussion, the above-mentioned items shall be referred to as samples:

1. A sample is in someone's custody if:
   - ***a.*** It is in one's actual physical possession;
   - ***b.*** It is in one's view, after being in one's physical possession;
   - ***c.*** It is in one's physical possession and then locked or sealed so that no one can tamper with it; and/or
   - ***d.*** It is kept in a secured area, restricted to authorized personnel only.
2. The COC records shall identify all individuals who physically handled individual samples
3. When possible, the number of people who physically handle the sample should be minimized.
4. A designated sample custodian shall be appointed to be responsible for receiving, storing and distributing samples
5. Efforts shall be made to limit the number of COC documents
6. Legal COC shall begin at the point establishedby the federal or State oversight program. This may begin at the point that cleaned sample containers are provided by the laboratory or the time sample collection occurs.
7. The COC forms shall remain with the samples during transport or shipment.
8. If shipping containers and/or individual sample containers are submitted with sample custody seals and any seals are not intact, the custodian shall note this on the COC and the client shall be contacted.
9. Mailed packages should be registered with return receipt requested. If packages are sent by common carrier, receipts shall be retained as part of the permanent COC documentation.
10. Once received by the laboratory, laboratory personnel are responsible for the care and custody of the sample and must be prepared to testify that the sample was in their possession and within view or secured in the laboratory at all times, from the

moment it was received from the custodian until the time that the analyses are completed or the time of sample disposal..

24.2 SAMPLE RECEIPT

Samples are received at the laboratory by designated sample receiving personnel and a unique laboratory project identification number is assigned. Each sample container shall be assigned a unique sample identification number that is cross-referenced to the client identification number such that traceability of test samples is unambiguous and documented. Each sample container is affixed with a durable sample identification label. Sample acceptance, receipt, tracking and storage procedures are summarized in the following sections.

24.2.1 Laboratory Receipt

When samples arrive at the laboratory, sample receiving personnel inspect the coolers and samples. The integrity of each sample must be determined by comparing sample labels or tags with the COC and by visual checks of the container for possible damage. Any non-conformance, irregularity, or compromised sample receipt must be documented on a Sample Check-In Form and brought to the immediate attention of the client. The COC, shipping documents, documentation of any non-conformance, irregularity, or compromised sample receipt, record of client contact, and resulting instructions become part of the project record.

24.2.1.1 Inspection of samples include a check for:

- Complete documentation to include sample identification, location, date and time of collection, collector's name, preservation type, sample type and any additional comments concerning the samples.
- All shipping containers containing samples known to be hazardous or from unknown origin (i.e. not drinking water or bioassay), shall be opened near the operating fume hood.
- Complete sample labels to include unique identification in indelible ink.
- Use of appropriate sample containers (see Section 23)
- Adherence to holding times as specified in the test method and/or summarized in Section 23.
- Adequate sample volume for required analyses.
- Damage or signs of contamination to sample container.

24.2.1.2 Check and record the temperature of the samples that require thermal preservation.

- Samples shall be deemed acceptable if arrival temperature is just above freezing and less than or equal to 6.0° C. Samples that are hand-delivered immediately after collection may not be at the required temperatures; however, if there is evidence that the chilling process has begun, such as the arrival on ice, the samples shall be considered acceptable. This will be documented on the Sample Check-In List.

- If the samples were shipped in ice and solid ice is still present and in direct contact with samples, report the samples as "received on ice." Direct contact means

samples must be surrounded by ice cubes or crushed ice. Ice present in a plastic bottle or other container does not constitute direct contact. Samples shipped with only "blue ice" may not be reported as "received on ice".

24.2.1.3 Check for correct sample preservative (i.e. pH) as specified in the test method. The results are documented on the Sample Check-In List.

24.2.1.4 After inspecting the samples, the sample receiving personnel sign and date the COC form, make any necessary notes of the samples' conditions and store them in appropriate storage locations.

24.2.1.5 If samples are received without a COC, TestAmerica will provide a generic COC form to be completed by the client when the samples are brought to the laboratory. The client is always provided with a copy of the completed COC form for their records.

24.2.1.6 If analyses with short holding times are requested, the dates and times are inspected to ensure that holding times have not already expired.

24.2.1.7 Samples received after normal working hours are left in their coolers and placed in a storage location. The person receiving the samples must sign the COC and record the date and time received

24.2.1.8 Any deviations from the sample acceptance criteria, that question the suitability of the sample for analysis, or incomplete documentation as to the tests required will be resolved by consultation with the client. If the sample acceptance criteria (Section 24.3) are not met, the laboratory shall either:

- Retain all correspondence and/or records of communications with the client regarding the disposition of rejected samples, or

- Fully document any decision, agreed upon by the client, to proceed with sample analysis that does not meet sample acceptance criteria.

24.2.2 Sample Log-in

All samples that are received by the laboratory are logged into the LIMS to allow the laboratory to track and evaluate sample progress. Each group of samples that are logged in together (typically one project from a given client/sampling event) is assigned a unique job number (SDG). Within each job, each sample receives a unique number. Sample numbers are generated sequentially over time, and are not re-assigned. A sample may be composed of more than one bottle since different preservatives may be required to perform all analyses requested. Even if multiple containers are received for a single sample, each container is uniquely identified with alphabetic letters added to the sample number. The LIMS generates sample labels that are attached to each bottle for a given sample.

Each job/set of samples is logged into LIMS with a minimum of the following information:

- Client Name, Project Name, Address, Phone, Fax, Report to information, invoice to information (most of this information is "default information" that is stored in the LIMS).
- Date and time sampled;
- Date and time received;
- Job and/or project description, sample description;
- Sample matrix, special sample remarks;
- Reporting requirements (i.e., QC level, report format, invoicing format);
- Turn-around-time requirements;
- Parameters (methods and reporting limits or MDLs are default information for a given parameter)

Upon receipt of a sample with a short hold time analysis, the appropriate analyst is notified by phone. Also, during login, the LIMS will identify a short hold time analysis and email the laboratory managers.

24.3 SAMPLE ACCEPTANCE POLICY

The laboratory has a written sample acceptance policy (Figure 24-3) that clearly outlines the circumstances under which samples shall be accepted or rejected.

24.4 SAMPLE STORAGE AND TRACKING

In order to avoid deterioration, contamination or damage to a sample during storage and handling, from the time of receipt until all analyses are complete, samples are stored in clean, dry, isolated areas suitable for the sample matrix and levels of activity. The storage areas are organized by Lot number to facilitate sample retrieval.

Analysts and technicians retrieve the sample container allocated to their analysis from the designated storage location and analyze the sample. All unused portions of samples, including empty sample containers (except empty bioassay containers), are returned to the secure designated sample control area.

The primary method for recording sample and fraction transfer is by using the electronic ICOC program. The sample containers, analytical batches, employees, SOP numbers and SOP revision numbers all have unique bar codes. The sample or batch, employee and SOP information is entered into the computer using bar codes or entered manually as described in the ICOC user guide. This electronic tracking system shall be used until the samples are disposed or returned to the client.

Access to the laboratory is controlled such that sample storage need not be locked at all times unless a project specifically demands it. Samples are accessible to laboratory personnel only. Visitors to the laboratory are prohibited from entering the laboratory areas unless accompanied by an employee of TestAmerica.

24.5 LABORATORY INTERNAL TRACKING

Tracking records shall include, by direct entry or linkage to other records:

1. Time of day and calendar date of each transfer or handling SOP;
2. Signatures/Electronic entries of all personnel who physically handle to samples;
3. All information necessary to produce unequivocal, accurate records that document the laboratory activities associated with sample receipt, preparation, analysis and reporting; and
4. COC forms received from the client and/or common carrier documents.

24.6 HAZARDOUS SAMPLES AND FOREIGN SOILS

To minimize exposure to personnel and to avoid potential accidents, hazardous and foreign soil samples are stored in a designated isolated area. For any sample that is known to be hazardous at the time of receipt or, if after completion of analysis the result exceeds the acceptable regulatory levels, the project manager shall indicate the need for isolation. For foreign soils, the sample itself is clearly marked with a red stamp, stamped on the sample label reading "HAZARDOUS" or "FOREIGN SOIL" and placed in a colored and/or marked bag to easily identify the sample. The date, log number, lab sample number, and the result or brief description of the hazard are all written on the Hazardous & Foreign Soil Sample Notice. A copy of the form must be included with the original COC and Work Order and the original must be given to the Sample Control Custodian. All hazardous samples are either returned to the client or disposed of appropriately through a hazardous waste disposal firm. Foreign soil samples are autoclaved or heat treated.

24.7 SAMPLE DISPOSAL

Samples should be retained for a minimum of 30 days after the project report is sent, however, provisions may be made for earlier disposal of samples once the holding time is exceeded. Some samples are required to be held for longer periods based on regulatory or client requirements. The laboratory must follow the longer sample retention requirements where required by regulation or client agreement. When required, the laboratory shall obtain client approval prior to disposal. Several possibilities for sample disposal exist: the sample may be consumed completely during analysis, the sample may be returned to the customer or location of sampling for disposal, or the sample may be disposed of in accordance with the laboratory's waste disposal procedures (SOP: RICH-HS-0008). All procedures in the laboratory Environmental, Health and Safety Manual are followed during disposal. Samples are normally maintained in the laboratory no longer than six months from receipt unless otherwise requested. Unused portions of samples found or suspected to be hazardous according to state or federal guidelines may be returned to the client upon completion of the analytical work.

If a sample is part of a known litigation, the affected legal authority, sample data user, and/or submitter of the sample must participate in the decision about the sample's disposal.

All documentation and correspondence concerning the disposal decision process must be kept on file. Pertinent information includes the date of disposal, nature of disposal (such as sample depletion, hazardous waste facility disposal, return to client), names of individuals who conducted the arrangements and physically completed the task. The laboratory will remove or deface sample labels prior to disposal unless this is accomplished through the disposal method (e.g., samples are incinerated). A Waste Disposal Record shall be maintained.

Figure 24-1.

Example: Chain of Custody (COC)

TestAmerica INCORPORATED

Nashville Division
2960 Foster Creighton
Nashville, TN 37204

Phone: 615-726-0177
Toll Free: 800-765-0980
Fax: 615-726-3404

To assist us in using the proper analytical n
this work being conducted for regulatory pu

Client Name: _____ Compliance Monitoring? Yes
Address: _____ Enforcement Action? Yes
City/State/Zip: _____ Report To: _____
Project Manager: _____ Invoice To: _____
Telephone Number: _____ Fax No.: _____ TA Quote #: _____
Sampler Name: (Print) _____ Sampling Location: _____ Project ID: _____
Sampler Signature: _____ Project #: _____

Sample ID / Description	Date Sampled	Time Sampled	No. of Containers Shipped	Grab	Composite	Field Filtered	Preservative: Ice	Preservative: HNO_3 (Red Label)	Preservative: HCl (Blue Label)	Preservative: NaOH (Orange Label)	Preservative: H_2SO_4 Plastic (Yellow Label)	Preservative: H_2SO_4 Glass(Yellow Label)	Preservative: None (Black Label)	Preservative: Other (Specify)	Matrix: Groundwater	Matrix: Wastewater	Matrix: Drinking Water	Matrix: Sludge	Matrix: Soil	Matrix: Other (specify):	Analyze For:	RUSH TAT (Pre-Schedule)	Standard TAT

Special Instructions:

Laboratory Comments:
Temperature Upon Receipt:
Sample Containers Intact? Y N
VOCs Free of Headspace? Y N

Relinquished by:	Date	Time	Received by:	Date	Time
Relinquished by:	Date	Time	Received by TestAmerica:	Date	Time

Figure 24-2.

Example: Custody Seal

CUSTODY SEAL

Date _____

Signature _____

Nalge Nunc International

I-CHEM® Brand Products

Figure 24-3. Sample Acceptance Policy

All incoming work will be evaluated against the criteria listed below. Where applicable, data from any samples that do not meet the criteria listed below will be noted on the laboratory report defining the nature and substance of the variation. In addition the client will be notified either by telephone, fax or e-mail ASAP after the receipt of the samples.

1) Samples must arrive with labels intact with a Chain of Custody filled out completely. **Information must be legible.** The following information must be recorded.
   - *Client name, address, phone number and fax number (if available)*
   - *Project name and/or number*
   - *The sample identification*
   - *Date, time and location of sampling*
   - *The collectors name*
   - *The matrix description*
   - *The container description*
   - *The total number of each type of container*
   - *Preservatives used*
   - *Analysis requested*
   - *Requested turnaround time (TAT)*
   - *Any special instructions*
   - *Purchase Order number or billing information (e.g. quote number) if available*
   - *The date and time that each person received or relinquished the sample(s), including their signed name.*

2) Samples must be properly labeled.
   - Use durable labels
   - Include a unique identification number
   - Include sampling date and time & sampler ID
   - Include preservative used.
   - Use indelible ink
   - **Information must be legible**

Proper sample containers with adequate volume for the analysis and necessary QC are required for each analysis requested.

3) Samples must be preserved according to the requirements of the requested analytical method.

   - Chemical preservation (pH) will be verified prior to analysis and the project manager will be notified immediately if there is a discrepancy. If analyses will still be performed, it will be noted in the case narrative.

4) Sample Holding Times
   - TestAmerica will make every effort to analyze samples within the regulatory holding time. Samples must be received in the laboratory with enough time to perform the sample analysis. Except for short holding time samples (< 48hr HT) sample must be received with at least 48 hrs (working days) remaining on the holding time for us to ensure analysis.

The project manager will be notified if any sample is received in damaged condition. TestAmerica will request that a sample be resubmitted for analysis

Figure 24-4. Sample Check-in List - Example

Date/Time Received:_____

Client:_____ SDG #:_____NA [ ] SAF#:_____NA [ ]

Work Order Number:_____ Chain of Custody # _____

Shipping Container ID:_____ Air Bill # _____

1. Custody Seals on shipping container intact? NA [ ] Yes [ ] No [ ]

2. Custody Seals dated and signed? NA [ ] Yes [ ] No [ ]

3. Chain of Custody record present? Yes [ ] No [ ]

4. Cooler temperature:____ NA [ ] 5.Vermiculite/packing materials is NA [ ] Wet [ ] Dry [ ]

6. Number of samples in shipping container:_____

7. Sample holding times exceeded? NA [ ] Yes [ ] No [ ]

8. Samples have: ____tape _____hazard labels
_____custody seals _____appropriate samples labels

9. Samples are: _____in good condition ____leaking
_____broken ___have air bubbles(Only for samples requiring head space)

8. Sample pH taken? NA [ ] pH<2 [ ] pH>2 [ ] adjusted pH [ ]

9. Sample Location, Sample Collector Listed? * Yes [ ] No [ ]
*For documentation only. No corrective action needed.

12. Were any anomalies identified in sample receipt? Yes [ ] No [ ]

13. Description of anomalies (include sample numbers):
Sample Custodian:_____Date:_____

Client Sample ID	Analysis Requested	Condition	Comments/Action

Client Informed on_____by_____ Person contacted_____

[ ] No action necessary; process as is.

Project Manager_____
Date_____

SECTION 25.0
ASSURING THE QUALITY OF TEST RESULTS
(NELAC 5.5.9)

25.1 OVERVIEW

In order to assure our clients of the validity of their data, the laboratory continuously evaluates the quality of the analytical process. The analytical process is controlled not only by instrument calibration as discussed in Section 21, but also by routine process quality control measurements (e.g. Blanks, Laboratory Control Samples (LCS), Matrix Spikes (MS) and duplicates (DUP). These quality control checks are performed as required by the method or regulations to assess precision and accuracy. In addition to the routine process quality control samples, Proficiency Testing (PT) Samples (concentrations unknown to laboratory) are analyzed to help ensure laboratory performance.

QC samples shall be analyzed as part of the analytical batches. Batch QC samples shall be prepared and counted in the same time frame and with the same instrumentation configurations as the samples.

25.2 CONTROLS

Sample preparation or pre-treatment is commonly required before analysis. Typical preparation steps include homogenization, grinding, acid digestion, distillation, evaporation, drying and ashing. During these pre-treatment steps, samples are arranged into discreet manageable groups referred to as preparation (prep) batches. Prep batches provide a means to control variability in sample treatment. Control samples are added to each prep batch to monitor method performance and are processed through the entire analytical procedure with investigative/field samples.

25.3 NEGATIVE CONTROLS

25.3.1 **Method Blanks and reagent blanks** are used to assess preparation and analysis for possible contamination during the preparation and processing steps.

25.3.1.1 The method blank is prepared from a clean matrix similar to that of the associated samples that is free from target analytes, when possible (e.g., Reagent water, Ottawa sand, glass beads, filters, etc.) and is processed along with and under the same conditions as the associated samples. Reagent blanks consist of reagents and reagent water.

25.3.1.2 The method blank goes through all of the steps of the process (including as necessary: filtration, clean-ups, etc.). The method blank sample shall be prepared with similar aliquot size to that of routine samples.

25.3.1.3 The specific frequency of use for method blanks during the analytical sequence is generally 1 for each batch of samples; not to exceed 20 environmental samples.

25.3.1.4 Evaluation criteria and corrective action for method blanks is defined in the specific standard operating procedure for data review. Generally, corrective action is taken if

the concentration of a target analyte in the blank is above the reporting limit as established by the method or regulation:

- The source of contamination is investigated
- Measures are taken to minimize or eliminate the source of the contamination
- Affected samples are reprocessed or the results are qualified on the final report. DOE clients shall be contacted to discuss implementation of corrective action and the documentation of the corrective action shall be included in the case narrative.

25.4 POSITIVE CONTROLS

Control samples (e.g., QC indicators) are analyzed with each batch of samples to evaluate data based upon (1) Method Performance (Laboratory Control Sample (LCS) or Blank Spike (BS)), which entails both the preparation and measurement steps; and (2) Matrix Effects (Matrix Spike (MS) or Sample Duplicate (DUP), which evaluates field sampling accuracy, precision, representativeness, interferences, and the effect of the matrix on the method performed. Each regulatory program and each method within those programs specify the control samples that are prepared and/or analyzed with a specific batch.

Note that frequency of control samples vary with specific regulatory, methodology and project specific criteria. Complete details on method control samples are as listed in each data review SOP.

The laboratory standards used to prepare the LCSs and MSs shall be from a source independent of the standards used for calibration. The radiochemical LCS and MS activities shall be at least 5 times the RDL.

25.4.1 Method Performance Control - Laboratory Control Sample (LCS)

25.4.1.1 The LCS measures the accuracy of the method in a blank matrix and assesses method performance independent of potential field sample matrix affects in a laboratory batch.

25.4.1.2 The LCS is prepared from a clean matrix similar to that of the associated samples that is free from target analytes (for example: Reagent water, Ottawa sand, glass beads, etc.) and is processed along with and under the same conditions as the associated samples. The LCS is spiked with verified known amounts of analytes or is made of a material containing known and verified amounts of analytes, taken through all preparation and analysis steps along with the field samples. In some instances where there is no practical clean solid matrix available, aqueous LCS's may be processed for solid matrices.

25.4.1.3 As stated in the opening of this section, the LCS goes through all of the steps of the process (including as necessary: filtration, clean-ups, etc.). The LCS shall be prepared with similar aliquot size to that of routine samples.

25.4.1.4 The specific frequency of use for LCS during the analytical sequence is generally 1 for each batch of samples; not to exceed 20 environmental samples.

25.4.1.5 **Accuracy Calculation**: Percent Recovery (%R) Calculation (applies to LCS and Matrix Spikes.

$$\%R = \frac{AV}{TV} \times 100$$

Where: AV = Analyzed Value
TV = True Value

25.5 SAMPLE MATRIX CONTROLS

25.5.1 Matrix Spikes (MS)

25.5.1.1 The Matrix spike is used to assess the effect sample matrix of the spiked sample has on the precision and accuracy of the results generated by the method used.

25.5.1.2 An MS is essentially a sample fortified with a known amount of the test analyte(s). At a minimum, with each matrix-specific batch of samples processed, an MS is carried through the complete analytical procedure. Unless specified by the client, samples used for spiking are randomly selected and rotated between different client projects.

25.5.1.3 Unless otherwise specified, matrix spikes are not required for radiochemical analyses if an isotopic tracer or carrier is used in the analysis, or for gross alpha, gross beta, gamma or non-aqueous tritium.

25.5.1.4 The percent recovery calculation for matrix spikes is essentially the same as the calculation shown in 25.2.1.5 except that:

AV = Sp – Sa

Where: Sp = Spike result
Sa = Sample result

For radiochemical analyses, the acceptance limits are specified in RICH-RC-0002. If the sample activity is greater than five times the spiking level, the acceptance criteria does not have to be met.

25.5.2 Duplicates

25.5.2.1 For a measure of analytical precision, with each matrix-specific batch of samples processed, a duplicate (DUP) sample, matrix spike duplicate (MSD), or LCS duplicate (LCSD) is carried through the complete analytical procedure. Duplicate samples are usually analyzed with methods that do not require matrix spike analysis. LCSDs are normally not performed except when regulatory agencies or client specifications require them. The recoveries for the spiked duplicate samples must meet the same laboratory established recovery limits as the accuracy QC samples. If an LCSD is analyzed both the LCS and LCSD must meet the same recovery criteria and be included in the final report.

SECTION 26.0
REPORTING RESULTS
(NELAC 5.5.10)

26.1 OVERVIEW

The results of each test are reported accurately, clearly, unambiguously, and objectively in accordance with State and Federal regulations as well as client requirements. Analytical results are issued in a format that is intended to satisfy customer and laboratory accreditation requirements as well as provide the end user with the information needed to properly evaluate the results. Where there is a conflict between the client requested formats and accreditation requirements or data usability information, accreditation requirements and data usability information will take precedence over client requests. A variety of report formats are available to meet specific needs.

In cases where a client asks for simplified reports, there must be a written request from the client. There still must be enough information that would show any analyses that were out of conformance (QC out of limits) and there should be a reference to a full report that is made available to the client.

26.2 TEST REPORTS

Analytical results are reported in a format that is satisfactory to the client and meets all requirements of applicable accrediting authorities and agencies. A variety of report formats are available to meet specific needs. The report is printed on laboratory letterhead, reviewed, and signed by the appropriate project manager. At a minimum, the standard laboratory report shall contain the following information:

26.2.1 A report title (e.g. Analytical Report For Samples) .

26.2.2 A unique identification of the report (e.g. work order number) and on each page an identification in order to ensure the page is recognized as part of the report and a clear identification of the end.

Note: Page numbers of report are represented as page # of ##. Where the first number is the page number and the second is the total number of pages. Or, the total number of pages are listed on the first page of the report as long as the subsequent pages are identified by the unique report identification and consecutive numbers.

26.2.3 A copy of the chain of custody (COC).

- Any COCs involved with Subcontracting are included.

26.2.4 The name and address of client and a project name/number, if applicable.

26.2.5 Client project manager or other contact

26.2.6 Description and unambiguous identification of the tested sample(s) including the client identification code.

26.2.7 Date of receipt of sample, date and time of collection, and date(s) of test preparation and performance, and time of preparation or analysis if the required holding time for either activity is less than or equal to 72 hours.

26.2.8 Date reported or date of revision, if applicable.

26.2.9 Method of analysis including method code (EPA, Standard Methods, etc).

26.2.10 Practical quantitation limits or reporting limit.

26.2.11 Method detection limits (if applicable)

26.2.12 Definition of Data qualifiers and reporting acronyms (e.g. ND).

26.2.13 Sample results.

26.2.14 QC data consisting of method blank, LCS, and MS/MSD recoveries.

26.2.15 Condition of samples at receipt. This may be accomplished in a narrative or by attaching sample login sheets.

26.2.16 A statement to the effect that the results relate only to the items tested and the sample as received by the laboratory.

26.2.17 A signature and title of the person(s) accepting responsibility for the content of the report and date of issue. Signatories are appointed by the Lab Director. For applying an electronic signature refer to the Electronic Signature Policy (Section 26.4).

When NELAC accreditation is required, the lab shall certify that the test results meet all requirements of NELAC or provide reasons and/or justification if they do not. ***Example: "At the time of analysis the laboratory was in compliance with the current NELAC standards and held accreditation for all analyses performed unless noted by a qualifier. The labs accreditation number is _____".***

26.2.18 Where applicable, a narrative to the report that explains the issue(s) and corrective action(s) taken in the event that a specific accreditation or certification requirement was not met.

26.2.19 Appropriate laboratory certification number for the state of origin of the sample, if applicable.

26.2.20 If only part of the report is provided to the client (client requests some results before all of it is complete), it must be clearly indicated on the report (e.g., partial or preliminary report), and that a complete report will follow once all of the work has been completed.

26.2.21 Any out of network subcontracted analysis results are provided as a separate report on the official letterhead of the subcontractor. All in-network subcontracting is clearly identified on the report as to which laboratory performed a specific analysis.

26.3 REPORTING LEVEL OR REPORT TYPE

Richland offers four levels of quality control reporting. Each level, in addition to its own specific requirements, contains all the information provided in the preceding level. The packages provide the following information in addition to the information described above:

- Level I is a report with the features described in Section 26.2 above.
- Level II is a Level I report plus summary information, including results for the method blank, percent recovery for laboratory control samples and matrix spike samples, and the RPD/RER values for all MSD and sample duplicate analyses.
- Level III contains all the information supplied in Level II, but presented on the CLP-like summary forms, and relevant calibration information. A Level II report is not included, unless specifically requested. No raw data is provided.
- Level IV is the same as Level III with the addition of all raw supporting data.

In addition to the various levels of QC packaging, the laboratory also provides reports in diskette deliverable form. Initial reports may be provided to clients by facsimile/email. Procedures used to ensure client confidentiality are outlined in Section 26.7.

26.3.1 Electronic Data Deliverables (EDDs)

EDDs are routinely offered as part of TestAmerica's services. Richland offers a variety of EDD formats including Environmental Restoration Information Management System (ERPIMS), Excel, Dbase and Text Files.

EDD specifications are submitted to the IT department by the PM for review and undergo the contract review process. Once the facility has committed to providing data in a specific electronic format, the coding of the format may need to be performed. This coding is documented and validated. The validation of the code is retained by the IT staff coding the EDD.

EDDs shall be subject to a review to ensure their accuracy and completeness. If EDD generation is automated, review may be reduced to periodic screening if the laboratory can demonstrate that it can routinely generate that EDD without errors. Any revisions to the EDD format must be reviewed until it is demonstrated that it can routinely be generated without errors. If the EDD can be reproduced accurately and if all subsequent EDDs can be produced error-free, each EDD does not necessarily require a review.

26.4 SUPPLEMENTAL INFORMATION FOR TEST

The lab identifies any unacceptable QC analyses or any other unusual circumstances or observations such as environmental conditions and any non-standard conditions that may have affected the quality of a result. This is typically in the form of a footnote or a qualifier and/or a narrative explaining the discrepancy in the front of the report.

26.4.1 Where quality system requirements are not met, a statement of compliance/non-compliance with requirements and/or specifications, including identification of test results derived from any sample that did not meet NELAC sample acceptance requirements such as improper container, holding time, or temperature.

26.4.2 Opinions and Interpretations - The test report contains objective information, and generally does not contain subjective information such as opinions and interpretations. If such information is required by the client, the Laboratory Director will determine if a response can be prepared. If so, the Laboratory Director will designate the appropriate member of the management team to prepare a response. The response will be fully documented, and reviewed by the Laboratory Director, before release to the client. There may be additional fees charged to the client at this time, as this is a non-routine function of the laboratory.

When opinions or interpretations are included in the report, the laboratory provides an explanation as to the basis upon which the opinions and interpretations have been made. Opinions and interpretations are clearly noted as such and where applicable, a comment should be added suggesting that the client verify the opinion or interpretation with their regulator. For DOE clients, client approval must be obtained prior to adding opinions and interpretations in a case narrative.

26.5 ENVIRONMENTAL TESTING OBTAINED FROM SUBCONTRACTORS

If Richland is not able to provide the client the requested analysis, the samples would be subcontracted following the procedures outlined in Section 8.

Data reported from analyses performed by a subcontractor laboratory are clearly identified as such on the analytical report provided to the client. Results from a subcontract laboratory outside of the TestAmerica network are reported to the client on the subcontract laboratory's original report stationary and the report includes any accompanying documentation.

26.6 CLIENT CONFIDENTIALITY

In situations involving the transmission of environmental test results by telephone, facsimile or other electronic means, client confidentiality must be maintained.

TestAmerica will not intentionally divulge to any person (other than the Client or any other person designated by the Client in writing) any information regarding the services provided by TestAmerica or any information disclosed to TestAmerica by the Client. Furthermore, information known to be potentially endangering to national security or an entity's proprietary rights will not be released.

Note: This shall not apply to the extent that the information is required to be disclosed by TestAmerica under the compulsion of legal process. TestAmerica will, to the extent feasible, provide reasonable notice to the client before disclosing the information.

Note: Authorized representatives of an accrediting authority are permitted to make copies of any analyses or records relevant to the accreditation process, and copies may be removed from the laboratory for purposes of assessment.

26.6.1 Report deliverable formats are discussed with each new client. If a client requests that reports be faxed or e-mailed, the reports are faxed with a cover sheet or e-mailed with the following note that includes a confidentiality statement similar to the following:

This material is intended only for the use of the individual(s) or entity to whom it is addressed, and may contain information that is privileged and confidential. If you are not the intended

recipient, or the employee or agent responsible for delivering this material to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone at the 1-509-375-3131 (or for e-mails: please notify us immediately by e-mail or by phone (1-509-375-3131) and delete this material from any computer).

26.7 FORMAT OF REPORTS

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

26.8 AMENDMENTS TO TEST REPORTS

Corrections, additions, or deletions to reports are only made when justification arises through supplemental documentation. Justification is documented using the laboratory's corrective action system (refer to Section 13).

The revised report is retained on the Archive data server, as is the original report. The revised report is stored in the Archive data server under the report number followed by an indication of amended report. The revised report will have the word "revised" or "amended" next to the date.

When the report is re-issued, a notation of Amended Report is placed on the cover/signature page of the report or at the top of the narrative page with a brief explanation of reason for the re-issue.

26.9 POLICIES ON CLIENT REQUESTS FOR AMENDMENTS

26.9.1 Sample Reanalysis Policy

Because there is a certain level of uncertainty with any analytical measurement a sample reanalysis may result in either a higher or lower value from an initial sample analysis. There are also variables that may be present (e.g. sample homogeneity, analyte precipitation over time, etc.) that may affect the results of a reanalysis. The data review SOPs address protocols for reanalysis.

26.9.2 Policy on Data Omissions or Reporting Limit Increases

Fundamentally, our policy is simply to not omit previously reported results (including data qualifiers). This policy has few exceptions. Exceptions are:

- Laboratory error.
- Sample identification is indeterminate (confusion between COC and sample labels).
- An incorrect analysis (not analyte) was requested. A written request for the change is required.
- Incorrect limits reported based on regulatory requirements.

- The requested change has absolutely *no possible* impact on the interpretation of the analytical results and there is *no possibility* of the change being interpreted as misrepresentation by anyone inside or outside of our company.

26.9.3 Multiple Reports

TestAmerica does not issue multiple reports for the same workorder where there is different information on each report (this does not refer to copies of the same report) unless required to meet regulatory needs and approved by QA.

Appendix 1.

TESTAMERICA
ETHICS POLICY No. CA-L-P-001

Refer to CA-L-P-001 for complete policy.

TestAmerica
EMPLOYEE ETHICS STATEMENT

I understand that TestAmerica is committed to ensuring the highest standard of quality and integrity of the data and services provided to our clients. I have read the Ethics Policy of the Company.

- *With regard to the duties I perform and the data I report in connection with my employment at the Company, I agree that:*
- *I will not intentionally report data values that are inconsistent with the actual values observed or measured.*
- *I will not intentionally report the dates, times, sample or QC identifications, or method citations of data analyses that are not the actual dates, times, sample or QC identifications, or method citations.*
- *I will not intentionally misrepresent another individual's work as my own or represent my own work as someone else's.*
- *I will not intentionally misrepresent any data where data does not meet Method or QC requirements. If it is to be reported, I will report it with all appropriate notes and/or qualifiers; I shall not modify data (either sample or QC data) unless the modification can be technically justified through a measurable analytical process, such as one deemed acceptable to the laboratory's Standard Operating Procedures, Quality Assurance Manual or Technical Director. All such modifications must be clearly and thoroughly documented in the appropriate laboratory notebooks/worksheets and/or raw data and include my initials or signature and date.*
- *I shall not make false statements to, or seek to otherwise deceive, members of Management or their representatives, agents, or clients/customers. I will not, through acts of commission, omission, erasure, or destruction, improperly report measurement standards, quality control data, test results or conclusions.*
- *I shall not compare or disclose results for any Performance Testing (PT) sample, or other similar QA or QC requirements, with any employee of any other laboratory, including any other TestAmerica laboratory, prior to the required submission date of the results to the person, organization, or entity supplying the PT sample.*
- *I shall immediately inform my supervisor or other member of management regarding any intentional or unintentional reporting of my own inauthentic data. Such report shall be given both orally and in writing to the supervisor or other member of management contacted and to the local Quality Assurance Manager. The Quality Assurance Manager will initial and date the information and return a copy to me. I shall not condone any accidental or intentional reporting of inauthentic data by other employees and will immediately report its occurrence. If I have actual knowledge of such acts committed by any other employees, and I do not report such information to designated members of Management, it shall be considered as serious as if I personally committed the offense. Accordingly, in that event, I understand that I may be subject to immediate termination of employment.*

- *I understand that if any supervisor, manager, or representative of TestAmerica management instructs, requests, or directs me to perform any of the aforementioned improper laboratory practices, or if I am in doubt or uncertain as to whether or not such laboratory practices are proper, I will not comply. In fact, I must report such event to all appropriate members of Management including, but not limited to, the Lab Director, all supervisors and managers with direct line reporting relationship between me and the Lab Director, and the local Quality Assurance representative, excluding such individuals who participated in such perceived improper instruction, request, or directive. In addition, I may contact Corporate Quality Assurance / Ethics Compliance Officer(s) for assistance.*
- *I understand the critical importance of accurately reporting data, measurements, and results, whether initially requested by a client, or retained by TestAmerica and submitted to a client at a later date, or retained by TestAmerica for subsequent internal use;*
- *I will not share the pricing or cost data of Vendors or Suppliers with anyone outside of the TestAmerica family of companies.*
- *I shall not accept gifts of a value that would adversely influence judgment.*
- *I shall avoid conflicts of interest and report any potential conflicts to the management (e.g. employment or consulting with competitors, clients, or vendors).*
- *I shall not participate in unfair competition practices (e.g. slandering competitors, collusion with other labs to restrict others from bidding on projects).*
- *I shall not misrepresent certifications and status of certifications to clients or regulators.*
- *I shall not intentionally discharge wastes illegally down the drain or onto the ground.*
- *I understand that any attempt by management or an employee to circumvent these policies will be subject to disciplinary action.*

As a TestAmerica employee, I understand that I have the responsibility to conduct myself with integrity in accordance with the ethical standards described in the Ethics Policy. I will also report any information relating to possible kickbacks or violations of the Procurement Integrity Act, or other questionable conduct in the course of sales or purchasing activities. I will not knowingly participate in any such activity and will report any actual or suspected violation of this policy to management.

I understand that if my job includes supervisory responsibilities, I shall not instruct, request, or direct any subordinate to perform any laboratory practice which is unethical or improper. Also, I shall not discourage, intimidate, or inhibit an employee who may choose to appropriately appeal my supervisory instruction, request, or directive which the employee perceives to be improper, nor retaliate against those who do.

The Ethics Policy has been explained to me by my supervisor or at a training session, and I have had the opportunity to ask questions if I did not understand any part of it. I understand that any violation of this policy subjects me to disciplinary action, which can include termination of my employment. In addition, I understand that any violation of this policy which relates to work under a government contract or subcontract could also subject me to the potential for prosecution under federal law.

EMPLOYEE SIGNATURE _____ Date _____

Supervisor/Trainer: _____ Date _____

TestAmerica
CONFIDENTIALITY AND PROPRIETARY INFORMATION AGREEMENT

TestAmerica and their predecessors, in their businesses, have developed and use commercially valuable technical and non-technical information and to guard the legitimate interests of TestAmerica and its clients, it is necessary to protect certain information as confidential and proprietary.

I, _____ , understand and acknowledge that during the term of my employment by TestAmerica, I will be privy to and entrusted with certain confidential information and trade secrets of TestAmerica and its clients.

Confidential information and trade secrets include, but are not limited to: customer and client lists; price lists; marketing and sales strategies and procedures; operational and equipment techniques; standard operating procedures; business plans and systems; quality control procedures and systems; special projects and technological research, including projects, research and reports for any government entity or client; client's plans and processes; client's manner of operation; the trade secrets of clients; client's data; vendor or supplier pricing; employee lists and personal information, and any other records, data, files, drawings, inventions, discoveries, applications, or processes which are not in the public domain.

I agree as follows:

1. I will not in any way, during the term of my employment, or at any time thereafter, except as authorized in writing by the Legal Department of TestAmerica or the client where client data is involved, disclose to others, use for my own benefit, remove from TestAmerica's premises (except to the extent off-site work is approved by my supervisor), copy or make notes of any confidential information and/or trade secrets of TestAmerica or its clients, excepting only that information which may be public knowledge. Technical and business information of any previous employer or other third party which I may disclose to TestAmerica shall be limited to that which was acquired legitimately and disclosed to me without restriction as to secrecy.

2. I agree that all inventions (whether or not patentable) conceived or made by me during the period of my employment by TestAmerica shall belong to TestAmerica, provided such inventions grow out of my work for TestAmerica and are related to the business of TestAmerica. I agree to disclose and assign such inventions to TestAmerica. In California, this provision shall not apply to any invention which qualifies fully under Section 2870 of the California Labor Code.

3. On termination of my employment from TestAmerica, I will deliver to TestAmerica all documents, records, notes, data, memoranda, files, manuals, equipment and things of any nature which relate in any way to confidential information and/or trade secrets of TestAmerica or its clients and which are in my possession or under my control.

4. I agree that during the period of my employment and for one (1) year from and after the termination (for any reason) of my employment with TestAmerica, I shall not directly or indirectly (without first obtaining the written permission of TestAmerica), recruit for employment, or induce to terminate his or her employment with TestAmerica, any person who is an active employee of TestAmerica on the last day of my employment with TestAmerica.

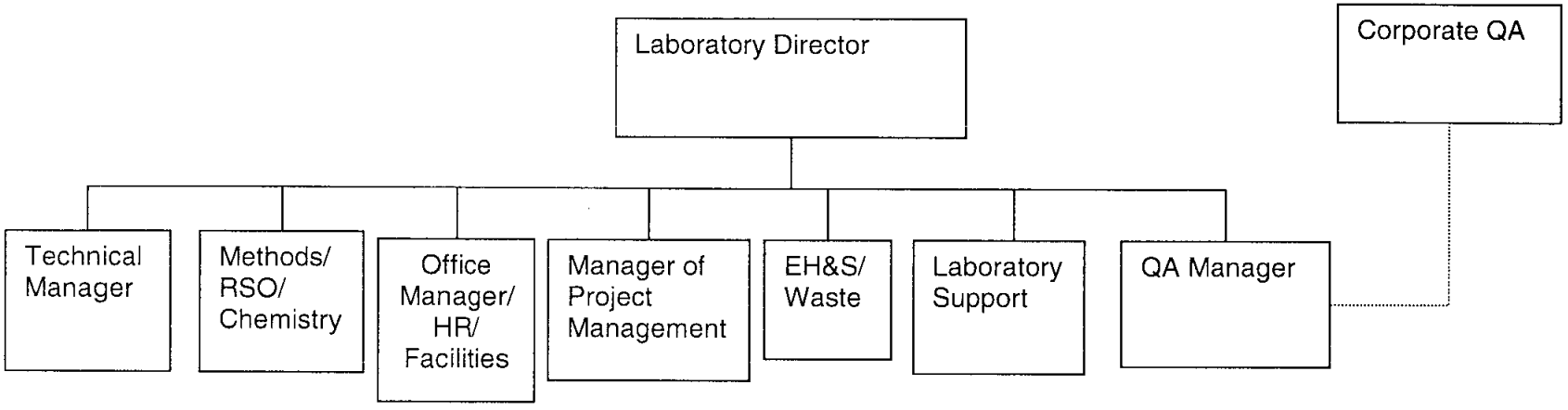
5. I acknowledge that if I were to breach any provision of this Confidentiality Agreement, money damages will be inadequate, and I hereby agree that TestAmerica shall be entitled, where appropriate, to specific performance and/or injunctive relief (i.e. to require me to comply with this Agreement). I further acknowledge that the willingness of TestAmerica to hire me or to continue my employment constitutes full and adequate consideration for the agreements, and obligations to which I have agreed as set forth in this document.

I have executed this Agreement, intending to be legally bound.

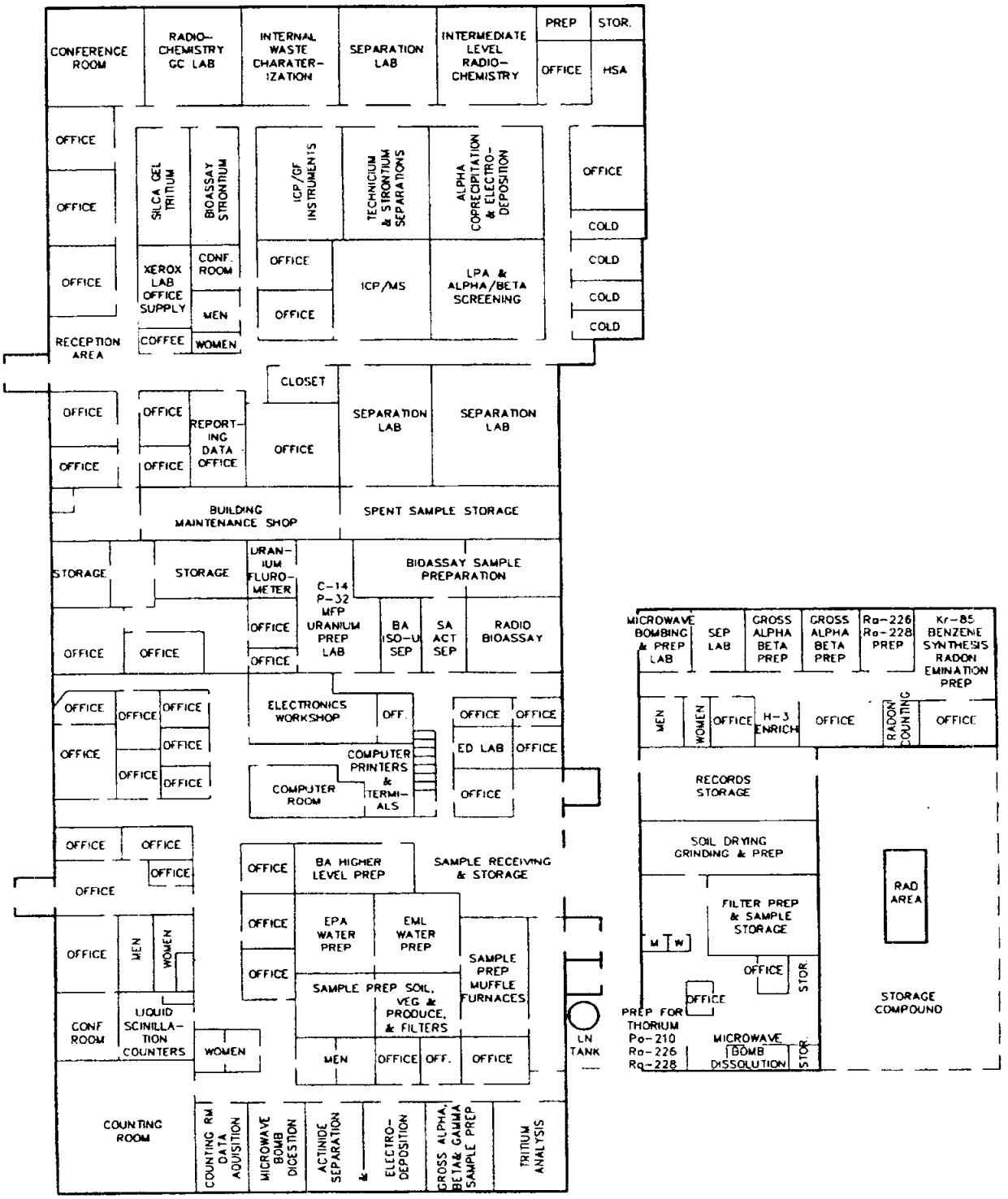
_____	_____	_____
Printed Name	*Signature*	*Date*

Appendix 2. Example Laboratory Organization Chart - Structure

(The most current chart can be obtained from the QA Manager or Lab Director)



Appendix 3. Laboratory Floor Plan



Appendix 4. Glossary/Acronyms

Glossary:

Acceptance Criteria:
Specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQC)

Accreditation:
The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. In the context of the National Environmental Laboratory Accreditation Program (NELAP), this process is a voluntary one. (NELAC)

Accrediting Authority:
The Territorial, State, or Federal Agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation (NELAC) [1.5.2.3]

Accuracy:
The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. (QAMS)

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

Assessment:
The evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of NELAC). (NELAC)

Assessment Criteria:
The measures established by NELAC and applied in establishing the extent to which an applicant is in conformance with NELAC requirements. (NELAC)

Assessment Team:
The group of people authorized to perform the on-site inspection and proficiency testing data evaluation required to establish whether an applicant meets the criteria for NELAP accreditation. (NELAC)

Assessor:
One who performs on-site assessments of accrediting authorities and laboratories' capability and capacity for meeting NELAC requirements by examining the records and other physical evidence for each one of the tests for which accreditation has been requested. (NELAC)
Audit:

A systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity. (EPA-QAD)

Batch:
Environmental samples which are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A preparation batch is composed of one to 20 environmental samples of the same matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch is composed of prepared environmental samples (extracts, digestates or concentrates) and /or those samples not requiring preparation, which are analyzed together as a group using the same calibration curve or factor. An analytical batch can include samples originating from various environmental matrices and can exceed 20 samples. (NELAC Quality Systems Committee)

Blank:
A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. (ASQC)

Blind Sample:
A sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process.

Calibration:
To determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument, or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements. (NELAC)

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

Calibration Method:
A defined technical procedure for performing a calibration. (NELAC)

Calibration Standard:
A substance or reference material used to calibrate an instrument (QAMS)

Carrier:
Carriers are stable counterparts of radioactive isotope(s) to be measured. When used, carriers are added to all samples in an analytical batch so that each sample has a specific measurable QC parameter (yield). The carrier yield is used in the data calculations to correct for all sources of analytical losses. The term carrier can also be used for a non-radioactive compound added to assist in isolation of the target analytie(s).

Certified Reference Material (CRM):
A reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body. (ISO Guide 30–2.2)

Chain of Custody:
An unbroken trail of accountability that ensures the physical security of samples and includes the signatures of all who handle the samples. (NELAC) [5.12.4]

Clean Air Act:
The enabling legislation in 42 U>S>C> 7401 et seq., Public Law 91-604, 84 Stat. 1676 Pub. L. 95-95, 91 Stat., 685 and Pub. L. 95-190, 91 Stat., 1399, as amended, empowering EPA to promulgate air quality standards, monitor and enforce them. (NELAC)

Comprehensive Environmental Response, Compensation and Liability Act (CERCLA/SUPERFUND):
The enabling legislation in 42 U.S.C. 9601-9675 et seq., as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), 42 U.S.C. 9601 et seq., to eliminate the health and environmental threats posed by hazardous waste sites. (NELAC)

Compromised Samples:
Those samples which are improperly sampled, insufficiently documented (chain of custody and other sample records and/or labels), improperly preserved, collected in improper containers, or exceeding holding times when delivered to a laboratory. Under normal conditions, compromised samples are not analyzed. If emergency situation require analysis, the results must be appropriately qualified. (NELAC)

Confidential Business Information (CBI):
Information that an organization designates as having the potential of providing a competitor with inappropriate insight into its management, operation or products. NELAC and its representatives agree to safeguarding identified CBI and to maintain all information identified as such in full confidentiality.

Conformance:
An affirmative indication or judgement that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements.

Corrective Action:
The action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence. (ISO 8402)

Data Audit:
A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data re of acceptable quality (i.e., that they meet specified acceptance criteria). (NELAC)

Data Reduction:
The process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useable form. (EPA-QAD)

Deficiency:
An unauthorized deviation from acceptable procedures or practices, or a defect in an item. (ASQC)

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

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

Duplicate Analyses:
The analyses or measurements of the variable of interest performed identically on two subsamples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation or storage internal to the laboratory. (EPA-QAD)

Environmental Detection Limit (EDL):
The smallest level at which a radionuclide in an environmental medium can be unambiguously distinguished for a given confidence interval using a particular combination of sampling and measurement procedures, sample size, analytical detection limit, and processing procedure. The EDL shall be specified for the 0.95 or greater confidence interval. The EDL shall be established initially and verified annually for each test method and sample matrix. (NELAC Radioanalysis Subcommittee)

Equipment Blank:
Sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures. (NELAC)

External Standard Calibration:
Calibrations for methods that do not utilize internal standards to compensate for changes in instrument conditions.

Federal Water Pollution Control Act (Clean Water Act, CWA):
The enabling legislation under 33 U.S.C. 1251 et seq., Public Law 92-50086 Stat 816, that empowers EPA to set discharge limitations, write discharge permits, monitor, and bring enforcement action for non-compliance. (NELAC)

Field Blank:
Blank prepared in the field by filing a clean container with pure de-ionized water and appropriate preservative, if any, for the specific sampling activity being undertaken (EPA OSWER)

Field of Testing:
NELAC's approach to accrediting laboratories by program, method and analyte. Laboratories requesting accreditation for a program-method-analyte combination or for an up-dated/improved method are required to submit to only that portion of the accreditation process not previously addressed (see NELAC, section 1.9ff). (NELAC)

Finding:
An assessment conclusion that identifies a condition having a significant effect on an item or activity. As assessment finding is normally a deficiency and is normally accompanied by specific examples of the observed condition. (NELAC)

Holding Times (Maximum Allowable Holding Times):
The maximum times that samples may be held prior to analyses and still be considered valid or not compromised. (40 CFR Part 136)

Inspection:
An activity such as measuring, examining, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformance is achieved for each characteristic.

Instrument Blank:
A clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD)

Laboratory:
A defined facility performing environmental analyses in a controlled and scientific manner. (NELAC)

Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample):
A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes, taken through all preparation and analysis steps. Where there is no preparation taken for an analysis (such as in aqueous volatiles), or when all samples and standards undergo the same preparation and analysis process (such as Phosphorus), there is no LCS. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

An LCS shall be prepared at a minimum of 1 per batch of 20 or less samples per matrix type per sample extraction or preparation method except for analytes for which spiking solutions are not available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. The results of these samples shall be used to determine batch acceptance.

Note: NELAC standards allow a matrix spike to be used in place of this control as long as the acceptance criteria are as stringent as for the LCS. (NELAC)

Laboratory Duplicate:
Aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently. (NELAC)

Least Squares Regression (1st Order Curve):
The least squares regression is a mathematical calculation of a straight line over two axes. The y axis represents the instrument response (or Response ratio) of a standard or sample and the x axis represents the concentration. The regression calculation will generate a correlation coefficient (r) that is a measure of the "goodness of fit" of the regression line to the data. A value of 1.00 indicates a perfect fit. In order to be used for quantitative purposes, r must be greater than or equal to 0.99 for organics and 0.995 for inorganics.

Limit of Detection (LOD):
An estimate of the minimum amount of a substance that an analytical process can reliably detect. An LOD is analyte- and matrix-specific and may be laboratory dependent. (Analytical Chemistry, 55, p.2217, December 1983, modified) See also Method Detection Limit.

Manager (however named):
The individual designed as being responsible for the overall operation, all personnel, and the physical plant of the environmental laboratory. A supervisor may report to the manager. In some cases, the supervisor and the manager may be the same individual. (NELAC)

Matrix:
The component or substrate that contains the analyte of interest. For purposes of batch and QC requirement determinations, the following matrix distinctions shall be used:

Aqueous: Any aqueous sample excluded from the definition of Drinking Water matrix or Saline/Estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.

Drinking Water: any aqueous sample that has been designated as a potable or potential potable water source.

Saline/Estuarine: any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

Non-aqueous Liquid: any organic liquid with ,15% settleable solids.

Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Solids: includes soils, sediments, sludges, and other matrices with .15% settleable solids.

Chemical Waste: a product or by-product of an industrial process that results in a matrix not previously defined.

Air: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbant tube, impinger solution, filter, or other device. (NELAC)

Matrix Spike (spiked sample or fortified sample):

Prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

Matrix spikes shall be performed at a frequency of one in 20 samples per matrix type per sample extraction or preparation method except for analytes for which spiking solutions are not available such as, total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. The selected sample(s) shall be rotated among client samples so that various matrix problems may be noted and/or addressed. Poor performance in a matrix spike may indicate a problem with the sample composition and shall be reported to the client whose sample was used for the spike. (QAMS)

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

Matrix spike duplicates or laboratory duplicates shall be analyzed at a minimum of 1 in 20 samples per matrix type per sample extraction or preparation method. The laboratory shall document their procedure to select the use of an appropriate type of duplicate. The selected sample(s) shall be rotated among client samples so that various matrix problems may be noted and/or addressed. Poor performance in the duplicates may indicate a problem with the sample composition and shall be reported to the client whose sample was used for the duplicate. (QAMS)

Method Blank:
A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses. (NELAC)

Method Detection Limit:
The minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. (40 CFR Part 136, Appendix B)

Minimum Detectable Concentration (MDC) - The minimum detectable concentration is defined as the smallest concentration of an analyte (activity or mass) in a sample that can be detected with a 5% probability of erroneously detecting activity, when in fact none was present (Type I error) and also, a 5% probability of not detecting activity, when in fact it is present (Type II error). Often used interchangeably with Minimum Detectable Activity, since the difference between the two terms is only one of units conversion.

National Environmental Laboratory Accreditation Conference (NELAC):
A voluntary organization of State and Federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP. (NELAC)

National Environmental Laboratory Accreditation Program (NELAP):
The overall National Environmental Laboratory Accreditation Program of which NELAC is a part. (NELAC)

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

NELAC Standards:
The plan of procedures for consistently evaluating and documenting the ability of laboratories performing environmental measurements to meet nationally defined standards established by the National Environmental Laboratory Accreditation Conference. (NELAC)

Performance Audit:
The routine comparison of independently obtained qualitative and quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory. (NELAC)

Performance Based Measurement System (PBMS):
A set of processes wherein the data quality needs, mandates or limitations of a program or project are specified and serve as criteria for selecting appropriate test methods to meet those needs in a cost-effective manner. (NELAC)

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

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

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

Proficiency Testing:
A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. (NELAC) [2.1]

Proficiency Testing Program:
The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories. (NELAC)

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

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

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

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

Quality Control Sample:
An uncontaminated sample matrix spiked with known amounts of analytes from a source independent from the calibration standards. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (EPA-QAD)

Quality Manual:
A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users. (NELAC)

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

Quantitation Limits:
The maximum or minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be quantified with the confidence level required by the data user. (NELAC)

Range:
The difference between the minimum and the maximum of a set of values. (EPA-QAD)

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

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

Reference Method:
A method of known and documented accuracy and precision issued by an organization recognized as competent to do so. (NELAC)

Reference Standard:
A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. (VIM-6.0-8)

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

Requirement:
Denotes a mandatory specification; often designated by the term "shall". (NELAC)

Resource Conservation and Recovery Act (RCRA):
The enabling legislation under 42 USC 321 et seq. (1976), that gives EPA the authority to control hazardous waste from the "cradle-to-grave", including its generation, transportation, treatment, storage, and disposal. (NELAC)

Safe Drinking Water Act (SDWA):
The enabling legislation, 42 USC 300f et seq. (1974), (Public Law 93-523), that requires the EPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations. (NELAC)

Sample Duplicate:
Two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method including sampling and analysis. (EPA-QAD)

Second Order Polynomial Curve (Quadratic): The 2^{nd} order curves are a mathematical calculation of a slightly curved line over two axis. The y axis represents the instrument response (or Response ratio) of a standard or sample and the x axis represents the concentration. The 2^{nd} order regression will generate a coefficient of determination (COD or r^2) that is a measure of the "goodness of fit" of the quadratic curvature the data. A value of 1.00 indicates a perfect fit. In order to be used for quantitative purposes, r^2 must be greater than or equal to 0.99.

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

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

Spike:
A known mass of target analyte added to a blank, sample or sub-sample; used to determine recovery efficiency or for other quality control purposes.

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

Standard Operating Procedures (SOPs):
A written document which details the method of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks. (QAMS)

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

Supervisor (however named):
The individual(s) designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees, supply and instrument adequacy and upkeep, quality assurance/quality control duties, and ascertaining that technical employees have the required balance of education, training and experience to perform the required analyses. (NELAC)

Systems Audit (also Technical Systems Audit):
A thorough, systematic, qualitative on-site assessment of the facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system. (EPA-QAD)

Technical Director:
Individuals(s) who has overall responsibility for the technical operation of the environmental testing laboratory. (NELAC)

Test:
A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process, or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate. (ISO/IEC Guide 2-12.1, amended)

Test Method:
An adoption of a scientific technique for a specific measurement problem, as documented in a laboratory SOP. (NELAC)

Traceability:
The property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons. (VIM-6.12)

Tracer:
Tracers are radioactive and/or massless. Where used, they are added to all samples in an analytical batch so that each sample has a specific measurable QD parameter (yield). Tracers are counted and the yield is used in the data calculations to correct for any and all sources of analytical losses.

Uncertainty:
A parameter associated with the result of a measurement that characterizes the dispersion of the value that could reasonably be attributed to the measured value. A measure of the total variability associated with a measurement that includes the two major error components: systematic error (bias) and random error (imprecision).

United States Environmental Protection Agency (EPA):
The Federal governmental agency with responsibility for protecting public health and safeguarding and improving the natural environment (i.e., the air, water, and land) upon which human life depends. (US-EPA)

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

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

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

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

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

Acronyms:

BS – Blank Spike
BSD – Blank Spike Duplicate
CAR – Corrective Action Report
CCV – Continuing Calibration Verification
CF – Calibration Factor
CFR – Code of Federal Regulations
COC – Chain of Custody
CRS – Change Request Form
DOC – Demonstration of Capability
DQO – Data Quality Objectives
DU – Duplicate
DUP - Duplicate
EHS – Environment, Health and Safety
EPA – Environmental Protection Agency
ICP - Inductively Coupled Plasma Atomic Emission Spectroscopy
ICV – Initial Calibration Verification
IDL – Instrument Detection Limit
IH – Industrial Hygiene
IS – Internal Standard
LCS – Laboratory Control Sample
LCSD – Laboratory Control Sample Duplicate
LIMS – Laboratory Information Management System
MDL – Method Detection Limit
MS – Matrix Spike
MSD – Matrix Spike Duplicate
MSDS - Material Safety Data Sheet
NELAC - National Environmental Laboratory Accreditation Conference
NELAP - National Environmental Laboratory Accreditation Program
PT – Performance Testing
QAM – Quality Assurance Manual
QA/QC – Quality Assurance / Quality Control
QAPP – Quality Assurance Project Plan
RF – Response Factor
RPD – Relative Percent Difference
RSD – Relative Standard Deviation
SD – Standard Deviation
SOP: Standard Operating Procedure
TAT – Turn-Around-Time

Appendix 5.

Laboratory Certifications, Accreditations, Validations

Richland maintains certifications, accreditations, certifications, and validations with numerous state and national entities. Programs vary but may include on-site audits, reciprocal agreements with another entity, performance testing evaluations, review of the QA Manual, Standard Operating Procedures, Method Detection Limits, training records, etc. At the time of this QA Manual revision, the laboratory has accreditation/certification/licensing with the following organizations:

The certificates and parameter lists (which may differ) for each organization may be found on the corporate web site, the laboratory's public server, the final report review table, and in the following offices: QA, marketing, and project management. Copies of these certifications and accreditations are also maintained in a separate cover as an addendum to this QAM.

Claims of Accreditation Status

Richland has agreed to make only valid claims as to its accreditation/certification status by any authority by ensuring that the expiration dates are not exceeded and the method-specific scope or parameter lists are supportable, as required by each. Any false claims would be reported to that authority. The agreement covers the use of the authority's name, such as "Authority-Accredited," logo, or certificate number. The only valid proof of accreditation/certification is the current certificate and scope of the authority. It is the responsibility of the laboratory to make these documents available to all staff, and it is the staff's duty to reference only the current documents.

A report with scope and non-scope analytes may only be presented on the same report if the non-accredited results are clearly and unambiguously identified. No report with non-scope analytes may be associated with the logo, "Authority accredited" phrase, or the certificate number. Only the analytes specified by a unique method are valid within the scope. There shall be no intentional misleading of the users of the laboratory's services in this regard.

No opinions and/or interpretations based on results outside the laboratory's scope may be presented on a document referenced by "Authority-accredited, the logo, or the certificate number. If these are made, they must be written in a separate letter which is not endorsed by the authority.

The "Authority-accredited" logo may only be affixed to equipment calibrated by a laboratory that is accredited by the authority. If calibration labels contain the logo, they must also show the calibration laboratory's name or its certificate number, the instrument's unique identification, the date of the last calibration, and a cross-reference to the last calibration certificate.

Should the company decide to use the "Authority-accredited" logo in marketing activities, no misrepresentation may occur. Only reference to the accredited scope at a specific laboratory site is allowed. If any "Authority-accredited" language is used in proposals or

quotations, any non-scope analytes must be clearly denoted as not accredited by that authority. The same is true for any use of laboratory letterhead with the "Authority-accredited" wording or logo. The logo may not be affixed to any material, item, product, part, or packaging, thereby implying accreditation status to that piece. In literature, any use of the logo must be positioned adjacent to the accredited laboratory's name and clearly state that the presence of the logo does not imply certification/approval of the products tested. At no time may the logo appear to suggest that a person is accredited. Misrepresentation of accreditation status is never allowed and must be reported if it occurs. If in doubt, the idea of the logo's use may be presented to the authority for approval.

If accreditation is terminated or suspended, the laboratory will immediately cease to use the "Authority-accredited" wording, the logo, or the certificate number reference in any way and inform clients impacted by the change.

Appendix 6 - Correlation of TestAmerica Quality Program with USDOE QSAS

USDOE Quality Systems for Analytical Services	TestAmerica Quality Program
4.1 DOE-1	QAM 4.2.14
4.2 DOE-1	QAM 6.2
4.2 DOE-2	QAM 9.3.1, 20.8.1 & 5.3
4.3 DOE-1	QAM 6.3
4.5 DOE-1	QAM 8.1
4.6 DOE-1	QAM 9.3.1
4.6 DOE-2	QAM 9.6
4.8 DOE-1	QAM 12.3
4.10 DOE-1	QAM 13.1, 13.3 & 5.5.1
4.11 DOE-1	QAM 14.1
4.12 DOE-1	QAM 15.1.4, 24.1.2, 24.5, 24.4, 8.3, 24.6
4.12 DOE-2	QAM 15.1.5
4.12 DOE-3	QAM 15.1.5
4.12 DOE-4	QAM 15.5.6.5
4.12 DOE-5	QAM 20.8.3
4.12 DOE-6	QAM 15.5.4
4.13 DOE-1	QAM 16.2
4.13 DOE-2	QAM 16.2
4.14 DOE-1	QAM 17.2
4.14 DOE-2	QAM 16.2.2, 16.3.2
4.14 DOE-3	QAM 17.2
5.2 DOE-1	QAM 18.3
5.2 DOE-2	QAM TABLE 13-1
5.2 DOE-3	QAM 5.3
5.3 DOE-1	QAM 16.2.4
5.3 DOE-2	QAM 16.2.4
5.4 DOE-1	QAM 5.3
5.4 DOE-2	QAM 5.3, 6.2
5.4 DOE-3	QAM 6.3
5.4 DOE-4	QAM 16.2.1.1, 20.8.1.1, 20.8.1, 20.8.1.2 & SOP RICH-IS-0001
5.5 DOE-1	QAM 21.3.5
5.5 DOE-2	QAM 21.3.3
5.5 DOE-3	QAM 22.3, 21.3
5.5 DOE-4	QAM 21.3, 9.3.3 & SOPs RICH-QA-5003, RICH-QA-5017
5.5 DOE-5	QAM 21.3.4
5.5 DOE-6	SOP RICH-RC-5058
5.5 DOE-7	N/A
5.5 DOE-8	N/A
5.5 DOE-9	IDB User Guide
5.5 DOE-10	QAM 9.4
5.6 DOE-1	QAM 9.3.3, 9.3.4, 22.4.1

USDOE Quality Systems for Analytical Services	TestAmerica Quality Program
5.6 DOE-2	QAM 9.3.3
5.8 DOE-1	QAM 18.1
5.8 DOE-2	QAM 24.1.1, 24.2.1.3
5.8 DOE-3	QAM 24.2.1.8
5.8 DOE-4	QAM 24.4
5.8 DOE-5	QAM TABLE 23-1
5.8 DOE-6	QAM 24.2.1.1 & SOP RICH-RC-0003
5.8 DOE-7	N/A
5.8 DOE-8	QAM 24.4
5.9 DOE-1	QAM 16.3.2
5.9 DOE-2	QAM Section 25
5.9 DOE-3	N/A
5.10 DOE-1	QAM 26.5.4
6.2.1	Radiation Safety Program "General Duties"
6.2.2	Radioactive Materials License
6.2.3	Radiation Safety Program "Foreword"
6.2.4	Radiation Safety Program "RSO Duties", "Radioactive Emergencies and Spills"
6.2.5	Radiation Safety Program "Radioisotope Inventory"
6.2.6	SOP RICH-HS-0001
6.3.1	N/A
6.3.2	N/A
6.3.3	N/A
6.4.1	CW-E-M-001 1.2
6.4.2	CW-E-M-001 Section 2
6.4.3	CW-E-M-001 5.7.2
6.4.4	SOP RICH-HS-0005
6.4.5	Laboratory Contingency Plan "Site Evacuation"
6.5.1	SOP RICH-HS-0007
6.5.2	SOPs RICH-HS-0001 4.2, RICH-HS-0007, RICH-HS-0008
6.5.3	SOPs RICH-HS-0007, RICH-HS-0002, RICH-HS-0001, RICH-RC-0015, RICH-HS-0008 & Radiation Safety Program "Radioactive Waste Handling", & CW-E-M-0001 Section 13
C.1 DOE-1	QAM 20.4.2
C.3 DOE-1	N/A
C.3 DOE-2	QAM 20.6.1.3
C.3 DOE-3	QAM 20.6.1.1
D.1 DOE-2	QAM 25.3.1.4
D.1 DOE-3	QAS
D.1 DOE-4	N/A
D.1 DOE-5	QAS
D.1 DOE-6	QAM 20.6.1.3

USDOE Quality Systems for Analytical Services	TestAmerica Quality Program
D.1 DOE-7	QAM 20.6.1.3
D.1 DOE-8	QAM Metals Addendum 20.1.1.1
D.1 DOE-9	QAM 20.6.1.3
D.1 DOE-10	QAM 21.1.1.1
D.1 DOE-11	SOPs RICH-RC-5015, RICH-QA-5006, RICH-RC-5058 & QAS
D.4 DOE-2	QAM 25.1
D.4 DOE-3	QAS
D.4 DOE-4	QAS
D.4 DOE-5	QAM 25.3.1.1
D.4 DOE-6	QAM 25.1
D.4 DOE-7	QAS
D.4 DOE-8	QAM 25.5.1
D.4 DOE-9	QAS
D.4 DOE-10	QAS
D.4 DOE-11	QAS
D.4 DOE-12	QAS
D.4 DOE-13	Analytical SOPs
D.4 DOE-14	QAS
D.4 DOE-15	QAS
D.4 DOE-16	QAM 21.4.1, 21.4.1.5 & SOP RICH-QA-5009
D.4 DOE-17	SOP RICH-RD-0007
D.4 DOE-18	SOP RICH-RD-0008
D.4 DOE-19	SOP RICH-RC-5005
D.4 DOE-20	QAS
D.4 DOE-21	SOP RICH-RD-0007
D.4 DOE-22	SOP RICH-RD-0008
D.4 DOE-23	SOP RICH-RD-0003
D.4 DOE-24	SOP RICH-RD-0001
D.4 DOE-25	RadCalc Validation and User Guides. QAS
D.4 DOE-26	SOP RICH-RC-0002
D.4 DOE-27	RadCalc Validation and User Guides. QAS
D.4 DOE-28	QAM 22.3
D.4 DOE-29	QAM 22.3
D.4 DOE-30	Analytical SOPs
D.4 DOE-31	QAM 19.3, 24.4
D.4 DOE-32	QAM 21.4.4, QAS