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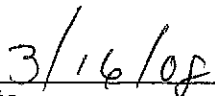
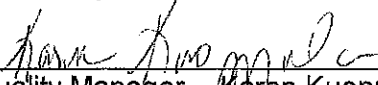
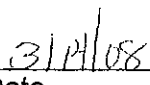
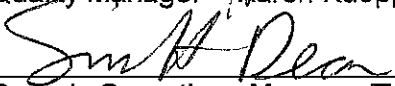
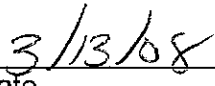
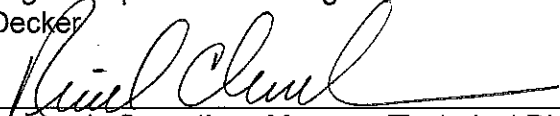
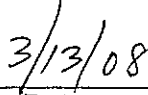
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CA-Q-S-003	Management of Change Procedure
CA-Q-S-004	Method Compliance & Data Authenticity Audits
CA-Q-S-005	Calibration Curves (General)
CW-Q-S-001	Corporate Document Control and Archiving
CW-Q-S-002	Writing a Standard Operating Procedure (SOPs)
CA-L-S-001	Internal Investigation of Potential Data Discrepancies and Determination for Data Recall
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CA-L-P-001	Ethics Policy
CA-L-P-002	Contract Compliance Policy
CW-L-P-001	Record Retention
CW-F-P-002	Authorization Matrix
CA-C-S-001	Work Sharing Process
CA-T-P-001	Qualified Products List
CW-F-S-004	Controlled Purchases Policy

SECTION 3

INTRODUCTION (NELAC 5.1 - 5.3)

3.1 INTRODUCTION AND COMPLIANCE REFERENCES

TestAmerica Denver'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 2003 National Environmental Laboratory Accreditation Conference (NELAC) standards and ISO/IEC Guide 17025 (1999). In addition, the policies and procedures outlined in this manual are compliant with the various accreditation and certification programs listed in Appendix 6. 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:

- EPA 600/4-88/039, *Methods for the Determination of Organic Compounds in Drinking Water*, EPA, Revised July 1991.
- EPA 600/R-95/131, *Methods for the Determination of Organic Compounds in Drinking Water*, Supplement III, EPA, August 1995.
- 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.
- Federal Register, 40 CFR Parts 136, 141, 172, 173, 178, 179 and 261.
- APHA, *Standard Methods for the Examination of Water and Wastewater*, 18th Edition, 19th, 20th and 21st Edition.
- U.S. Department of Energy, *Quality Systems for Analytical Services*, Revision 2.1, November 2005.
- U.S. Department of Defense, *Quality Systems Manual for Environmental Laboratories*, Final Version 3, January 2006.
- U.S. Department of Defense, *Air Force Center for Environmental Excellence Quality Assurance Project Plan(QAPP)*, Version 4.0.02, May 2006.
- Nuclear Regulatory Commission (NRC) quality assurance requirements.
- Toxic Substances Control Act (TSCA).

3.2 TERMS AND DEFINITIONS

A Quality Assurance Program is a company-wide system designed to ensure that data produced by TestAmerica Denver 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 5 for the Glossary/Acronyms.

3.3 SCOPE / FIELDS OF TESTING

TestAmerica Denver analyzes thousands of environmental and industrial samples every month. Sample matrices vary among drinking water, effluent water, groundwater, hazardous waste, sludge and soils. The Quality Assurance Program contains specific procedures and methods to test samples of differing matrices for chemical, physical, and biological parameters. 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 water, industrial waste, and soil 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 Appendix 4. 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 TestAmerica Denver 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 TestAmerica Denver'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/Manager, 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.

Laboratory-specific QAM changes are approved and documented through the Management of Change process (Refer to SOP No. CA-Q-S-003, Management of Change Procedure).

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 TestAmerica Denver'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 TestAmerica Denver policy QA-001, "Preparation and Management of Standard Operating Procedures (SOPs) and Other Controlled Documents".

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
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_____ COO - East	_____ Date
---------------------	---------------

Local:

_____ Organic Operations Manager Approval Technical Director	_____ Date	_____ Quality Assurance Approval	_____ Date
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_____ Laboratory Director Approval	_____ Date	_____ Inorganic Operations Manager Approval Technical Director	_____ Date
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1. Purpose

2. Procedure

3. Attachments

4. References/Cross References

SECTION 4

ORGANIZATION AND MANAGEMENT (NELAC 5.4.1)

4.1 OVERVIEW

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

***TestAmerica Denver
4955 Yarrow Street
Arvada, CO 80002
Federal ID# CO0026***

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:

TestAmerica Anchorage
TestAmerica Austin
TestAmerica Buffalo
TestAmerica Burlington
TestAmerica Cedar Falls
TestAmerica Chicago
TestAmerica Connecticut
TestAmerica Corpus Christi
TestAmerica Dayton
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 Richland
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. More extensive job descriptions are maintained by laboratory management.

4.2.1 Quality Assurance Program

The responsibility for quality lies with every employee of TestAmerica Denver. 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.

4.2.2 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.

4.2.3 Chief Operating Officer (COO)

The COO serves as the ranking executive for all respective analytical laboratory operational functions and reports to the President/CEO of the Analytical Division. The COO is responsible for the daily management of all analytical laboratories, long-term planning and development of technical policies and management plans. The COO ensures the attainment of corporate objectives through the selection, development, motivation, and evaluation of top management personnel. The COO approves all operating budgets and capital expenditures. The COO signs-off on the final QAM template that contains company policies for implementing the Quality Program.

4.2.4 General Manager (GM)

Each GM reports directly to the 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.

4.2.5 Vice President of Client and Technical Services

The Vice President (VP) of Client and Technical Services reports directly to the President/CEO and is responsible for offerings to clients including quality assurance, environmental health and safety, risk management, technical assistance, legal compliance and contract administration. The VP of Client and Technical Services provides support and direction to the Executive Director and Directors of these areas, and supports the COO in decisions regarding long term planning, resource allocation and capital expenditures.

4.2.6 Executive Director of Quality and Environmental Health and Safety (QA/EHS)

The Executive Director of QA/EHS reports to the VP of Client and Technical Services. With the aid of the Senior Management Team, Laboratory Director/ Managers, Quality Directors, EHS Directors, QA Managers and EHS Coordinators, the Executive Director-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.
- Working 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 Team 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 Executive Director-QA/EHS. Together with the Executive Director-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.
- Working with management to develop a plan of correction when a laboratory's quality system is determined to be inadequate.

- Review of QA/QC aspects of national projects.
- Assistance with certification activities.
- Providing assistance as needed in the selection of Quality Assurance Managers and reviewing their effectiveness.

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-Client and Technical Services and the Executive Director–QA/EHS. 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 CEO, COO, 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 Director of Technical Services

The Director of Technical Services is responsible for establishing, implementing and communicating TestAmerica'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.

4.2.10 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.

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

The EHSDs report directly to the Executive Director-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.
- Development and execution of the company Environmental Health and Safety Internal Audit program.
- 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.

4.2.12 Laboratory Director

TestAmerica Denver'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:

- Provides one or more technical directors for the appropriate fields of testing. The name(s) of the Technical Director will be included in the national database. If the Technical Director is absent for a period of time exceeding 15 consecutive calendar days, the Laboratory Director must designate another full time staff member meeting the qualifications of the Technical Director to temporarily perform this function. If the absence exceeds 65 consecutive calendar days, the primary accrediting authority must be notified in writing. The role of the Technical Director at TestAmerica Denver is fulfilled by the Laboratory Director or appointed designee(s).
- Ensures that all analysts and supervisors have the appropriate education and training to properly carry out the duties assigned to them and ensures that this training has been documented.
- Ensures that personnel are free from any commercial, financial and other undue pressures which might adversely affect the quality of their work.
- 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. Procedures that do not meet the standards set forth in the QAM or laboratory SOPs may be temporarily suspended by the Laboratory Director.
- Reviews and approves all SOPs prior to their implementation and ensures all approved SOPs are implemented and adhered to.
- Pursues and maintains appropriate laboratory certification and contract approvals. Supports ISO 17025 requirements.
- Ensures client specific reporting and quality control requirements are met.
- Captains the management team, consisting of the QA Manager, the Technical Director(s), and the Operations Manager as direct reports.

4.2.13 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 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. Corporate QA may be used as a resource in dealing with regulatory requirements, certifications and other quality assurance related items. The QA Manager directs the activities of the QA officers to accomplish specific responsibilities, which include, but are not limited to:
- Having functions independent from laboratory operations for which he/she has quality assurance oversight.
- Maintaining and updating the QAM.
- Monitoring and evaluating laboratory certifications; scheduling proficiency testing samples.
- Monitoring and communicating regulatory changes that may affect the laboratory to management.
- 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 all 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 of document control of SOPs, MDLs, control limits, and miscellaneous forms and information.
- Review a percentage of all final data reports for internal consistency. Review of Chain of Custody (COC), correspondence with the analytical request, batch QC status, completeness of any corrective action statements, 5% of calculations, format, holding time, sensibility and completeness of the project file contents.
- Review of external audit reports and data validation requests.
- Follow-up with audits to ensure client QAPP requirements are met.
- Establishment of reporting schedule and preparation of various quality reports for the Laboratory Director, clients and/or Corporate QA.
- Development of suggestions and recommendations to improve quality systems.
- Research of current state and federal requirements and guidelines.
- Captains the QA team to enable communication and to distribute duties and responsibilities.

4.2.14 Quality Assurance Specialist

The Quality Assurance Specialist performs several roles. The QA Specialist reports to the facility QA Manager. The QA Specialist is responsible for QA documentation and involvement in the following activities:

- Assist the QA Manager in performing the annual internal laboratory audits, compiling the evaluation, and coordinating the development of an action plan to address any deficiency identified.
- Facilitate external audits, coordinating with the QA Manager and Laboratory Staff to address any deficiencies noted at the time of the audit and subsequently presented in the final audit report.
- Assist the QA Manager in the preparation of new SOP's and in the maintenance of existing SOPs, coordinating annual reviews and updates.
- Manages the performance testing (PT) studies, coordinates follow up studies for failed analytes and works with QA Manager and Laboratory Staff to complete needed corrective action reports.
- Personnel training records review and maintenance.
- Document control maintenance.
- Assists the Quality Manager and Project Management Group in the review of program plans for consistency with organizational and contractual requirements. Summarize and

convey to appropriate personnel anomalies or inconsistencies observed in the review process.

- Manages certifications and accreditations.
- Monitors for compliance the following QA Metrics: Temperature Monitoring of refrigeration units and incubators; thermometer calibrations; balance calibrations; eppendorf/pipette calibrations; and proper standard/reagent storage.
- Periodic checks on the proper use and review of instrument logs.
- Initiate the Mint-miner data file review process for organic instrumentation. Maintain tracking sheet of activity.
- Initiate the annual Instrument review.
- Assist in the technical review of data packages which require QA review.

4.2.15 Technical Director

The Technical Director(s) report(s) directly to the Laboratory Director. The role of the Technical Director at TestAmerica Denver is fulfilled by the Operations Managers or appointed designee(s). He/she is accountable for all analyses and analysts with respect to ISO 17025. The scope of responsibility ranges from the new-hire process and existing technology through the ongoing training and development programs for existing analysts and second- and third-generation 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. He/she develops standard costing of SOPs to include supplies, labor, overhead, and capacity (design vs. demonstrated versus first-run yield) utilization.
- Reviewing and approving, with input from the QA Manager, proposals from marketing, in accordance with an established procedure for the review of requests and contracts. This procedure addresses the adequate definition of methods to be used for analysis and any limitations, the laboratory's capability and resources, the client's expectations. Differences are resolved before the contract is signed and work begins. A system documenting any significant changes is maintained, as well as pertinent discussions with the client regarding their requirements or the results of the analyses during the performance of the contract. All work subcontracted by the laboratory must be approved by the client. Any deviations from the contract must be disclosed to the client. Once the work has begun, any amendments to the contract must be discussed with the client and so documented.
- 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. Training includes instruction on calculations, instrumentation management to include troubleshooting and preventive maintenance.
- Enhancing efficiency and improving quality through technical advances and improved LIMS utilization. Capital forecasting and instrument life cycle planning for second generation methods and instruments as well as asset inventory management.
- Coordinating sample management from “cradle to grave,” insuring that no time is lost in locating samples.
- Scheduling all QA/QC-related requirements for compliance, e.g., MDLs, etc.
- Captains department supervisors to communicate quality, technical, personnel, and instrumental issues for a consistent team approach.
- Coordinates audit responses with supervisors and QA Manager.

4.2.16 LIMS Administrator

The LIMS Administrator reports to corporate IT. 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.
- Develops expertise in the requirements described in Good Automated Laboratory Practices (GALP)-EPA 2185, 1995 Edition, in order to ensure compliance.
- Programs and tests software modifications/changes.
- Coordinates testing to ensure that all LIMS software accurately performs its intended functions. Testing is performed and documented after installation or when modifications/changes are made.
- 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.
- LIMS database back-up once daily.

4.2.17 LAN Analyst

The LAN Analyst reports to the LIMS Administrator. Specific responsibilities include, but are not limited to:

- Working with corporate IT to solve problems and standardize laboratory IT equipment and processes
- Monitoring and supporting office automation so LAN is operational for internal and external communications
- Troubleshooting problems throughout the laboratory relating to computers, software, telephones, and other electronic equipment
- Managing software and hardware for all computer applications to give users legal and operational equipment to perform daily tasks
- Responsible for new user setup on network, LIMS, telephone, and voice mail
- Maintaining tape backups for multiple computer servers
- Providing after hour on-call support to keep network and PCs functioning properly
- Analyzing server log files for errors to look for potential problems with file servers
- Installing or upgrading computers and other equipment

4.2.18 Operations Manager

The Operations Manager manages and directs the analytical production sections of the laboratory. He/She reports directly to the Laboratory Director. He/She acts as the Technical Director in determining the most efficient instrument utilization. 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.
- Fully supports the quality system and, if called upon in the absence of the QA Manager, serves as his substitute in the interim.

4.2.19 Radiation Safety Officer

The Radiation Safety Officer (RSO) is responsible for implementing TestAmerica Denver's radiation safety program. The RSO reports directly to the Technical Director. The RSO's duties consist of:

- Manage the personnel radiation dosimetry program
- Maintains the Radioactive Materials License and radionuclide inventory
- Monitors laboratory operation for compliance with the Radiation Safety Manual

- Training, documenting, and evaluating the TestAmerica Denver personnel for handling radioactive material
- Creating, releasing, and decontaminating of Radiological Control Areas (RCAs)
- Monitoring and tracking of radioactive materials
- Conducting the radioactive material waste disposal program in accordance with State and Federal regulations
- Maintaining all records related to the radiation safety program

4.2.20 Employee Health and Safety Coordinator

The EH&S Coordinator is responsible for administering the EH&S program that provides a safe, healthy working environment for all employees and the environment. The Employee Health and Safety Coordinator (EH&S Coordinator) reports directly to the Laboratory Director and the corporate Environmental Health and Safety Director. He/She monitors all areas for unsafe conditions, acts, and potential hazards. Specific responsibilities include, but are not limited to:

- Staying current with the hazardous waste regulations
- Continuing training on hazardous waste issues
- Reviewing and updating annually the Hazardous Waste Contingency Plan in the Environmental Health & Safety Manual.
- Auditing the staff with regard to compliance with the Hazardous Waste Contingency Plan
- Contacting the hazardous waste subcontractors for review of procedures and opportunities for minimization of waste
- Conduct ongoing, necessary safety training and conduct new employee safety orientation.
- Assist in developing and maintaining the Chemical Hygiene/Safety Manual.
- Administer dispersal of all Material Safety Data Sheet (MSDS) information.
- Perform regular chemical hygiene and housekeeping instruction.
- Give instruction on proper labeling and practice.
- Serve as chairman of the laboratory safety committee.
- Provide and train personnel on protective equipment.
- Oversee the inspection and maintenance of general safety equipment – fire extinguishers, safety showers, eyewash fountains, etc. and ensure prompt repairs as needed.
- Supervise and schedule fire drills and emergency evacuation drills.
- Determine what initial and subsequent exposure monitoring, if necessary to determine potential employee exposure to chemicals used in the laboratory.
- When determined necessary, conduct exposure monitoring assessments.
- Determine when a complaint of possible over-exposure is “reasonable” and should be referred for medical consultation.

- Assist in the internal and external coordination of the medical consultation/monitoring program conducted by TestAmerica's medical consultants.

4.2.21 Hazardous Waste Specialist

The Hazardous Waste Specialist is responsible for coordinating and implementing the divisional hazardous waste program to ensure compliance with all federal, state, local laws, and company policies. The Hazardous waste specialist reports to the EH&S Coordinator. The duties consist of:

- Staying current with the hazardous waste regulations
- Conducts weekly inspections of satellite accumulation areas and all hazardous waste storage areas
- Operates and maintains on-site wastewater treatment system
- Coordinates the proper storage, packing and disposal of laboratory wastes according to Department of Transportation (DOT) and Resource Conservation and Recovery Act (RCRA) regulations
- Maintains waste disposal records
- Coordinates spill response activities including documentation for waste storage areas

4.2.22 Waste Disposal Technician

The Waste Disposal Technician is responsible for proper disposal of spent chemicals, process waste, and unused laboratory samples used in the laboratory according to corporate, federal, state, and local guidelines. The Waste Disposal Technician reports to the Hazardous Waste Specialist and EH&S Coordinator. The duties consist of:

- Packaging hazardous waste for transport per DOT, RCRA and TSCA guidelines
- Identifying waste streams and maintaining satellite accumulation areas
- Packages expired chemicals for shipment or disposal
- Tracks volume of waste generated for reporting to corporate and EPA
- Prepares and tracks implementation of the Waste Minimization Plan
- Empties satellite containers into bulk containers and returns to the laboratory for reuse

4.2.23 Department Manager

Department Managers report to the Operations Manager. At TestAmerica Denver there are two levels of Department Managers (I or II). The level designation is based on the level of experience. Each one is responsible to:

- Ensure that analysts in their department adhere to applicable SOPs and the QA Manual. They perform frequent SOP and QA Manual review to determine if analysts are in compliance and if new, modified, and optimized measures are feasible and should be added to these documents.

- With regard to analysts, participates in the selection, training (as documented in Section 8.1), 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 Personnel 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 and/or operate multiple instruments efficiently while performing maintenance and documentation, self-supervise, and function as a department team.
- 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. Each is responsible for 100% of the data review and documentation, non-conformance and CPAR issues, the timely and accurate completion of performance evaluation samples and MDLs, for his department.
- 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.
- Ensure that preventive maintenance is performed on instrumentation as detailed in the QA Manual or SOPs. He is responsible for developing and implementing a system for preventive maintenance, troubleshooting, and repairing or arranging for repair of instruments.
- Maintain adequate and valid inventory of reagents, standards, spare parts, and other relevant resources required to perform daily analysis.
- Achieve optimum turnaround time on analyses and compliance with holding times.
- Conduct efficiency and cost control evaluations on an ongoing basis to determine optimization of labor, supplies, overtime, first-run yield, capacity (designed vs. demonstrated), second- and third-generation production techniques/instruments, and long-term needs for budgetary planning.
- Develop, implement, and enhance calibration programs.
- Provide written responses to external and internal audit issues.

4.2.24 Laboratory Analysts

Laboratory analysts are responsible for conducting analysis and performing all tasks assigned to them by the group leader or supervisor. The Analyst position at TestAmerica Denver is divided into levels. These levels range from Analyst I to Analyst V. The level designation is based on experience, expertise, and responsibilities. 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 or member of QA staff.
- Perform 100% review of the data generated prior to entering and submitting for secondary level review.
- Suggest method improvements to their supervisor, the Technical Director, and the QA Manager. These improvements, if approved, will be incorporated. Ideas for the optimum performance of their assigned area, for example, through the proper cleaning and maintenance of the assigned instruments and equipment, are encouraged.
- 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.

4.2.25 Laboratory Technician

Laboratory Technicians are responsible for the preparation of samples and performing all tasks assigned to them by the group leader or supervisor. The Laboratory Technician position at TestAmerica Denver is divided into three levels. These levels are Laboratory Technician I, Laboratory Technician II, and Laboratory Technician III. The level designation is based on experience, expertise, and responsibilities. The responsibilities of the Laboratory Technician are listed below:

- Retrieving samples from Sample Control for analysis
- Performing sample preparation 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.
- Documenting standard and sample preparation, sample matrix effects, and any observed non-conformance on worklists, benchsheets, lab notebooks and/or the Non-Conformance Database
- Report all non-conformance situations, sample preparation 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 or member of QA staff.
- 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.

4.2.26 Laboratory Assistant

The Laboratory Assistant position is an entry-level position to learn basic laboratory technician skills. The Laboratory Assistant reports to their group leader or supervisor. The Laboratory Assistant's duties include the following:

- Assisting the Laboratory Technicians in preparation of samples for analysis
- Preparing routine forms and reports
- Collecting and preparing materials and supplies for the laboratory
- Assisting technicians in conducting routine analysis

4.2.27 Sample Control Manager

The Sample Control Manager reports to the Project Management Manager. The responsibilities are outlined below:

- Direct the logging of incoming samples into the LIMS
- Ensure the verification of data entry from login
- Provide daily assessments of sample receipts
- Monitor the preparation and shipment of bottle kits to clients
- Oversee the receipt, log in, and storage of samples
- Schedules couriers for sample pickup from customer sites

4.2.28 Sample Control Technician

The Sample Control Technician reports to the Sample Control Manager. The Sample Control Technician position at TestAmerica Denver is divided into levels. These levels range from Sample Control Technician I to Sample Control Technician IV. The level designation is based on experience and responsibilities of the Technician. The Sample Control Technician responsibilities include the following:

- Receive and unload samples or consignments in accordance with DOT regulations
- Verify samples against the Chain of Custody (COC)
- Log in sample into the LIMS to assign a lot number for tracking purposes and distribute the paperwork to the Project Managers and Department Managers
- Label samples with lot number assigned and deliver the samples to the appropriate labs for analysis daily
- Monitor freezer and cooler temperatures daily to confirm that the readings are within SOP guidelines
- Ship all subcontracted samples to designated lab in accordance with DOT regulations as needed

4.2.29 Shipping/Maintenance Technician

The Shipping/Maintenance Technician reports to the Sample Control Manager and the Project Management Manager. The Shipping/Maintenance Technician duties include the following:

- Maintaining the inventory control system
- Receiving and distributing incoming supplies
- Preparing and shipping bottle sampling kits to clients or on-site crews
- Maintaining bottle and cooler inventory
- Packing in-house samples for shipment to other laboratories

4.2.30 Courier

The Courier reports to the Sample Control Manager and the Project Management Manager. The Courier's duties include the following:

- Picking up and delivering samples and reports to clients and the laboratory
- Receiving and signing the chain of custody for samples
- Preparing and shipping bottle sampling kits to clients or on-site crews
- Performing preventative maintenance on company vehicles

4.2.31 Project Management Manager

The Project Management Manager reports to the Laboratory Director and serves as the interface between the laboratory's technical departments 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.
- Coordinate requests for sample containers and other services (data packages).

4.2.32 Project Manager

The Project Managers report to the Project Management Manager and serve as liaisons between the laboratory and its clients. At TestAmerica Denver there are two levels of Project Managers (I or II). The level designation is based on experience, expertise, and responsibilities. The Project Manager's responsibilities include:

- Ensuring client specifications are met by communicating project and quality assurance requirements to the laboratory.
- Notifying laboratory personnel of incoming projects and sample delivery schedules.
- Monitoring the status of all projects in-house to ensure timely delivery of reports.
- Informing clients of project-related problems, resolving service issues and coordinating technical issues with the laboratory staff.
- Coordinating client requests for sample containers and other services.
- Scheduling sample pick-ups from client offices or project sites and notifying the laboratory staff of incoming samples.
- Coordinating subcontract work.
- Assisting clients in procuring the proper sampling supplies.
- Responding to client inquiries concerning sample status.
- Assisting clients with resolution of problems concerning Chains-of-Custody

4.2.33 Project Management Assistant

The Project Management Assistant reports to the Project Management Manager and designated Project Manager. The Project Management Assistant assists the Project Manager in servicing the client's needs and communicating those needs to the laboratory. The Project Management Assistant's responsibilities include:

- Collating data reports, expanded deliverables, CLP data packages and electronic data deliverables (EDD's) for delivery to clients.
- Writing case narratives accompanying data packages to communicate anomalies to clients
- Entering data from subcontracted laboratories
- Proof reading and filing data reports received from the laboratory

- Assisting Project Managers in changing compound lists, TAT, and setting up tables in Word or Excel
- Monitoring report due dates for timely delivery
- Invoicing completed data packages
- Generating credit or debit invoices to ensure proper payment
- Copying and paginating reports

4.2.34 Support Supervisor

The Support Supervisor reports to the Laboratory Director and Project Management Manager. He/She is responsible for ensuring the timely and correct shipment of data reports to clients. He/She oversees the data review and data packaging groups. In addition, he/she:

- Coordinates work projects with project managers
- Supervises the review of data packages and authorizes its release
- Oversees the completion, mailing, and archiving of data reports
- Supervises the review of data packages for compliance with any Quality Assurance Program Plan (QAPP)

4.2.35 Data Review Analyst

The Data Review Analyst reports to the Support Supervisor. The Data Review Analyst is responsible for the reviewing of analytical data for contract compliance, completeness, and appropriate documentation. In addition, the Data Review Analyst performs the following:

- Reviews routine and non-routine data as recorded/produced by instrumentation
- Looks for discrepancies/inconsistencies with other project related results
- Assures contract compliance and compliance with client expectations have been met
- Checks data for compliance with the QAPP

4.2.36 Data Packaging Technician

The Data Packaging Technician reports to the Support Supervisor. The Data Review Analyst is responsible for preparing complete and accurate client report packages in accordance with contract compliance. Data Review Technicians perform the following duties:

- Compiling of data packages
- Paginating of data packages
- Creating hard copy deliverables
- Entering of data needed for final reports into the appropriate database
- Printing of final reports

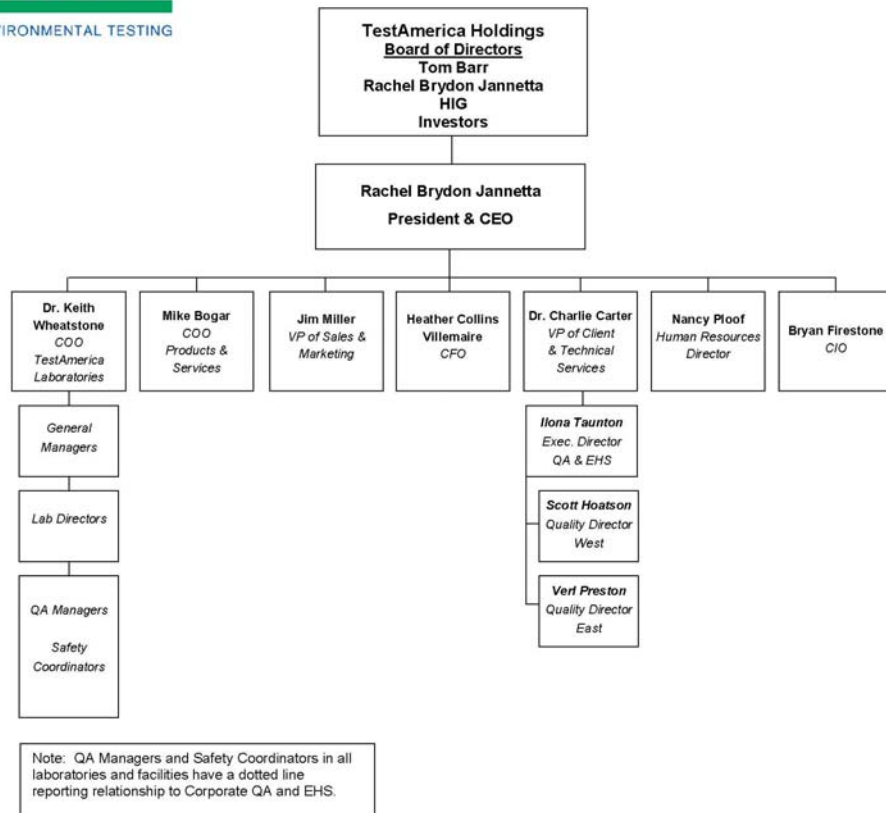
4.3 **DEPUTIES**

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

Key Personnel Title	Key Personnel	Deputy
Laboratory Director	Robert C. Hanish	Brett VanDelinder
QA Manager	Karen Kuoppala	Maria Fayard
Organic Operations Manager Organic Technical Director	Susan Decker	Richard Clinkscates
Inorganic Operations Manager Inorganic Technical Director	Richard Clinkscates	Susan Decker
Project Management Manager	Brett VanDelinder	Pat McEntee
Organic MS Manager	William Rhoades	Susan Decker
Organic GC Manager	Dennis Jonsrud	Susan Decker
Metals Manager	Doug Gomer	Richard Clinkscates
Wet Chemistry Manager	Claire Likar	Richard Clinkscates
LCMS Manager	Andria Lenoble	Susan Decker
Support Supervisor	Dee Kettula	Brett VanDelinder
EHS Coordinator	Adam Alban	Robert Fayard
Radiation Safety Officer	Andrew Meyer	Adam Alban

Figure 4-1.

Corporate Organization Chart



SECTION 5

QUALITY SYSTEM (NELAC 5.4.2)

5.1 QUALITY POLICY STATEMENT

The management of TestAmerica and TestAmerica Denver 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.

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

Every staff member at TestAmerica Denver 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, all 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 and Technical
- Corporate TestAmerica QA/QC Policy Memorandums (Refer to Section 3.4).
- Laboratory QA/QC Policy Memorandums (Refer to Section 3.4).

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), 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. The calculation of precision is described in Section 25.

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. The calculation of accuracy is described in Section 25.

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 columns or detectors (separation and identification), specific wavelengths (identification), specific mass spectra (identification), specific electrodes (separation and identification), etc..

5.4.7 Sensitivity

Sensitivity refers to the amount of analyte necessary to produce a detector response that can be reliably detected (Method Detection Limit) or quantified (Reporting Limit).

5.5 CRITERIA FOR QUALITY INDICATORS

The laboratory prepares a Reference Data Summary (aka. Browser Report) that summarizes the precision and accuracy acceptability limits for analyses performed at TestAmerica Denver. This summary is updated each time new limits are generated and is obtained with the use of the QC Browser software/program. The new and previous limits are listed in a table format along with the control chart data generated from TestAmerica Denver's TraQar Control Limits program. The limits, control charts, and any notations pertaining to the data are compiled into a package that contains the effective date. The control limit data package is then scanned and stored in the QA/Read/Control Limits folder on the L drive. Unless otherwise noted, limits within these tables are laboratory generated. Some acceptability limits are derived from US EPA methods when they are required. Where US EPA method limits are not required, TestAmerica Denver has developed limits from evaluation of data from similar matrices. Criteria for the development of control limits are contained in Section 25.

5.6 STATISTICAL QUALITY CONTROL

Statistically-derived precision and accuracy limits are required by selected methods (such as SW-846) and programs [such as the Ohio Voluntary Action Plan (VAP)]. TestAmerica Denver routinely utilizes statistically-derived limits to evaluate method performance and determine when corrective action is appropriate. The control charting process is defined in detail in SOP DV-QA-003P section 6. If a method defines the QC limits, the method limits are used. The analysts are instructed to use the current limits in the laboratory (dated and approved by the Department Manager and QA Manager) and entered into the Laboratory Information Management System (LIMS). The Quality Assurance Department maintains an archive of all limits used within the laboratory. If a method defines QC limits, the method limits are used.

If a method requires the generation of historical limits, the lab develops such limits from recent data in the QC database of the LIMS following the guidelines described in Section 25. All calculations and limits are documented and dated when approved and effective. On occasion, a client requests contract-specified limits for a specific project.

Surrogate limits are determined for a specific time period as defined above. The resulting ranges are entered in LIMS.

Current QC limits are entered and maintained in the LIMS analyte database. As sample results and the related QC are entered into LIMS, the sample QC values are compared with the limits in LIMS to determine if they are within the acceptable range. The analyst then evaluates if the sample needs to be rerun or re-extracted/rerun or if a comment should be added to the report explaining the reason for the QC outlier.

5.6.1 QC Charts

As the QC limits are calculated, QC charts are generated showing warning and control limits for the purpose of evaluating trends. Refer to SOP DV-QA-003P section 6 for a description of the control charting process and evaluation of trending.

5.7 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 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 specific SOP DV-QA-0010, Document Control provides additional information for TestAmerica Denver procedures.

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 or designee is responsible for the maintenance of the system and maintains the items in the QA Office.

Controlled documents are authorized by the QA Department and other management. In order to develop a new document, a department manager submits an electronic or hardcopy 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 annually 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

For changes to the QA Manual, refer to SOP No. DV-QA-001P. Requirements for TestAmerica corporate quality documents are described in Corporate SOP no. CW-Q-S-001. Uncontrolled copies must not be used within the laboratory. Previous revisions and back-up data are stored by the QA department as described in SOP DV-QA-0005, Document Archiving Procedure. Electronic copies are stored on the Public server in the QA folder for the applicable revision under L:\QA\READ\SOPS\ESOPS\ALL.

For changes to SOPs, refer to SOP No. DV-QA-001P, Preparation and Management of Standard Operating Procedures (SOPs).

Forms, worksheets, work instructions, white papers, protocols, and information are organized by department and document type in the QA office. Electronic versions are kept on the Public server in the QA folder under L:\QA\READ\SOPS\ESOPS. The procedure for the care of these documents is in SOP DV-QA-001P.

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 marked obsolete on the cover or 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

TestAmerica has established procedures for the review of work requests 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 compound 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 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 Customer Service Manager (CSM) is considered adequate. The CSM 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. It is recommended that, where there is a sales person assigned to the account, an attempt should be made to contact that sales person to inform them of the incoming samples.

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 Project Manager
- Customer Service Representative
- 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. TestAmerica Denver's Customer Service Department maintains copies of all signed contracts for reference locally.

7.3 DOCUMENTATION

Appropriate records are maintained for every contract or work request. All stages of the contract review process are documented and include records of any significant changes. See Figure 7-3 for contract review forms.

The contract will be distributed to and maintained by the appropriate sales/marketing personnel and the Regional Account Manager. A copy of the contract and formal quote will be filed with the laboratory CSM and the Lab Director/Manager. Contracts filed by the CSM group are filed in locked fire proof cabinets.

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 keeps a phone log of conversations with the client. These are logged in the PMs notebook which is archived by the QA group upon completion.

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, TestAmerica Denver 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 QC requirements. The bid document form in figure 7-3 is used to disseminate information from the CSM staff to the PM.

PM's are the direct client contact and they ensure resources are available to meet project requirements. Although PM's do not have direct reports or staff in production, they coordinate opportunities and work with laboratory management and supervisory staff to ensure the 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, holding 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 during production meetings. 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. Unique or large programs generally have a Quality Assurance Summary prepared by the PM. This summary is posted on the outlook folders for anyone in the lab to access. The Quality Assurance Summary documents all requirements that are non-standard.

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 also communicated to the laboratory management during production meetings. 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 Department Manager. After the modification is implemented into the laboratory process, documentation of the modification is made in the case narrative of the data report(s).

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.

Figure 7-3.

Contract Review Requirements Checklist

CONTRACT NO.: _____

DATE: _____

Exception Criteria		Comments
<input type="checkbox"/>	The contract value is over \$100K.	
<input type="checkbox"/>	Payment terms are over 90 days, or payment terms requested indicate that TAL will be paid when the client is paid, with no maximum time limit.	
<input type="checkbox"/>	A waiver of subrogation by TAL or our insurance company is required.	
<input type="checkbox"/>	The warranty clause does not refer to TAL quality documents or the "standards of a competent professional in this industry."	
<input type="checkbox"/>	Remedies for breach of warranty include resampling costs paid for by TAL.	
<input type="checkbox"/>	The indemnification clause is very broad and can include liability for consequential damages.	
<input type="checkbox"/>	There is a liquidated damages or penalty clause.	
<input type="checkbox"/>	FAR flow down clauses impose cost accounting standards or defective pricing liability.	
<input type="checkbox"/>	There is an organizational conflict of interest clause.	
<input type="checkbox"/>	Insurance limits are over TAL's: a. General Liability - \$2,000,000, Limits Requested _____ b. Automobile Liability - \$1,000,000, Limits Requested _____ c. Workers Compensation—Other than statutory limit, Limits Requested _____ d. Employer's Liability - \$1,000,000, Limits Requested _____ e. Professional/Pollution Liability - \$5,000,000, Limits Requested _____ f. Umbrella Liability - \$4,000,000, Limits Requested _____	

REVIEWER: _____

**Figure 7-3.
Contract Summary Form**

Prepared By:		Contract No.:		Date:	
This Summary is for:	(check one) <input checked="" type="checkbox"/> Completed contract <input type="checkbox"/> Contract/proposal review due by:				
	(check one) <input type="checkbox"/> Client contract <input checked="" type="checkbox"/> Subcontract <input type="checkbox"/> Teaming Agreement <input type="checkbox"/> Vendor Contract				
The estimated value of the Contract over its life (\$000) is:		Signed Original Contract Location:		Term of Agreement:	
Contracting Party:					
Ultimate Client:					
Date of Contract:		Project/Program Name/Location:			
Responsible TAL Contacts:	Sales:		PM/Technical:	Contract Reviewer(s):	
Primary TAL Location(s):			Secondary TAL Location(s): (List All)		
Contracting Party Technical Contact:					
Address:					
Telephone:			Fax:		
Contracting Party Contracts Contact:					
Address:					
Telephone:			Fax:		
Type of Work: (check all that apply)	<input type="checkbox"/> Lab Testing <input type="checkbox"/> Consulting <input type="checkbox"/> On-site Lab <input type="checkbox"/> On-site Field Support <input type="checkbox"/> Courier Service <input type="checkbox"/> Includes work to be Subcontracted Work is <input type="checkbox"/> Environmental or <input type="checkbox"/> Not Environmental				
Contract Type: (check all that apply)	<input type="checkbox"/> MSA <input type="checkbox"/> BOA <input type="checkbox"/> Project-Specific <input type="checkbox"/> Work Order under MSA or BOA <input type="checkbox"/> Direct with Fed Gov't <input type="checkbox"/> Fed Gov't Subcontract <input type="checkbox"/> Direct State/Local Gov't <input type="checkbox"/> State/Local Gov't Subcontract <input type="checkbox"/> Commercial Client <input type="checkbox"/> E/C Firm				

Pricing:	<input type="checkbox"/> Included <input type="checkbox"/> Not Included		
Standard TAL Term & Conditions?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Required Routine TAT:	<input type="checkbox"/> EDD <small>(# of Days)</small> <input type="checkbox"/> Hard Copy <small>(# of Days)</small> <input type="checkbox"/> Business Days <input type="checkbox"/> Calendar Days
Reporting Formats Required:	<input type="checkbox"/> Standard <input type="checkbox"/> Standard + raw data <input type="checkbox"/> Full CLP-Like <input type="checkbox"/> Batch QC <input type="checkbox"/> Project-specific QC		
EDD Formats Required:	<input type="checkbox"/> EDD <input type="checkbox"/> CDROM <input type="checkbox"/> iQ		
Client Forecasts Required	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, how much advance notice?	
QAPP or Lab-standard Requirements?	<input type="checkbox"/> QAPP <input type="checkbox"/> Lab-Standard	Certification Required: (Describe)	
Liquidated Damages or penalties?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, Summarize:	
Payment Terms		Sample Disposal:	<input type="checkbox"/> Not stated or <input type="checkbox"/> Must retain for Select One and/or <input type="checkbox"/> Must get client approval for disposal
Record Retention Requirement?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, Summarize:	
Special Invoicing Requirements?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, Summarize:	
How are Change Orders Handled?			
Other Special Requirements/ Comments/Notes:			
<u>TOPIC</u>	<i>COMMENTS</i>		

Figure 7-3.

Contract File

Company Name: _____

Site: _____

Contract Number _____

Contract Type
<input type="checkbox"/> C=Contract
<input type="checkbox"/> CO=Change Order
<input type="checkbox"/> DO=Delivery Order
<input type="checkbox"/> Mod=Modification
<input type="checkbox"/> MSA=Master Service Agreement
<input type="checkbox"/> PO=Purchase Order
<input type="checkbox"/> SC=Subcontract
<input type="checkbox"/> TO=Task Order
<input type="checkbox"/> WO=Work Order
<input type="checkbox"/> WR=Waiver/Release

Effective Date: _____

Expiration Date: _____

NTE Value: _____

Quote #: _____

Payment Terms: _____

Action	Completed	Date
Prepare Contract Summary	<input type="checkbox"/>	
Legal Review	<input type="checkbox"/>	
New Clients Only - Accounting Department Approval	<input type="checkbox"/>	
TAL Execute Contract	<input type="checkbox"/>	
Signed Contract to Client (Waiting on Executed Copy) <input type="checkbox"/> OR Signed Contract Received From Client <input type="checkbox"/>	<input type="checkbox"/>	
Fully Executed Contract Received from Client <input type="checkbox"/> OR Fully Executed Contract Returned to Client <input type="checkbox"/> <input type="checkbox"/> PDF-Email <input type="checkbox"/> Original <input type="checkbox"/> FAX	<input type="checkbox"/>	
Scan to Network (Fully Executed Contract)	<input type="checkbox"/>	
Provide Contract Copy to Project Manager	<input type="checkbox"/>	
Request Insurance Certificate	<input type="checkbox"/>	

PM: _____

Final Lien Release Required ☐

Log Contract

TAL Denver Spread Sheet	<input type="checkbox"/>
TAL Corporate Spread Sheet	<input type="checkbox"/>
TAL Denver Signature Log	<input type="checkbox"/>

Comments:

Figure 7-3. Con't

BID DOCUMENTATION FORM

ORIGINATOR: _____ DATE: _____

PROJECT NAME: _____ SITE: _____

QUANTIMS QUOTE NO.: _____

TestAmerica LIMS QUOTE NO.: _____ CLIENT CODE: _____

EXISTING TA CONTRACT/PROJECT: ☐ Yes ☐ No TA LAB: _____

TA CONTRACT/PO NO.: _____ TA PRICING: ☐ Yes ☐ No

CREDIT CARD: ☐ AMEX ☐ Master Card ☐ VISA Other _____
☐ PM obtain name, account number, expiration date

CLIENT STATUS: ☐ Gold ☐ Gold Exception ☐ Standard
☐ Phase I ☐ Phase II

EMF FEE: ☐ Yes ☐ No

Minimum Log in Fee: ☐ Yes \$____ ☐ No

CONTRACT/PO NO.: _____

PAYMENT TERMS: ☐ 30 Days ☐ 45 Days ☐ 60 Days ☐ 90 Days ☐ Other _____

PROJECT TYPE: ☐ Commercial ☐ State ☐ Federal: _____

QA/REGULATORY OVERSIGHT:
☐ EPA ☐ AFCEE ☐ USACE ☐ DOE ☐ STATE ☐ NONE

REGULATORY AREA: ☐ RCRA/RFI/GW ☐ NPDES/CWA/WW ☐ SDWA/DW
☐ TSCA ☐ CERCLA

TestAmerica ACCOUNT EXECUTIVE: _____ TestAmerica PROJECT MANAGER: _____

☐ AE Input Provided (See Attachment or Notes) ☐ No AE Input Received

CLIENT CONTACT: _____ PHONE: _____

FAX: _____ MOBILE: _____

E-MAIL: _____

COMPANY: _____
MANAGING
OFFICE
ADDRESS: _____

REPORT TO: _____

INVOICE TO: _____

PROJECT _____

MANAGER: _____ PHONE: _____

FAX: _____

E-MAIL: _____

PROJECT
CHEMIST: _____ PHONE: _____

FAX: _____

E-MAIL: _____

DATA
VALIDATOR: _____ PHONE: _____

FAX: _____

E-MAIL: _____

FIELD
CONTACT: _____ PHONE: _____

FAX: _____

E-MAIL: _____

START DATE: _____ DURATION: _____

BOTTLE ORDER REQUIREMENTS:

SHIP TO: _____

DELIVERY DUE DATE: _____

RUSH SHIPPING BILLABLE ☐ YES (5 BUSINESS DAY'S NOTICE, MINIMUM, REQUESTED)

COURIER SERVICE REQUESTED ☐ YES
(BILLABLE FOR EVENT < \$200; \$25 MINIMUM; \$1.00 PER MILE)

SAMPLING MATERIALS: ☐ COC Forms ☐ Labels ☐ Custody Seals
☐ USDA Permit ☐ PPQ Form 550 Stickers
☐ Quarantined Soil Stickers (DEN-QA-0019, NY, MD,
NC, SC, GA, FL, AL, MS, LA, AR, TX)
VOA Vials ☐ Preserved ☐ Unpreserved
☐ Trip Blanks ☐ Temperature Blanks

☐ Encore Samplers ☐ Terra Core Samplers
☐ 3 EnCore/kit, \$30 ☐ 1 Terra Core/kit, \$15
☐ EnCore T Handle

☐ Client will accept palletized containers
☐ Client will not accept palletized containers

SAMPLING
FREQUENCY: ☐ Single Event ☐ Weekly ☐ Monthly ☐ Quarterly
☐ Semi-Annual ☐ Annual

CERTIFICATIONS/
APPROVALS: ☐ STATE _____ ☐ USACE ☐ AFCEE
☐ DoD QSM Self Declaration Form ☐ Other _____
☐ NELAP ☐ None
☐ DOE/Radioactive Materials License

RADIOACTIVITY: known radioactivity at site: ☐ NO ☐ Yes
☐ μ Ci levels ☐ mCi levels (if yes, contact RSO)
☐ prescreening required (always, if radioactivity suspected)

QAPP/SOW: ☐ AFCEE 3.0 ☐ AFCEE 3.1 ☐ AFCEE 4.0
☐ USACE Shell ☐ DOD QSM V3 ☐ TECQ TRRP
☐ Project/Client Specific (See Attachment) ☐ None

☐ MDL current
☐ need to request MDL from QA Department and Operations Manager
☐ MDLV required
☐ need to request MDLV from QA Department and Operations Manager

TAT REQUIREMENTS
(BUSINESS DAYS): ☐ FAX _____ ☐ E-MAIL _____ ☐ CD _____
☐ HARDCOPY _____ ☐ EDD _____

SERVICE REQUIREMENTS: ☐ Email Sample Confirmation Receipt Form
☐ Notify client of all nonconformances within 1 business day of occurrence

HARDCOPY
DELIVERABLES: ☐ Standard ☐ CLP-Like Forms ☐ AFCEE Forms

☐ Raw Data ☐ Other: _____

☐ MULTIPLE REPORTS ISSUED/REISSUED
☐ LEVEL IV HARDCOPY REPORT, \$40 EACH
☐ LEVEL III HARDCOPY REPORT, \$25 EACH

☐ Airbill ☐ Chain of Custody ☐ Sample Confirmation Receipt Form

EDDs: ☐ QUA 08 ☐ ERPIMS 4.0 ☐ None
(Standard)

☐ Client-Specific _____

☐ Specifications Attached

☐ STL STANDARD EDD, \$10 EACH
☐ ALL OTHER EDDs, \$25 EACH

SACs: ☐ STL DEN Standard, short spike list, standard data flags (QC 01)
☐ AFCEE 3.1 QAPP, AFCEE spike list, AFCEE flags (9G)
☐ AFCEE 4.0 QAPP, AFCEE spike list, AFCEE flags (A4)
☐ Full spike list, IDLs for metals, non-verified MDLs, standard data flags (9H)
☐ DoD QSM V3, full spike list, verified MDLs, routine data flags (Q3)
☐ Need New SAC? _____

PROJECT
QC: ☐ Batch MS/MSDs ☐ Project-Specific MS/MSDs
☐ See CoC for client designation
☐ Lab designate MS/MSD
☐ MS/MSD billable at unit cost
☐ MS/MSD gratis

☐ LCS ☐ LCSD

- ☐ MS/MSD -- for AFCEE/QSM: Method SW8081A requires toxaphene, technical chlordane, and single component pesticides if these are target compounds
- ☐ Standard Spike List ☐ Full Spike List (Attached)
- ☐ Standard QC Limits ☐ Project-Specific QC Limits (Attached)
- ☐ Field Blanks ☐ Field Duplicates ☐ Laboratory Duplicates
- ☐ Custom Calibration/Calibration Verification Requirements (Attached)
- ☐ Project-Specific QC Evaluation Criteria (Attached)

PROJECT
PARAMETERS/
MDLs/RLs:

- ☐ Standard Method List (Attached) ☐ Project-Specific List (Attached)

GC/MS TICs needed? ☐ Yes
☐ No

Number per fraction: ____

- ☐ Report on Dry Weight Basis ☐ Report on As-Received Basis
☐ Weigh out additional amount to compensate for dry weight correction
- ☐ Report to MDL ☐ Report to RL

Multiple dilutions required to be analyzed and reported?

☐ Yes ☐ No

- ☐ ANALYTICAL DILUTION > 10X, EXTRACTED SAMPLE. 50% SURCHARGE, EACH SAMPLE.
☐ ANALYTICAL DILUTION > 10X, DAI/P&T SAMPLE. 70% SURCHARGE, EACH SAMPLE.

Metals preparation for water samples:

☐ Total ☐ Total Recoverable ☐ Dissolved

SPECIAL TECHNICAL REQUIREMENTS:

Method 8260B:

Acrolein, Acrylonitrile or
2-Chloroethyl vinyl ether required? ☐ Yes ☐ No

Unpreserved analysis required? ☐ Yes ☐ No

Client apprised of impact on results? ☐ Yes ☐ No

7-Day holding time specified in special
instructions? ☐ Yes ☐ No

Method 624

Acrolein, Acrylonitrile or
2-Chloroethyl vinyl ether required? ☐ Yes ☐ No

3-Day holding time specified in special
instructions? ☐ Yes ☐ No

Method 524.2:

Unpreserved analysis required? ☐ Yes ☐ No

Client apprised of 24 hour HT for
unpreserved samples? ☐ Yes ☐ No

DV-WC-0048H
(Hydrazines)

Client apprised of 48 hour HT for
laboratory filtration and preservation
of water samples? ☐ Yes ☐ No

Client apprised of requirement for
unchlorinated water sample?

☐ Yes

☐ No

Client apprised of potentially
elevated soil RLs due to required
dilutions?

☐ Yes

☐ No

TX1005

PM apprised of requirement to store
soil samples at -12°C ?

☐ Yes

☐ No

PFOA/APFO

☐ Report target compound as PFOA (perfluorooctanoic acid)

☐ Report target compound as APFO (ammonium perfluorooctanoate)

BTEX/GRO

☐ analyze separately, using two SACs -- BTEX requires 2nd column confirmation; GRO
quantified from gasoline standard

☐ analyze together, using "XU" SAC -- BTEX does not require 2nd column confirmation; GRO quantified
from synthetic HC standard

SW5035 Sampling

☐ EnCore Sampler required

☐ Terra Core Sampler required

☐ 48h HT to freezing or methanol preservation

☐ 7d HT to freezing or methanol preservation

☐ 14d HT to freezing or methanol preservation

☐ methanol preservation required

☐ sodium bisulfate preservation required

Hexachlorophene by Method SW8270C -- Appendix IX analyses

☐ client advised that 40CFR Part 264 advises PQL = 10ug/L; STL DEN's
estimated PQL = 300ug/L

☐ client advised that TAL DEN analyzes a single-point standard at 1000ug/L, estimates
a DL of 30-330ug/L, and has no MDL value for this compound (compound
subject to non-reproducible performance)

☐ PM needs to include disclaimer in case narrative

Digestion of Soil Samples by Method SW3050B / SW6020

☐ client advised that alternate digestion procedure exists for antimony, which improves
solubility and recovery of antimony from soil matrices (Section 7.5)

☐ client declined alternate digestion for antimony (Section 7.5)

☐ client requested alternate digestion procedure for antimony (Section 7.5)

Metals Analysis

☐ Beryllium by ICP/AES only

☐ "QO" method Code only for SW6010B

☐ "AS" method Code only for EPA200.7

☐ Cations by ICP/AES only

☐ New ICP/MS instrument is operated in collision cell mode. This instrument may not be
used for drinking water compliance monitoring (per Method EPA 200.8). If
samples are analyzed for drinking water compliance monitoring and Method EPA
200.8 is required, then include this text in Special Instructions: "EPA 200.8
Drinking Water -- collision cell instrument may not be used to analyze samples."

Fluoride by 340.2

☐ Client notified that the lab does not perform distillation -- needed for wastewater

☐ If for wastewater compliance, EPA 300 is used, subcontract lab, or the client already
has history of comparability for distillation vs. no distillation & ISE.

SAMPLE/EXTRACT STORAGE AND WASTE DISPOSAL

☐ Storage beyond 30 days after invoice billable at \$____/container.

- ☐ Lab refrigerate samples and extracts 30 / 60 / 90 / ____ days after invoice
- ☐ Lab maintain samples and extracts at room temperature 30 / 60 / 90 / ____ days after invoice
- ☐ Lab dispose of samples and extracts 30 / 60 / 90 / ____ days after invoice
- ☐ Return samples and extracts 30 / 60 / 90 / ____ days after invoice

DATA RETENTION

- ☐ 5 / 7 / 10 years after invoice

PROJECT KICKOFF MEETING

- ☐ Need to schedule with departments: ☐ Organics ☐ Metals ☐ Wet Chemistry
☐ Reporting

PROJECT TESTS BY MATRIX

METHOD	WATER	SOIL	WASTE	BIOTA	AIR	COMMENTS

Comments:

SUBCONTRACTED TESTS:

TEST	MINIMUM SAMPLE AMOUNT	SAMPLE CONTAINER/ PRESERVATIVE	UNIT COST (\$)

SUBCONTRACT

VENDOR: _____
VENDOR POC: _____

PHONE: _____ FAX: _____

ADDRESS: _____

SATURDAY DELIVERY: ☐ YES ☐ NO ☐ VENDOR ADDRESS ☐ HOLD AT CARRIER

VENDOR
QUOTE NO.: _____ VENDOR
QUOTE DATE: _____

VENDOR TAT
(BUSINESS DAYS) _____ VENDOR
DELIVERABLES: _____

ADDITIONAL
INFORMATION:

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. Refer to TestAmerica Denver's SOP DV-QA-0027 for laboratory specific procedures.

For DOD projects the subcontractor laboratories used must have an established and documented laboratory quality system that complies with DoD QSM requirements. The subcontractor laboratories are evaluated following the procedures outlined below and as seen in Figure 8-1. The subcontractor laboratory must receive written project-specific approval from the DoD client before any samples are analyzed.

The QSM has 5 specific requirements for subcontracting:

1. Subcontractor laboratories must have an established laboratory quality system that complies with the QSM.
2. Subcontractor laboratories must be approved by the specific DoD Component laboratory approval process.
3. Subcontractor laboratories must demonstrate the ability to generate acceptable results from the analysis of PT samples, subject to availability, using each applicable method, in the specified matrix, and provide appropriate documentation to the DoD client.
4. Subcontractor laboratories must receive project-specific approval from the DoD client before any samples are analyzed.
5. Subcontractor laboratories are subject to project-specific, on-site assessments by the DoD client or their designated representatives.

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: TestAmerica Denver discloses, in all work proposals/contracts, the laboratories that could be used as a subcontract laboratory. 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. It is required to have written approval from the client, whether it be email or in the contract itself, for all subcontract work.

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 (in JD Edwards): A listing of all approved subcontracting laboratories and supporting documentation is available on the TestAmerica intranet site. Verify necessary accreditation for the requested tests prior to sending samples.
- Firms identified in accordance with the company's Small Business Subcontracting program as small, women-owned, veteran-owned and/or minority-owned businesses;
- NELAC, A2LA, State and/or Federal accredited laboratories.
- In addition, the firm must hold the appropriate certification to perform the work required.

All intra-company laboratories are pre-qualified for work sharing 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 has not been previously approved, CSMs, 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/Manager. The Laboratory Director/Manager 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 Preliminary Evaluation Documentation Checklist (Figure 8-1) has been completed and have supporting documentation on file prior to initiation of any work. This does not apply to other TestAmerica facilities. A letter or e-mail is sent to the lab requesting the following information:

8.2.1.1 If a lab is NELAC or A2LA accredited,

8.2.1.1.1 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.

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

8.2.1.1.3 USDA soil permit if available**

8.2.1.2 For Laboratories accredited by other agencies with an auditing program:

8.2.1.2.1 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.

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

8.2.1.2.3 USDA soil permit if available**

8.2.1.2.4 Description of Ethics and Data Integrity Plan.

8.2.1.2.5 The most recent 2 sets of full proficiency testing (PT) results relevant to the analyses of interest and any associated corrective action.

8.2.1.2.6 State Audit with Corrective Action Response

8.2.1.2.7 Example final report to confirm format is compliant and provides the necessary information. Minimally, it must be determined that Batch QC results are included in the laboratory reports and data is appropriately qualified.

8.2.1.2.8 A copy of raw data associated with the first project is requested for internal review. The raw data is reviewed by the QA Manager and the PM to ensure that the results meet the client's needs. If the QA manager is unfamiliar with the analysis being performed, notify Corporate QA for guidance on the review (it may need to be sent elsewhere for evaluation). This requirement can be skipped if an on-site visit of the laboratory is planned. (This requirement is effective as of the effective date of this section. Laboratories worked with previously [minimum of 6 months] are grandfathered in.)

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

- 8.2.1.3** For laboratories performing tests that are unaccredited or accredited by an agency without an audit program:
- 8.2.1.3.1** 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.
 - 8.2.1.3.2** Copy of necessary certifications (if available) 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.
 - 8.2.1.3.3** Insurance Certificate. This is required by TestAmerica's Chief Financial Officer.
 - 8.2.1.3.4** USDA soil permit if available**
 - 8.2.1.3.5** 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.
 - 8.2.1.3.6** Description of Ethics and Data Integrity Plan.
 - 8.2.1.3.7** The most recent 2 sets of full proficiency testing (PT) results relevant to the analyses of interest and any associated corrective action.
 - 8.2.1.3.8** Example final report to confirm format is compliant and provides the necessary information. (minimally, it must be determined that Batch QC results are included in the laboratory reports and data is appropriately qualified.
 - 8.2.1.3.9** Statement of Qualification (SOQ) or summary list of Technical Staff and Qualifications – position, education and years of experience.
 - 8.2.1.3.10** DoD work includes additional requirements as described in Section 8.1 above.
 - 8.2.1.3.11** A copy of raw data associated with the first project is requested for internal review. The raw data is reviewed by the QA Manager and the PM to ensure that the results meet the client's needs. If the QA manager is unfamiliar with the analysis being performed, notify Corporate QA for guidance on the review (it may need to be sent elsewhere for evaluation). This requirement can be skipped if an on-site visit of the laboratory is planned. (This requirement is effective as of the effective date of this section. Laboratories worked with previously [minimum of 6 months] are grandfathered in.)
- 8.2.2** Once the information is received by the QA Manager, it is evaluated for acceptability and forwarded to Corporate Contracts for formal contracting with the laboratory. They will add the lab to the approved list on the intranet site along with the associate documentation and notify the finance group for JD Edwards.

**USDA permit is required 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.

8.2.3 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 qualified subcontractors on the intranet site are known to meet minimal standards. 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.

8.2.4 The status and performance of qualified subcontractors will be monitored periodically by the Corporate Contract Department. Any problems identified will be brought to Corporate QA attention.

- 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 and Corporate Contracts if any laboratory requires removal 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 (or RAE or CSM) 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, with the initial setup of each project or annual basis, on a Verification of Subcontract Lab Status (Figure 8-2) 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

The Laboratory Director/Manager 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 - Preliminary Evaluation Documentation Checklist

Laboratory Under Evaluation:				
Client/Project For Which the Lab Will Be Subcontracted:				
Type of Analytical Services Required: <input type="checkbox"/> Inorganic <input type="checkbox"/> Radiochemistry <input type="checkbox"/> General <input type="checkbox"/> Organic <input type="checkbox"/> Physical Testing <input type="checkbox"/> Microbiological		Type of Sample Matrices Required: <input type="checkbox"/> Drinking Water <input type="checkbox"/> Waste Water <input type="checkbox"/> Groundwater <input type="checkbox"/> Mixed Waste <input type="checkbox"/> Hazardous Waste		
Item	Yes	No	NA	Comments
1. Which parameters will be subcontracted to this laboratory? List all:				
Did the subcontractor submit the following items and are they acceptable:				
2. Was a most recent audit, of requested parameters, performed by a state or federal agency, NELAP or other related third party audit submitted? Did the laboratory pass the state or the federal agency, NELAP, or other related third party audit?				
a. Was the Corrective action response sent to the state for federal agency? Was the laboratory corrective action response sufficient to address the problems found by the auditor?				
3. Were the two most recent PE samples for the requested parameters submitted?				
a. Did the PE samples pass criteria? If not, was the laboratory's corrective action response sufficiently explanatory?				
4. From the list of equipment submitted, does the auditor feel that sufficient equipment is available for performing the subcontracted analysis? Are equipment appropriate of the required test(s)?				
5. Was the laboratory QA manual submitted? Does the laboratory have a valid QA program and a QA manual?				
a. Are all subcontracted methods referenced in the QA manual?				

Laboratory Under Evaluation:				
Client/Project For Which the Lab Will Be Subcontracted:				
Type of Analytical Services Required:		Type of Sample Matrices Required:		
<input type="checkbox"/> Inorganic <input type="checkbox"/> Radiochemistry <input type="checkbox"/> General <input type="checkbox"/> Organic <input type="checkbox"/> Physical Testing <input type="checkbox"/> Microbiological		<input type="checkbox"/> Drinking Water <input type="checkbox"/> Waste Water <input type="checkbox"/> Groundwater <input type="checkbox"/> Mixed Waste <input type="checkbox"/> Hazardous Waste		
Item	Yes	No	NA	Comments
b. Do reporting limits; referenced methods numbers; sample containers, preservations and holding times; summary of method calibrations; laboratory quality control samples/criteria; and preventive maintenance referenced in the QA manual. If not, list the missing key elements:				
6. Were MDLs and reporting limits (RLs) submitted? Are they acceptable? From the MDLs and RLs submitted, can the potential subcontractor routinely meet the required RLs for the listed parameters?				
7. Are required local state agency certifications for laboratory testing available, current, and acceptable?				
8. Does the laboratory use EPA approved standard methods? Does the laboratory have the necessary SOPs to perform the required analyses?				
9. Does the laboratory meet client/project-specific analytical and QA requirements?				
10. Was an example of a standard client sample data report for the above parameters submitted? Is it acceptable?				
11. From the documentation presented by the potential subcontractor, does the QA auditor reviewing the data feel that the subcontractor can be used? If response is no, explain why?				
12. Has the auditor discussed these reasons with the TestAmerica Denver laboratory management, that requested the laboratory, and are the concerns shared by TestAmerica Denver management?				
13. Does the auditor feel that an on-site laboratory audit of the potential subcontractor is required?				
a. Has a date and time been set for the on-site audit?				

Laboratory Under Evaluation:				
Client/Project For Which the Lab Will Be Subcontracted:				
Type of Analytical Services Required:		Type of Sample Matrices Required:		
<input type="checkbox"/> Inorganic <input type="checkbox"/> Radiochemistry <input type="checkbox"/> General <input type="checkbox"/> Organic <input type="checkbox"/> Physical Testing <input type="checkbox"/> Microbiological		<input type="checkbox"/> Drinking Water <input type="checkbox"/> Waste Water <input type="checkbox"/> Groundwater <input type="checkbox"/> Mixed Waste <input type="checkbox"/> Hazardous Waste		
Item	Yes	No	NA	Comments
14. If radioactive materials involved, Radioactive Materials License and Radiation Protection Program.*				
*Any questions, contact the Corporate Health & Safety Director.				
Additional Comments:				
Prepared By:		Date:		
Reviewed By:		Date:		

Figure 8-2.
Example - Verification of Subcontract Lab Status.

TestAmerica Denver is responsible to our clients for on-going assurance that subcontracted analytical services meet TestAmerica Denver's expectations for quality. As part of this program, we require on-going verification that the following statements are true. Please return the completed form with the final report to TestAmerica Denver.

Laboratory Name: _____

	True	False	N/A	Comments
Your laboratory continues to hold current certifications as applicable to the requested fields of testing?				
Your laboratory has successfully completed PT samples for at least 2 of the last 3 of the requested fields of testing?				
Your laboratory has successfully completed method detection limits for the requested fields of testing within the last 12 months?				
There are no changes in equipment that affect the laboratory's capability to perform the requested fields of testing?				
There are no changes in qualified personnel that affect the laboratory's capability to perform the requested fields of testing?				
All testing is performed at the location to which the samples were delivered?				
Your laboratory does not have any OSHA, DOT, DoE, DoD, or EPA citations or pending investigations?				

Completed by: _____ on _____.
Name

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 the 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. Solvents and acids are pre-tested in accordance with Corporate SOP on Solvent & Acid Lot Testing & Approval, SOP No. CA-Q-S-001, *Verification and Storage of Chemical Standards*, SOP No. DV-QA-0015, and the TestAmerica Addendum to S-T-001, SOP No. S-T-001 DEN-1.

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. The Department Manager should complete the Purchase Request Order Form (Figure 9-1) when requesting reagents, standards, or supplies.

The analyst must provide the item number, item description, package size, and the quantity needed. The Department Manager completes the purchase request order form and provides it to the Shipping/Maintenance Technician. The Shipping/Maintenance Technician places the order with the corporate office, which in turn places the order with the vendor.

9.3.2 Receiving

It is the responsibility of the Shipping/Maintenance Technician to receive the shipment. It is the responsibility of the Shipping/Maintenance Technician to date the material when received for the vendor storage and purchasing area. If the material received was ordered directly by the lab for laboratory use, the analyst that placed the order is responsible for dating the material when received. Once the ordered reagents or materials are received, the shipping/maintenance technician 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 maintained and updated by the EH&S officer 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.

- Expiration dates can be extended if the dry chemical is found to be satisfactory based on acceptable performance of quality control samples (Continuing Calibration Verification (CCV), Blanks, Laboratory Control Sample (LCS), etc.).
- If the dry chemical is used for the preparation of standards, the expiration dates can be extended 6 months if the dry chemical is compared to an unexpired independent source in performing the method and the performance of the dry chemical is found to be satisfactory. The comparison must show that the dry chemical meets CCV limits. The comparison studies are maintained within each department.

Wherever possible, standards must be traceable to national or international standards of measurement or to national or international reference materials. Records to that effect are available to the user.

Compressed gases in use are checked for pressure and secure positioning daily. The minimum total pressure must be 100 psig. The tank regulators are set at 100 psig, when the tank pressure goes at/below 100 psig the automatic system switches to a tank with higher pressure, and then the empty tank must 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 conductivity is checked and recorded daily. If the water's conductivity is less than the specified limit, the Laboratory Director must be notified immediately in order to notify all departments, decide on cessation (based on intended use) of activities, and make arrangements for correction.

The laboratory may purchase reagent grade water (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.

Standard lots are verified before first time use if the laboratory switches manufacturers or has historically had a problem with the type of standard.

Purchased VOA vials must be certified clean and the certificates must be maintained. If uncertified VOA vials are purchased, all lots must be verified clean prior to use. This verification must be maintained.

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. Table 9-1 details specific storage instructions for reagents and chemicals. Section 22 discusses conditions for standard storage.

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/Manager. 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, approved by corporate (CapEx), and the order is given to the corporate office to place the actual order.

Upon receipt of a new or used piece of equipment, it is given a short name, such as HP-20, added to the equipment list described in Section 21 that is maintained by the QA Department and IT must be notified so that can be linked for back-ups. The instrument name is then added into the LIMS system for data recording purposes. Its capability is assessed to determine if it is adequate or not for the specific application. For instruments, a calibration curve is generated, followed by MDLs, Demonstration of Capabilities (DOCs), and other relevant criteria (see Section 20). For software, its operation must be deemed reliable and evidence of instrument verification must be retained by the IT Department or QA Department as specified in the laboratory's procedure for software verification (see SOP S-ITQ-007). Software certificates supplied by the vendors are filed with the LIMS Administrator. The manufacturer's operation manual is retained within the department that the equipment/instrument is located.

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 Department Managers. The service providers that perform the services are approved by the Department Managers/Laboratory Director.

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 spend and the potential impact on TestAmerica business. Vendors that provide test and measuring equipment, solvents, 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

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 9-2).

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 Laboratory Director are consulted with vendor and product selection that have an impact on quality.

Figure 9-1.
Purchase Order Request Form

TestAmerica Denver
Purchase Order Request Form

Vendor Name	Vendor #	Item Description	Item #	Qty.	U/M	Unit Cost	Total	Billing Acct. Number	Requested Delivery Date	Requested By
							\$0.00			
							\$0.00			
							\$0.00			
							\$0.00			
							\$0.00			
							\$0.00			
							\$0.00			
			Total	0		Total	\$0.00			

Department # _____

Order Placed By: _____

Group Leader Approval: _____

Date: _____

Manager Approval _____

Req Creation Date: _____

Type of Shipping	
Overnight Rush (1-day)	
Rush 2 Day (2-days)	
Ship Ground (5-7 days)	
Ship For Sure - (Date)	

If type of shipping is not designated the order will ship ground.
Rush orders processed late will need an extra day for delivery.
Please fill out form in its entirety.
Ordering days are Tues. and Thurs. before 10 am.

Accounting Codes:

58100 - Building MX
60000 - Glassware
61000 - Sample Bottles
62500 - Consumable Lab Supplies
63000 - Solvents/Chemicals
63000.001 - Standards
64000 - Gases
71000 - MX and Repairs (Contract)
71100 - MX & Repairs (Non-Contract)
77000 - Office Supplies

Table 9-1.
Storage of Reagents and Chemicals

Chemical	Storage Requirements
Concentrated Acids and Bases	Stored in the original containers at room temperature. All organic acids must be stored separately from inorganic acids. Acids should not be stored with bases.
Bulk Dry Chemicals	Stored in the original containers at room temperature. All organic acids must be stored separately from inorganic acids. Acids should not be stored with bases.
Working Solutions containing Organic Compounds	Stored as per method recommendation/ requirement. They are generally stored refrigerated at 4°C± 2°C.
Working Solutions containing only Inorganics	Stored at room temperature; refrigeration is optional, but recommended.
Flammable Solvents	Stored in solvent cabinets at room temperature.
Non-Flammable Solvents	Stored separately from the flammable solvents in cabinets at room temperature.

Figure 9-2
Example – JD Edwards Vendor Add Request Form



JD Edwards Vendor Add Request Form

Vendor name:	Lab location <u>and</u> 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

<input type="checkbox"/> Cost Reduction	Estimated Annual Savings \$
<input type="checkbox"/> Replace Current Vendor	Reason?
	Vendor being Replaced?
<input type="checkbox"/> New Product / Service	Describe:
<input type="checkbox"/> ISO Approved (<u>Required for Aerotech / P&K only</u>)	

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

TestAmerica Denver 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).

Note: ISO 17025/NELAC 2003 states that a laboratory "shall afford clients or their representatives cooperation to clarify the client's request". This topic is discussed in Section 7.

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 all requested information pertaining to the analysis of their samples. An additional charge may apply for additional data/information that was not requested prior to the time of sample analysis or 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.

The QA Manager or Technical Director 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.

TestAmerica Denver 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

TestAmerica Denver 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 SOP DV-QA-013P, Customer Complaints. 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.

Complaints fall into two categories: correctable and non-correctable. An example of a correctable complaint would be one where a report re-issue would resolve the complaint. An example of a non-correctable complaint would be one where a client complains that their data was repeatedly late. Non-correctable complaints should be reviewed for preventive action measures to reduce the likely hood of future occurrence and mitigation of client impact.

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

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. Refer to SOP DV-QA-0031, Nonconformance and Corrective Action System for the procedure to handle such situations.

Project Management may encounter situations where a client may request that a special procedure be applied to a sample that is not standard lab practice. Based on a technical evaluation, the lab may accept or opt to reject the request based on technical or ethical merit. An example might be the need to report a compound that the lab does not normally report. The lab would not have validated the method for this compound following the procedures in Section 20. The client may request that the compound be reported based only on the calibration. Such a request would need to be approved by the Department Manager and QA Manager, documented and included in the project folder. Deviations **must** also be noted on the final report with a statement that the compound is not reported in compliance with NELAC (or the analytical method) requirements and the reason. Data being reported to a non-NELAC state would need to note the change made to how the method is normally run.

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 Department Manager, with approval from the 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.. In most cases, the client will be informed of the departure prior to the reporting of the data. Any departures must be well documented using the laboratory's corrective action procedures described in Section 13 and in SOP DV-QA-0031, Nonconformance and Corrective Action

System. Any impacted data must be referenced in a case narrative and/or flagged with an appropriate data qualifier.

Any misrepresentation or possible misrepresentation of analytical data discovered by any laboratory staff member must be reported to facility senior laboratory management within 24-hours. The Senior Management staff is comprised of the Laboratory Director, the QA Manager, the Department Manager, the Manager of the PM staff, and the Operations 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.

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/Manager (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.

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 persons noted in Section 12.2, Paragraph 5 above.

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/Manager.

The Laboratory Director/Manager 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 method/target or 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 method, target or 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/Manager to hold all reporting and to notify all relevant laboratory personnel regarding the suspension/restriction (i.e., Project Management, Log-in, etc...). Clients will NOT generally be notified at this time. 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, QA Manager, Department Manager) 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.

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) (refer to Figure 13-1).

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 the method specific SOPs. The analyst will most frequently be the one to identify the need for this action as a result of calibration checks and 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..

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
- Holding Time Violations
- Observations

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.
- 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 Department Manager, QA Manager (or QA designee), or Technical Director is consulted. The laboratory may also consult the technical contacts designated in the company for assistance.

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 Department Manager 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. Department Managers are accountable to the Laboratory Director to ensure final acceptable resolution is achieved and documented appropriately.
- Each NCM and CAR is entered into a database for tracking purposes 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 or CAR, refer to SOP DV-QA-0031, Nonconformance and Corrective Action System.

Table 13-1 includes examples of general technical corrective actions. For specific criteria and corrective actions refer to the analytical methods or specific method SOPs, SOP DV-QA-024P, Requirements for Federal Programs, or Appendix 4.

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, SOP DV-QA-003P, SOP DV-QA-024P, and Appendix 4, 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.

13.6 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.

Figure 13-1.
Example Non-Conformance Memo

Clouseau Nonconformance Memo



NCM #: 04-0124656	Classification: Anomaly
NCM Initiated By: Tim O'Donnell	Status: PMQA
Date Opened: 12/07/2007	Production Area: AASG
Date Closed:	Tests: 6860
	Lot #'s (Sample #'s): D7J300318 (5),
	QC Batches: 7319162,
Nonconformance: QC Failure Due to Matrix	
Subcategory: IS in sample failed	

Problem Description / Root Cause

<u>Name</u>	<u>Date</u>	<u>Description</u>
Tim O'Donnell	12/07/2007	Sample 318-005 failed IS area %REC low (41.58%, limit=50-150%). All other QC meet acceptance criteria. Probable matrix effect.

Corrective Action

<u>Name</u>	<u>Date</u>	<u>Corrective Action</u>
Tim O'Donnell	12/07/2007	PM please advise.

Client Notification Summary

<u>Client</u>	<u>Project Manager</u>	<u>Notified</u>	<u>Response</u>	<u>How Notified</u>	<u>Note</u>
			<u>Response</u>		<u>Response Note</u>

Quality Assurance Verification

<u>Verified By</u>	<u>Due Date</u>	<u>Status</u>	<u>Notes</u>
			This section not yet completed by QA.

Approval History

<u>Date Approved</u>	<u>Approved By</u>	<u>Position</u>
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Figure 13-1. Con't
Example - Corrective Action Report

TestAmerica Corrective Action Plan

TAL Audit # ***Program:*** ***Requirements Document:***

Purpose: Not entered ***Company Auditing:***

Date Audited: ***Lead Auditor:***

Date Report Received: ***Response Due Date:***

TAL Issue Number

Status:

Title:

Reference Citation:

Lab Process:

Lab Section:

Client Issue #:

Type of Issue:

Method #:

Finding Description:

Cause Analysis:

Corrective Action Plan:

Lab Responsible Party:

Planned Completion Date:

Figure 13-1. Con't
Example Open Corrective Action Summary Table

TestAmerica Denver
Summary of Open Federal Audits

LabName	AuditDate	Audit#	ProgName	Doc	CoAuditing	RcvdDate	DueDate
Denver	10/9/2006	63	Internal CA	NELAC	STL Denver	9/20/2006	10/9/2006
Denver	10/9/2006	74	External CA	Other	Clean Harbors/S	9/28/2006	10/31/2006
Denver	10/9/2006	64	Internal CA	NELAC	STL Denver	10/9/2006	10/9/2006
Denver	10/24/2006	71	Internal Audit	Other	STL Denver	10/24/2006	10/24/2006
Denver	10/26/2006	81	State Audit	Other	State of Arizona	11/29/2006	1/16/2007
Denver	11/7/2006	72	Internal Audit	Other	STL Denver	11/7/2006	11/10/2006
Denver	11/27/2006	76	Internal CA	Other	STL Denver	11/27/2006	11/28/2006
Denver	11/30/2006	78	Client Audit	Other	USGS	11/30/2006	12/5/2006
Denver	12/13/2006	86	AFCEE	AFCEE 4.0	EQM	1/9/2007	2/9/2007
Denver	1/17/2007	83	PT Failures	NELAC	STL Denver	1/16/2007	1/19/2007
Denver	4/27/2007	103	Internal Audit	Other	STL Denver	4/27/2007	5/4/2007
Denver	5/10/2007	113	Client Audit	NELAC	Parsons	5/10/2007	5/11/2007
Denver	5/11/2007	111	Internal Audit	AFCEE 4.0	STL Denver	5/4/2007	5/11/2007
Denver	5/16/2007	117	Client Audit	QSM V. 3	USACE	5/21/2007	6/4/2007
Denver	7/11/2007	123	Client Audit	Other	SM Stoller		7/13/2007
Denver	7/30/2007	127	PT Failures	NELAC	ERA	7/30/2007	8/13/2007
Denver	8/15/2007	131	State Audit	Other	State of WV	9/11/2007	9/26/2007
Denver	8/23/2007	133	Client Audit	QAPjP	ENSR	10/3/2007	10/30/2007
Denver	8/30/2007	129	State Audit	Other	State of Colorado	9/5/2007	9/28/2007

Table 13-1. Con't

General Corrective Action Procedures

QC Activity (Individual Responsible for Initiation/Assessment)	Acceptance Criteria	Recommended Corrective Action
Initial Instrument Blank (Analyst)	- Instrument response < ½ RL	- Prepare another blank. - If same response, determine cause of contamination: reagents, environment, instrument equipment failure, etc.
Initial Calibration Standards (Analyst, Supervisor)	- Correlation coefficient > 0.99. - Standard concentrations should bracket reporting limit. - % Recovery within acceptance range. - See details in Method SOP.	- Reanalyze standards. - If still unacceptable, remake standards and recalibrate instrument.
Independent Calibration Verification (Second Source) (Analyst, Supervisor)	- % Recovery within control limits as defined in the method SOPs.	- Remake and reanalyze standard. - If still unacceptable, then remake calibration standards or use new primary standards and recalibrate instrument.
Continuing Calibration Standards (Analyst, Data Reviewer)	% Recovery within control limits as defined in the method SOPs. SOP DV-QA-027P has additional information for GC analyses.	- Reanalyze standard. - If still unacceptable, then recalibrate and rerun affected samples.
Matrix Spike / Matrix Spike Duplicate (MS/MSD) (Analyst, Data Reviewer)	- % Recovery within limits documented in LIMS.	- 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. See SOP DV-QA-003P for detailed corrective actions.
Laboratory Control Sample (LCS) (Analyst, Data Reviewer)	- % Recovery within limits specified in LIMS.	See SOP DV-QA-003P for detailed corrective actions.
Surrogates (Analyst, Data Reviewer)	- % Recovery within limits of method or within three standard deviations of the historical mean (limits stored in LIMS).	See SOP DV-QA-003P for detailed corrective actions.
Method Blank (MB_ (Analyst, Data Reviewer)	< Reporting Limit ¹	See SOP DV-QA-003P for detailed corrective actions.

QC Activity (Individual Responsible for Initiation/Assessment)	Acceptance Criteria	Recommended Corrective Action
Proficiency Testing (PT) Samples (QA Manager, Department Manager/Supervisor)	- Criteria supplied by PT Supplier.	- Any failures or warnings 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, Department Manager/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, Department Manager, 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 and DV-QA-019P.
Client Complaints (Project Managers, Lab Director/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). See SOP DV-QA-013P.
QA Monthly Report (Refer to Section 17 for an example) (QA Manager, Lab Director/Manager, Department Supervisors/Managers)	- QAM, SOPs.	- Corrective action is determined by the type of issue. For example, CARs for the month are reviewed and possible trends are investigated.

QC Activity (Individual Responsible for Initiation/Assessment)	Acceptance Criteria	Recommended Corrective Action
Health and Safety Violation (Safety Officer, Lab Director/Manager, Department Supervisor/Manager)	- Environmental Health and Safety (EHS) Manual.	- Non-conformance is investigated and corrected through CAR system.

Note:

1. Except as noted below for certain compounds, the method blank should be below the reporting limit (several programs require controlling to ½ the RL, see SOP DV-QA-024P for Federal Program Requirements). Concentrations up to five times the reporting limit will be allowed for the ubiquitous laboratory and reagent contaminants: methylene chloride, toluene, acetone, 2-butanone, phthalates, zinc, iron, copper, and lead provided they appear in similar levels in the reagent blank and samples. This allowance presumes that the detection limit is significantly below any regulatory limit to which the data are to be compared and that blank subtraction will not occur. For benzene and ethylene dibromide (EDB) and other analytes for which regulatory limits are extremely close to the detection limit, the method blank must be below the method detection limit

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 submitted for management review.

Dedicating resources to an effective preventive action system emphasizes TestAmerica Denver'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, and the Management of Change process (see below).

Note: There may be varying levels of formality and documentation during the preventive action process due to the simplicity/complexity of the action taken.

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)

TestAmerica Denver 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 combination system of a paper filing and database system, 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 Department Manager or their designee.

Table 15-1. Record Index¹

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	Quality Assurance Manual (QAM)	Internal and External Audits/ Responses	Sample receipt and COC Documentation	Finance and Accounting
Logbooks ²	Work Instructions	Certifications	Contracts and Amendments	EH&S Manual, Permits, Disposal Records
Standards	SOPs	Corrective/Preventive Action	Correspondence	Employee Handbook
Certificates	Manuals	Management Reviews	QAPP	Personnel files, Employee Signature & Initials, Administrative Training Records (e.g., Ethics)
Analytical Records		Method & Software Validation, Verification data	SAP	
Lab Reports		Data Investigation	Telephone Logbooks	
	Policies		Lab Reports	Administrative Policies
				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.

All records are legible and stored and retained in such a way that they are secure and readily retrievable at the laboratory facility or the Iron Mountain data storage facility that provides a suitable environment to prevent damage or deterioration and to prevent loss. The laboratory retains analytical records for 2 months on-site at the laboratory and client reports for 6 months, after their generation and moved offsite for the remainder of the required storage time. Records are maintained for a minimum of five years unless other wise specified by a client or regulatory requirement.

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 and are subject to the requirements in Section 15.1.3. 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 15-3, 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 container or box containing that data is marked as to who to contact for authorization prior to destroying the data. The specific requirements for the length of retention of documents are listed in the statement of work in the contract set up between the client and the laboratory. The laboratory then marks the Iron Mountain storage box with the longer time of storage.

Table 15-2. Special Record Retention Requirements

Program	¹Retention Requirement
Drinking Water – All States	10 years (project records)
Drinking Water Lead and Copper Rule	12 years (project records)
FIFRA – 40 CFR Part 160	Retain for life of research or marketing permit for pesticides regulated by EPA
Housing and Urban Development (HUD) Environmental Lead Testing	10 years
Alaska	10 years
Louisiana – All	10 years
Navy Facilities Engineering Service Center (NFESC)	10 years
TSCA - 40 CFR Part 792	10 years after publication of final test rule or negotiated test agreement

¹Note: Extended retention requirements must be noted with the archive documents or addressed in facility-specific records retention procedures.

15.1.2 All records are held secure and in confidence. Records maintained at the laboratory are located in Arvada. Records archived off-site are stored in a secure location where a record is maintained of any entry into the storage facility. Logs are maintained in each storage box to note removal and return of records.

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 20.12.1 'Computer and Electronic Data Related Requirements' for more information. Refer to SOP DV-QA-025P, Electronic Data Backup.

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 (Records stored off site should be accessible within 2 days of a request for such records). 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 laboratory's copy of the chain of custody is stored with the invoice and the work order sheet generated by the LIMS. 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 per the Data Archiving SOP No. DV-QA-0005. Instrument data is stored sequentially by instrument. A given day's analyses are maintained in the order of the analysis. Run logs are maintained for each instrument or method; a copy of each day's run long or instrument sequence is stored with the data to aid in re-constructing an analytical sequence. Where an analysis is performed without an instrument, bound logbooks or bench sheets are used to record and file data. Standard and reagent information is recorded in logbooks, entered into the LIMS or the standards log program for each method as required.
- 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 20.13.1 ‘Computer and Electronic Data Related Requirements’.

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 (previous discussions relate where most of this information is maintained – specifics may be added below):

- 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 the method specific logbook or 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 periods or subculture, 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 in the LIMS, on specific analytical report formats, and in client specific QAPPs and QASs.

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, strip charts, 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;

and

- 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.

15.5.4 TestAmerica Denver has a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage and reporting. Laboratory notebooks are issued on a per analysis basis, and are numbered sequentially within a given analysis and/or instrument. No analysis and/or instrument have more than one active notebook at a time, so all data are recorded sequentially within a series of sequential notebooks. Bench sheets are filed sequentially by method and analysis date. Standards are maintained in the Standards Log program – no logbooks are used to record that data.

15.5.5 Records are considered archived when moved off-site. Access to archived hard-copy information is documented with an access log and in/out records is used in archived boxes to note data that is removed and returned. 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. Access to the data is limited to laboratory and company employees.

15.5.6 In the event that the laboratory transfers ownership or goes out of business, TestAmerica Denver 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.

15.5.7 Records Disposal

- 15.5.7.1** 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.
- 15.5.7.2** Electronic copies of records must be destroyed by erasure or physically damaging off-line storage media so no records can be read.
- 15.5.7.3** 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).]

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.
	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, the

DoD Quality Systems Manual, and other Federal Programs. A schedule of the internal audits is maintained by the QA Manager in the *Internal Audit Workbook*. An example can be found in Attachment 1.

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 of the *Internal Audit Workbook*. 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 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.

Refer to SOP DV-QA-0029, Independent QA Data Review for details on TestAmerica Denver's internal lab audit process.

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 is 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 (*Internal Audit Workbook*).

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. 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 1 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 Managers and Laboratory Directors/Managers. 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.

16.3 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 department managers 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.

Be aware that NELAC requires that the audit response report be acceptable to the primary accrediting authority after the second submittal. The lab shall have accreditation revoked for all or any portion of its scope of a accreditation for any or all fields of testing, a method, or analyte within a field of testing if it is not corrected.

TestAmerica Denver 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, on-site 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 semi-annually through the analysis of PT samples provided by a third party. The laboratory generally participates in the following types of PT studies: Water Pollution studies, Water Supply studies, Soil and Hazardous Waste studies, DMRQA studies, and project specific or client requested studies.

- 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 (e.g. if a client requests, as PT clients do, that we split VOA coeluters, then dual analysis IS normal practice).
- The type, composition, concentration and frequency of quality control samples analyzed with the PT samples shall be the same as with routine environmental samples.
- Instructions may be included in the laboratory's SOPs for how low level samples are analyzed, including concentration of the sample or adjustment of the normality of titrant. When a PT sample falls below the range of the routine analytical method, the low-level procedure may be used.
- 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 Department Manager 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.

Figure 16-1.

Example - Internal Audit Workbook

Laboratory: TAL Denver

Internal Audit Schedule 2007

*Schedule to be completed 4/2007 for remainder of the year.

Area Audited	Type	Cycle	SOP Reference	Comments	Scheduled	Audited	Closed
Balances	System	6 mo	DEN-QA-0014	CHRISTINA	5/7/2007	5/1/2007	5/1/2007
					12/7/2007	9/19/2007	9/19/2007
Temperature Logs/Thermometers	System	6 mo	DEN-QA-0001 & DEN-QA-0002	MARIA	5/7/2007	5/15/2007	5/15/2007
					12/7/2007	12/10/2007	12/10/2007
Sample Storage and Disposal	System	1 yr	DEN-QA-0003	MIKE	7/1/2007		
Maintenance Logs	System	6 mo	QA-008	CHRISTINA	5/7/2007	5/1/2007	5/1/2007
					12/7/2007		
Holding Blanks for Volatile Ref/Freezers (where required)	System	6 mo	DEN-QA-0013	Although blanks are tracked routinely, a six-month review of all VOA blanks will be	4/6/2007	4/6/2007	4/6/2007
Lab Water Quality Testing	System	6 mo	DEN-QA-0026	See audit database	4/7/2007	5/17/2007	5/17/2007
					11/7/2007		
Sample Control (Log In)	System	1 yr	DEN-QA-0003	MIKE	7/1/2007		
Shipping Procedures	System	1 yr	DEN-QA-0017	CHRISTINA	6/1/2007		
Computer Operations (LIMS)	System	1 yr	S-ITQ-001	MIKE	7/1/2007		
SOP Distribution System	System	1 yr	QA-001	MARIA	8/1/2007		
Archiving of Paper Records	System	1 yr	DEN-QA-0005	CHRISTINA	8/1/2007	5/30/2007	5/30/2007
Statistical Process Control	System	1 yr	QA-003	MIKE	8/1/2007	8/14/2007	8/14/2007
Electronic Archiving	System	1 yr	QA-025	MARIA	9/1/2007		
Data Review System	System	1 yr	QA-012	CHRISTINA	9/1/2007	9/10/2007	9/26/2007
Final Report Generation	System	1 yr	DEN-QA-0022	CHRISTINA	9/1/2007	10/19/2007	11/2/2007
Standards/Reagents	System	6 mo	DEN-QA-0015	MIKE	5/7/2007	5/1/2007	5/1/2007
					12/7/2007	10/22/2007	11/2/2007
Manual Integration	System	1 yr	DPOL-QA-011	MIKE	10/1/2007		
Corrective Action System	System	1 yr	DEN-QA-0031	CHRISTINA	10/1/2007	11/6/2007	
Training Records	System	6 mo	DEN-QA-0024	MARIA	5/7/2007	6/28/2007	6/28/2007
					12/7/2007	11/7/2007	11/7/2007
MDLs	System	1 yr	QA-005	CHRISTINA	11/1/2007		
SOPs	System	1 yr	QA-001	MARIA	11/1/2007		
Purchasing/Procurement	System	1 yr	STL.PG-001	MIKE	11/1/2007		
Pipette/Diluter/Dispenser Calibration Check	System	6 mo	DEN-QA-0008	MIKE	5/7/2007	7/9/2007	7/9/2007
					12/7/2007		
Subcontract Lab Approval	System	1 yr	DEN-QA-0027	CHRISTINA	11/1/2007	11/21/2007	
Customer Complaint System	System	1 yr	QA-013	MARIA	11/1/2007		
Annual Systems Audit	System	1 yr	NA	Larry Penfold	January 7-10		
Methods	Method	2 yr					

Figure 16-2.

Example – Internal Audit System Checklist: Corrective Actions



(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 specified 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

Figure 16-2. Con't
Example Internal Lab Section Audit Checklist

TestAmerica Denver

Organic Preparation QA Data Audit Checklist

Date Audited: _____ Batch Number(s) Audited: _____

Method: _____ Auditor: _____

Analyst(s): _____

Evaluation	Acceptance Criteria	Acceptable (Y/N/NA)?	Comments
IDOC on file?	Required for each analyst		
Is internal COC complete?	All required info entered.		
Is original handwritten version of benchsheet available?	Original records must be kept 5 yrs		
Is Data Recording Policy followed?	Entries in ink, single line cross-out, date & initials		
Method and/or SOP# clearly indicated?	Entry must be made		
Personnel clearly indicated?	Everyone involved must be listed		
Sample pH entered?	Entry must be made for most tests		
Times on & off for extraction recorded?	CLLE & Soxhlet need it		
All standards traceable?	Std #s required		
All reagents traceable?	Lot #s required		
Nonconformances recorded?	See NCM SOP		
NCMs described accurately in case narrative?	All NCMs must be communicated to client		
All required fields entered?	Per method SOP		
2 nd -level review documented?	Name or initials & date		

Overall Comments:

Corrective Action Required:

A copy of this report will be maintained in the Quality Assurance office.

Auditor Signature _____ Date _____

L:/QA/Read/Audit/Data Audit/QA Data Review Forms/Organic Prep
9/10/07 version

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 Operations 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/Manager, 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.
- **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 Section 6.2.2 in 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 MDLs/ 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, 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. This section is also used to communicate the status on any Management of Change Request Forms (CRFs) that have missed targeted due dates.
- **Next Month:** Report on plans for the upcoming month.

- **Lab Director Comments Section:** This section gives the Laboratory Director/Manager 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/Manager.
- **Metrics:** 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, Operations Manager, Department Managers, and QA Manager) 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/Manager. 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 can not 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. 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.
- Minutes from prior Senior Management team meetings. Issues that may be raised from these meetings include:
 - 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),
- Review of the ACIL seal of excellence program performance.
- Compliance to the Ethics Policy and Data Integrity Plan. Including any evidence/incidents of inappropriate actions or vulnerabilities related to data Integrity.

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 (Action Table)].

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

QUALITY REPORT TO MANAGEMENT

LABORATORY: TAL Denver

PERIOD COVERED: November 2007

PREPARED BY: QA Manager DATE: December 10, 2007

DISTRIBUTED TO: Corporate QA, Lab Director, Program Manager, Operations Manager

THREE KEY ISSUES FOR MONTH:

1. Working through QAM update, scheduled to be complete 12/15/07.
2. DOE acceptance of corrective action report received.
3. Owe Corporate Federal QA Manager limits/SOPs/MDLs for FUDS Contract.

1. METRICS

Data submitted for WP153 and soil study 60.

2. SOPs

Please see the SOP tracking database, and weekly QA % currency updates.

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

Reviewed/Revised in October:

DV-OP-0013 Multi-increment Sampling

DV-OP-0013 Multi-increment Sampling for Metals only

DV-GC-0020 Chlorinated Pesticides by 8081

2. CORRECTIVE ACTION

Highlights:

Received DOE acceptance for CAR

Revised Reports:

Please see the attached metrics.

Data Investigations/Recalls (Corporate Data Investigation/Recall SOP) :

none.

Client Feedback and Complaints:

- 1.) Several client complaints were received regarding TAT. Reduced TAT is occurring as lab backlog drops.
- 2.) The PM and lab received compliments from Mactec for performance on the DFC work.

4. MDLs AND CONTROL LIMITS

MDLs Due:

Please see the MDL tracking database and Denver QA HelpDesk Records.

of MDLs in QA pending review/update:1

of MDLs in QA being reviewed: 0

The GCMS lab is working on MDLs for APIX SVOC compounds.

CSLP MDLs are completed and will be turned in to QA this week.
Meeting was held with GC, GCMS, and Organic Extractions this week to prepare MDL schedule.

Control Limits Due:

5. AUDITS

INTERNAL AUDITS

Electronic Data back-up:

A CAPEX has been placed to replace computers that require removal of the drive for backup. The IT staff estimates a 30 day time frame for completion of the software program that will run each night and perform backups for LCMS and some of the other instruments currently requiring manual backup. This issue will be closed when that program is completed.

EXTERNAL AUDITS

Response for Navy audit due 12/13//07.

6. PT SAMPLES

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

WP153

Soils study #60

7. CERTIFICATIONS

Certification Packages Being Worked On (Include Due Date):

Arizona

Describe any issues, lapses, or potential revocations.

8. REGULATORY UPDATE

Lab still updating quotes and notifying clients of Method Update Rule (MUR) changes.

9. MISCELLANEOUS

On-time delivery is poor due to lab backlog. Average for the month $\approx 50\%$.

10. NEXT MONTH

The lab will be audited by Larry Penfold January 7-10.

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 in Appendix 2.

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.

18.2 EDUCATION AND EXPERIENCE REQUIREMENTS FOR TECHNICAL PERSONNEL

TestAmerica makes every effort to hire analytical staff that possess a college degree (AA, BA, BS) in an applied science with some chemistry in the curriculum. Exceptions can be made based upon the individual's experience and ability to learn. There are competent analysts and technicians in the industry who have not earned a college degree. 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 requirements 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 occasionally accepted in lieu of a college degree (basic lab skills such as using a balance, colony counting, aseptic or quantitation techniques, etc. are also considered).

As a general rule for analytical staff:

Specialty	Education	Experience
Extractions, Digestions, some electrode methods (pH, DO, Redox, etc.), or Titrimetric and Gravimetric Analyses	H.S. Diploma	On the job training (OJT)
GFAA, CVAA, FLAA, Single component or short list Chromatography (e.g., Fuels, BTEX-GC, IC	A college degree in an applied science or 2 years of college and at least 1 year of college chemistry	Or 2 years prior analytical experience is required
ICP, ICPMS, Long List or complex chromatography (e.g., Pesticides, PCB, Herbicides, HPLC, etc.), GCMS	A college degree in an applied science or 2 years of college chemistry	or 5 years of prior analytical experience
Spectra Interpretation	A college degree in an applied science or 2 years of college chemistry	And 2 years relevant experience Or 5 years of prior analytical experience
Department Managers – <u>General</u>	Bachelors Degree in an applied science or engineering with 24 semester hours in chemistry An advanced (MS, PhD.) degree may substitute for one year of experience	And 2 years experience in environmental analysis of representative analytes for which they will oversee
Department Manager – <u>Wet Chem</u> only (no advanced instrumentation)	Associates degree in an applied science or engineering or 2 years of college with 16 semester hours in chemistry	And 2 years relevant experience

Specialty	Education	Experience
Department Manager – Microbiology	Bachelors degree in applied science with at least 16 semester hours in general microbiology and biology An advanced (MS, PhD.) degree may substitute for one year of experience	And 2 years of relevant experience

When an analyst does not meet these requirements, they can perform a task under the direct supervision of a qualified analyst, peer reviewer or Department Manager, and are considered an analyst in training. The person supervising an analyst in training is accountable for the quality of the analytical data and must review and approve data and associated corrective actions.

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:

Required Training	Time Frame*	Employee Type
Environmental Health & Safety – Initial Training	Prior to work in designated area	All
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	1 week 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.

Further details of the laboratory's training program are described in the Laboratory Training SOP (DV-QA-0024).

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

TestAmerica Denver is a 54,000 ft² secure laboratory facility with controlled access and designed to accommodate an efficient workflow and to provide a safe and comfortable work environment for employees. All visitors sign in and are escorted by laboratory personnel. 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 and media, glassware, and portable equipment. Ample space is also provided for refrigerated 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, volatile organic sample analysis, non-volatile organic 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 effect the results of environmental tests as required by the relevant specifications, methods, and procedures. Such environmental conditions include humidity, voltage, temperature, and vibration levels in the laboratory.

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.

The lab is equipped with a generator to maintain temperature on the sample refrigerators in the event of a power outage. The laboratory walk-in refrigerators are monitored around the clock and linked to an alarm system, which notifies the appropriate personnel of any temperature outages.

19.3 WORK AREAS

There is effective separation between neighboring areas when the activities therein are incompatible with each other. Examples include:

- Sample grinding and sample analytical areas.
- Organic chemical handling areas, including sample preparation and waste disposal, and volatile organic chemical analysis areas.
- Waste disposal and sample/extract handling areas.

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.

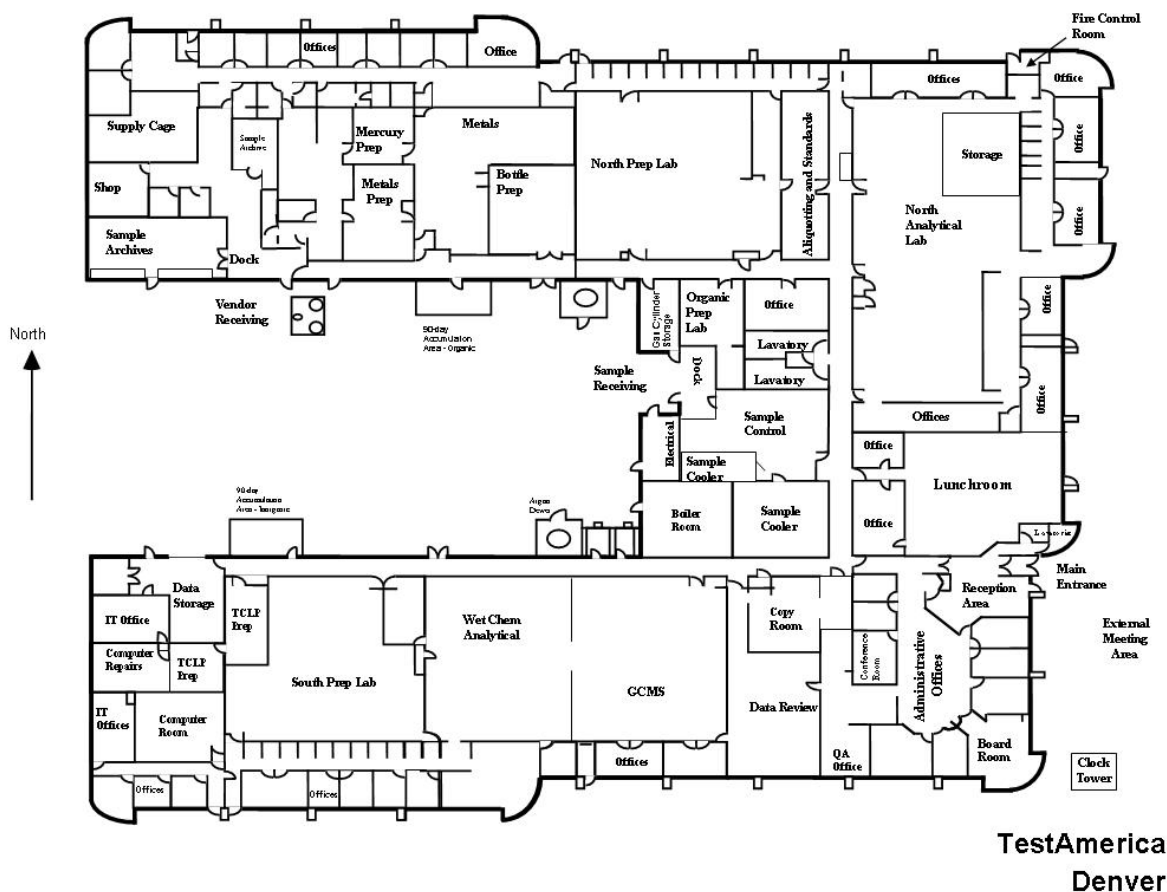
Adequate measures are taken to ensure good housekeeping in the laboratory and to ensure that any contamination does not adversely affect data quality. These measures include regular cleaning to control dirt and dust within the laboratory.

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.

Refer to Standard Methods, 20th Ed., 9020B, Section 2 for specific requirements for microbiological laboratory facility requirements.

19.4 FLOOR PLAN



19.5 BUILDING SECURITY

Building security cards and alarm codes are distributed to employees as necessary.

Visitors to the laboratory sign in and out in a visitor's logbook. A visitor is defined as any person who visits the laboratory who is not an employee of TestAmerica Denver. In addition to signing into the laboratory, the Environmental, Health and Safety Manual contains requirements for visitors and vendors. There are specific safety forms that must be reviewed and signed.

Visitors (with the exception of company employees) are escorted by laboratory personnel at all times, or the location of the visitor is noted in the visitor's logbook.

SECTION 20.0

TEST METHODS AND METHOD VALIDATION (NELAC 5.5.4)

20.1 OVERVIEW

TestAmerica Denver 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)

TestAmerica Denver 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. 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) and SOP DV-QA-001P.
- 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 and DV-QA-001P, Preparation and Management of Standard Operating Procedure.

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.

In general, TestAmerica Denver follows procedures from the referenced methods shown below in 20.4.1.1.

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:

- Method 1664, Revision A: N-Hexane Extractable Material (HEM; Oil and Grease) and Silica Gel Treated N-Hexane Extractable Material (SGT-HEM); Non-polar Material) by Extraction and Gravimetry, EPA-821-R-98-002, February 1999
- Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act, and Appendix A-C; 40 CFR Part 136, USEPA Office of Water. Revised as of July 1, 1995. Appendix A to Part 136 - Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater (EPA 600 Series)
- Methods for Chemical Analysis of Water and Wastes, EPA 600 (4-79-020), 1983.
- Methods for the Determination of Inorganic Substances in Environmental Samples, EPA-600/R-93/100, August 1993.
- Methods for the Determination of Metals in Environmental Samples, EPA/600/4-91/010, June 1991. Supplement I: EPA-600/R-94/111, May 1994.

- Methods for the Determination of Organic Compounds in Drinking Water, EPA-600/4-88-039, December 1988, Revised, July 1991, Supplement I, EPA-600-4-90-020, July 1990, Supplement II, EPA-600/R-92-129, August 1992. Supplement III EPA/600/R-95/131 - August 1995 (EPA 500 Series) (EPA 500 Series methods)
- Technical Notes on Drinking Water Methods, EPA-600/R94-173, October 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.
- Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW846), Third Edition, September 1986, Final Update I, July 1992, Final Update IIA, August 1993, Final Update II, September 1994; Final Update IIB, January 1995; Final Update III, December 1996.
- 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 (e.g., Underground Storage Tank methods), 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.

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 Operations Manager 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).

20.4.2.3 The laboratory must have an approved SOP, demonstrate satisfactory performance, and conduct a method detection limit study (when applicable). There may be other requirements as stated within the published method or regulations (i.e., retention time window study).

Note: In some instances, a situation may arise where a client requests that an unusual analyte be reported using a method where this analyte is not normally reported. If the analyte is being reported for regulatory purposes, the method must meet all procedures outlined within this QA Manual (SOP, MDL, and Demonstration of Capability). If the client states that the information is not for regulatory purposes, the result may be reported as long as the following criteria are met:

- The instrument is calibrated for the analyte to be reported using the criteria for the method and ICV/CCV criteria are met (unless an ICV/CCV is not required by the method).
- The reporting limit is set at or above the first standard of the curve for the analyte.
- The client request is documented and the lab informs the client of its procedure for working with unusual compounds. The final report must be footnoted: *Reporting Limit based on the low standard of the calibration curve.*
- Refer to Section 12 (Control of Non-Conforming Work).

20.4.3 **Initial Demonstration of Capability (IDOC) Procedures**

20.4.3.1 Refer to SOP DV-QA-0024, Employee Training.

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 analyst's training folder.

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 if the method is a non-standard method (not a published or routinely accepted method). The client must also be in agreement to the use of the non-standard method. 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 compounds in the specific matrix or matrices from other analytes or interference. In some cases to achieve the required selectivity for an analyte, a confirmation 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 laboratory determinations of MDLs are described in Section 20.6.

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 SOP DV-QA-0024, Employee Training. Continued demonstration of method performance is generally accomplished by batch specific QC samples such as LCS, method blanks or PT samples.

20.7 METHOD DETECTION LIMITS (MDL)/ LIMITS OF DETECTION (LOD)

Method detection limits (MDL) are initially determined in accordance with 40 CFR Part 136, Appendix B. MDL is also sometimes referred to as Limit of Detection (LOD). The MDL theoretically represents the concentration level for each analyte within a method at which the Analyst is 99% confident that the true value is not zero. The MDL is determined for each analyte initially during the method validation process and updated as required in the analytical methods, whenever there is a significant change in the procedure or equipment, or based on project specific requirements (refer to 20.7.10). The analyst prepares at least seven replicates of solution spiked at one to five times the estimated method detection limit (most often at the lowest standard in the calibration curve) into the applicable matrix with all the analytes of interest. Each of these aliquots is extracted (including any applicable clean-up procedures) and analyzed in the same manner as the samples. Where possible, the seven replicates should be analyzed over 2-4 days to provide a more realistic MDL. This low level standard may be analyzed every batch or every week or some other frequency rather than doing the study all at once. In addition, a larger number of data points may be used if the appropriate student t-value is used. TestAmerica Denver's SOP procedures are outlined in detail in SOP DV-QA-003P, Determination of Method Detection Limits for Chemical Tests.

20.7.1 METHOD DETECTION LIMITS (MDL)/ LIMITS OF DETECTION (LOD)

Method detection limits (MDL) are initially determined in accordance with 40 CFR Part 136, Appendix B. For details, refer to SOP DV-QA-003P, Determination of Method Detection Limits for Chemical Tests.

DL for reportiMDL's are initially performed for each individual instrument and non-microbiological method analysis. Unless there are requirements to the contrary, the laboratory will use the highest calculated MDL for all instruments used for a given method as the Mng purposes. This MDL is not required for methods that are not readily spiked (e.g. pH, turbidity,

etc.). Titration and gravimetric methods where there is no additional preparation involved, the MDL is based on the lowest discernable unit of measure that can be observed.

20.7.2 MDL's must be run against acceptable instrument QC, including ICV's and Tunes. This is to insure that the instrument is in proper working condition and falsely high or low MDL's are not calculated.

20.7.3 Use only clean matrix which is free of target analytes (e.g.: Laboratory reagent water, Ottawa Sand) unless a project specific MDL is required in a field sample matrix.

20.7.4 The Reporting Limit (also may be referred to as Limit of Quantitation or LOQ) should generally be between 2 and 5 times the MDL (see SOP DV-QA-024P for federal program requirements). If the MDL is being performed during method development, use this guideline to determine the Reporting Limit for the analysis. If a sample is diluted, the reported MDL is adjusted according to the dilution factor.

20.7.5 If the MDL is $< 1/10$ of the spike concentration for more than 10% of the analytes in the method ($< 1/5$ of spike recovered for DoD for water samples) the MDL must be repeated (including extraction or digestion) using a lower spike level unless the % recovery is $< 50\%$ or $> 150\%$ of the "true value". Note: The concentration of the spike will be at a level below the calibration range.

20.7.6 The calculated MDL cannot be not greater than the spike amount.

20.7.7 If the most recent calculated MDL does not permit qualitative identification of the analyte then the laboratory may use technical judgment for establishing the MDL (e.g., calculate what level would give a qualitative ID, compare with IDL (20.7), spike at a level where qualitative ID is determined and assign that value as MDL, minimum sensitivity requirements, Standard deviation of method blanks over time, etc.). Refer to SOP DV-QA-003P for details.

20.7.8 Each of the 7 spikes must be qualitatively identifiable (e.g., appear in both columns for dual column methods, characteristic ions for GCMS mass spectra, etc). Manual integrations to force the baseline for detection are not allowed.

20.7.9 The initial MDL is calculated as follows:

$$\text{MDL} = t_{(n-1, 1-a = 0.99)} \times (\text{Standard Deviation of replicates})$$

where $t_{(n-1, 1-a = 0.99)} = 3.143$ for seven replicates.

20.7.10 Subsequent to the initial MDL determination, periodic MDL verification, confirmation or determinations may be performed by the procedure in 40 CFR Part 136, Appendix B or alternatively by other technically acceptable practices (e.g., method blanks over time, single standard spikes that have been subjected to applicable sample prep processes, etc.). Refer to SOP DV-QA-003P for details.

20.7.11 Because of the inherent variability in results outside of the calibration range, TestAmerica does not recommend the reporting of results below the lowest calibration point in a curve; however, it is recognized that some projects and agencies require the reporting of results

below the RL. Any result that falls between the MDL and the Reporting limit, when reported, will be qualified as an estimated value.

20.7.12 Detections reported down to the MDL must be qualitatively identified.

20.7.13 MDLs and Reporting limits are adjusted in LIMs based on moisture content. Adjustments for sample aliquot size are made if the aliquot used is less than 80% or more than 120% of the standard aliquot, or if it is required for a given project.

20.8 INSTRUMENT DETECTION LIMITS (IDL)

20.8.1 The IDL is sometimes used to assess the reasonableness of the MDLs or in some cases required by the analytical method or program requirements. IDLs are most used in metals analyses but may be useful in demonstration of instrument performance in other areas.

20.8.2 IDLs are calculated to determine an instrument's sensitivity independent of any preparation method. IDLs are calculated either using 7 replicate spike analyses, like MDL but without sample preparation, or by the analysis of 10 instrument blanks and calculating 3 x the absolute value of the standard deviation.

20.8.3 If IDL is > than the MDL, it may be used as the reported MDL.

20.9 VERIFICATION OF DETECTION AND REPORTING LIMITS

20.9.1 Once an MDL is established, it must be verified, on each instrument, by analyzing a quality control sample (prepared as a sample) at approximately 2-3 times the calculated MDL for single analyte analyses (e.g. most wet chemistry methods, Atomic Absorption, etc.) and 1-4 times the calculated MDL for multiple analyte methods (e.g. GC, GCMS, ICP, etc.). The analytes must be qualitatively identified or see section 20.6.7 for other options. This verification does not apply to methods that are not readily spiked (e.g. pH, turbidity, etc.) or where the lab does not report to the MDL. If the MDL does not verify, then the lab will not report to the MDL, or redevelop their MDL or use the level where qualitative identification is established (See 20.6.7). MDLs must be verified at least annually (see SOP DV-QA-024P for federal program frequency requirements).

20.9.2 When a Reporting limit is established, it must be initially verified by the analysis of a low level standard or QC sample (LCS at 1-2 the reporting limit) and annually thereafter. Unless there are requirements to the contrary the acceptance criteria is $\pm 50\%$. The annual requirement is waived for methods that have an annually verified MDL.

20.10 RETENTION TIME WINDOWS

Most organic analyses and some inorganic analyses use chromatography techniques for qualitative and quantitative determinations. For every chromatography analysis each analyte will have a specific time of elution from the column to the detector. This is known as the analyte's retention time. The variance in the expected time of elution is defined as the retention time window. As the key to analyte identification in chromatography, retention time windows must be established on every column for every analyte used for that method.

For GC, HPLC and IC methods, there must be sufficient separation between analyte peaks so as to not misidentify analytes. In the mid-level standard, the distance between the valley and peak height cannot be any less than 25% of the sum of the peak heights of the analytes. This also applies to GCMS in the case where the two compounds share the same quantitation ion.

Note: Some analytes do not separate sufficiently to be able to identify or quantitate them as separate analytes (e.g. m-xylene and p-xylene) and are quantitated and reported as a single analyte (e.g. m,p-xylenes).

Once the analyst has determined that the instrument is in optimum working condition through calibration and calibration verification procedures, he or she uses a mid-range calibration or calibration verification standard to establish the retention times for each of the individual analytes in a method. The analyst makes three injections of the same standard over a 72-hour (24 hr period for 300.0) period, tabulating the retention times for each analyte for each of the three injections. The width of retention time window is normally the average absolute retention time \pm 3 Standard Deviations (see SOP DV-QA-024P for federal program requirements). A peak outside the retention time window will not be identified by the computer as a positive match of the analyte of interest.

It is possible for the statistically calculated RT window to be too tight and need to be adjusted based on analyst experience. In these instances method default retention time windows may be used (e.g., for 8000 series methods a default of 0.03 minutes may be used, and EPA CLP 0.05 minutes is used). The same concept is applied when any peak outside of that window will not be identified by the computer as a positive match.

The calibration verification standard at the beginning of a run may be used to adjust the RT for an analyte. This is essentially re-centering the window but the size of the window remains the same. The RTs are verified when all analytes are within their RT windows and are properly identified.

20.11 EVALUATION OF SELECTIVITY

The laboratory evaluates selectivity by following the checks within the applicable analytical methods, which include mass spectral tuning, second column confirmation, ICP interelement interference checks, chromatography retention time windows, spectrochemical, and specific electrode response factors.

20.12 ESTIMATION OF UNCERTAINTY OF MEASUREMENT

20.12.1 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 analytical result” (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 result is believed to lie within at least a 95% confidence level with the coverage factor $k=2$.

20.12.2 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.

20.12.3 The uncertainty associated with results generated by the laboratory can be determined by using the Laboratory Control Sample (LCS) accuracy range for a given analyte. The LCS limits are used to assess the performance of the measurement system since they take into consideration all of the laboratory variables associated with a given test over time (except for variability associated with the sampling). The percent recovery of the LCS is compared either to the method-required LCS accuracy limits or to the statistical, historical, in-house LCS accuracy limits.

20.12.4 To calculate the uncertainty for the specific result reported, multiply the result by the decimal of the lower end of the LCS range percent value for the lower end of the uncertainty range, and multiply the result by the decimal of the upper end of the LCS range percent value for the upper end of the uncertainty range. These calculated values represent a 99%-certain range for the reported result. As an example, suppose that the result reported is 1.0 mg/l, and the LCS percent recovery range is 50 to 150%. The uncertainty range would be 0.5 to 1.5 mg/l, which could also be written as 1.0 +/- 0.5 mg/l.

20.12.5 In the case where a well recognized test method specifies limits to the values of major sources of uncertainty of measurement (e.g. 524.2, 525, etc) and specifies the form of presentation of calculated results, no further discussion of uncertainty is required.

20.13 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.

20.13.1 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 SOPs P-I-006, Virus Protection Policy, P-I-008, internet Security Policy, and P-I-003 Computer Systems Account and Naming Policy. The laboratory is currently running Quantims which is a custom in-house developed LIMS system that has been highly customized to meet the needs of the laboratory. It is referred to as LIMS for the remainder of this section. The LIMS utilizes IBM DB-2 which is an industry standard relational database platform. It is referred to as Database for the remainder of this section.

20.13.1.1 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 in a Non-Conformance Memo. Details are specified in SOP DV-QA-019P, Result and Report Revisions.
- 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. Query 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. In addition, changes to qualifiers in the LIMS master list must be approved by corporate QA.

20.13.1.2 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 file servers.
- 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. Refer to SOP DV-QA-025P, Electronic Data Backup.

20.13.1.3 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. Individuals with access at TestAmerica Denver are: Wendlee Fischler, Michael Sara, Mark Dean, Damien Kaaz, Conner Sargent, Stephen Madrid, Jeff Woodruff, Nathan Mead, and Joanne Thomas.
- 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.

20.13.2 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. Details for data review at TestAmerica Denver are defined in SOP DV-QA-0020, Data Review.

For manual data entry, e.g., Wet Chemistry, the data is reduced by the analyst and then entry into the LIMS is verified by the second level reviewer. The review checklists are signed by both the analyst and second level reviewer to confirm the accuracy of the manual entry(s) as well as review the data for technical accuracy. Refer to SOP DV-QA-0020, Data Review for details of the review process.

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 and TestAmerica Denver SOP DV-QA-0033.

Analytical results are reduced to appropriate concentration units specified by the PM in LIMS, 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 manufacturer's indication; otherwise, it should not be performed. Calculations are independently verified by second level review staff. Calculations and data reduction steps for various methods are summarized in the respective analytical SOPs or program requirements.

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

20.13.2.2 In general, concentration results are reported in milligrams per liter (mg/L) or micrograms per liter ($\mu\text{g/L}$) for liquids and milligrams per kilogram (mg/kg) or micrograms per kilogram ($\mu\text{g/Kg}$) for solids. The units "mg/L" and "mg/kg" are the same as "parts per million (ppm)". The units " $\mu\text{g/L}$ " and " $\mu\text{g/kg}$ " are the same as "parts per billion (ppb)." Some low level methods utilized primarily for aqueous samples are reported in "ng/L", which are the same as "parts per trillion" (ppt). For values greater than 10,000 mg/L, results can be reported in percent, i.e., 10,000 mg/L = 1%.

- Several environmental methods, such as color, turbidity, conductivity, use very specific, non-concentration units to report results (e.g., NTU, umhos/cm etc).
- Occasionally, the client requests that results be reported in units which take into account the measured flow of water or air during the collection of the sample. When they provide this information, the calculations can be performed and reported.

20.13.2.3 Refer to SOP DV-QA-004P, Rounding and Significant Figures for details regarding the number of significant figures to report for each step in the process.

20.13.2.4 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.

20.13.2.5 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 after reviewing the quantitation report, and removing unrequested or poor spectrally-matched compounds. The analyst prints a copy of what has been entered to check for errors. This printout and the instrument's printout of calibrations, concentrations, retention times, chromatograms, and mass spectra, if applicable, are retained with the data file. The data file is stored in a monthly folder on the instrument computer; periodically, this file is transferred to the server and, eventually, to a tape file.

20.13.3 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.)

- 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"ed out, signed and dated.
- Worksheets are created with the approval of the Department Manager/QA Manager at the facility. The QA Department controls all worksheets following the procedures in Section 6.

20.13.4 Review / Verification Procedures

Review procedures are outlined in several SOPs (DV-QA-0003, Sample Management and Chain of Custody, DV-QA-0020, Data Review, and DV-QA-0022, Package Assembly), 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 laboratory also has an SOP discussing Manual Integrations to ensure the authenticity of the data, SOP DV-QA-0033, Acceptable Manual Integration Practices. The general review concepts are discussed below, more specific information can be found in the SOPs.

20.13.4.1 The data review process at TestAmerica Denver 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 Sample Control Supervisor reviews the transaction of the chain-of-custody forms and the inputted information. The Project Managers perform final review of the chain-of-custody forms and inputted information. Refer to SOP DV-QA-0003.

20.13.4.2 The next level of data review occurs with the Analysts. As results are generated, analysts review their work to ensure that the results generated meet QC requirements and relevant EPA methodologies. The Analysts transfer the data into the LIMS and add data qualifiers if applicable (see Appendix 7 for list of common data qualifiers). To ensure data compliance, a different analyst performs a second level of review. Second level review is accomplished by checking reported results against raw data and evaluating the results for accuracy. During the second level review, blank runs, QA/QC check results, continuing calibration results, laboratory control samples, sample data, qualifiers and spike information are evaluated. TestAmerica Denver performs second level review on all batches, verifying 100% of data manually entered into LIMS and at least 10% of data that is automatically uploaded to the LIMS. Manual integrations are also electronically reviewed utilizing auditing software to help ensure compliance to ethics and manual integration policies. 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
- Inconsistent peak integration

- Transcription errors
- Results outside of calibration range

20.13.4.3 Unacceptable analytical results may require reanalysis of the samples. Any problems are brought to the attention of the Laboratory Director, Project Manager, Quality Assurance Manager, Technical Manager, or Department Manager for further investigation. Corrective action is initiated whenever necessary. SOP DV-QA-018P, *Repeat Analysis and Reporting* provides detail on this process.

20.13.4.4 The results are then entered or directly transferred into the computer database and a hard copy (or .pdf) is printed for the client.

20.13.4.5 As a final review prior to the release of the report, the Project Manager reviews the report 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):

- Total Results are \geq Dissolved results (e.g. metals)
- Total Solids (TS) \geq TDS or TSS
- TKN \geq Ammonia
- TKN \geq total organic nitrogen
- TKN = ammonia + total organic nitrogen
- Total Phosphorus \geq Orthophosphate
- COD \geq TOC
- Total cyanide \geq Amenable Cyanide
- TDS \geq individual anions
- TDS \geq total alkalinity
- TDS \geq hardness
- Hexavalent chromium \leq total chromium

20.13.4.6 Some federal programs require independent review of a percentage of the report packages by the QA Department (see SOP DV-QA-024P). The Project Manager then signs the final report. (*Also see section 26 on Reporting Results*). When complete, the report is sent out to the client.

20.13.4.7 A visual summary of the flow of samples and information through the laboratory, as well as data review and validation, is presented in Figure 20-3.

20.13.5 **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 SOP DV-QA-0033, *Acceptable Manual Integration Practices* as the guidelines.

- 20.13.5.1** The analyst must adjust baseline or the area of a peak in some situations, for example when two compounds are not adequately resolved or when a peak shoulder needs to be separated from the peak of interest. 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.
- 20.13.5.2** 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.
- 20.13.5.3** Client samples, performance evaluation samples, and quality control samples are all treated equally when determining whether or not a peak area or baseline should be manually adjusted.
- 20.13.5.4** All manual integrations receive a second level review. Manual integrations must be indicated on an expanded scale “after” chromatograms such that the integration performed can be easily evaluated during data review. Expanded scale “before” chromatograms are also required for all manual integrations on QC parameters (calibrations, calibration verifications, laboratory control samples, internal standards, surrogates, etc.) unless the laboratory has another documented corporate approved procedure in place that can demonstrate an active process for detection and deterrence of improper integration practices.

Figure 20-1. Example - Demonstration of Capability

TestAmerica <small>THE LEADER IN ENVIRONMENTAL TESTING</small>	<i>Analyst Demonstration of Capability</i> Certification Statement	
Date: 11-Dec-07	8270C-SIM - 8270C-SIM SOP: Matrix: Water	
<hr/>		
STL - Denver laboratory 4955 Yarrow Street Arvada, CO 80002 (303) 736-0100		
<hr/>		
We, the undersigned, CERTIFY that:		
<ol style="list-style-type: none">1. The analyst identified above, using the cited test method with the specifications in the cited SOP, which is in use at this facility for the analysis of samples under the TestAmerica Quality Assurance Plan, has met the Initial or Ongoing Demonstration of Capability.2. The test method was performed by the analyst identified on this certification following the TestAmerica SOP3. A copy of the laboratory-specific SOP is available for all personnel on-site.4. The data associated with the initial/ongoing demonstration of capability are true, accurate, complete and self-explanatory (*). These data are attached to this certification statement.5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized inspectors.		
Comments/Observations:		
 <hr/>		
Analyst's Name	Signature	Date
Technical Director's Name	Signature	Date
QA Manager's Name	Signature	Date
<small>* True: Consistent with supporting data. Accurate: Based on good laboratory practices consistent with sound scientific principles/practices.. Complete: Includes the results of all supporting performance testing. Self-explanatory: Data properly labeled and stored so that the results are traceable and require no additional explanation.</small>		
<hr/>		

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(yies)

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

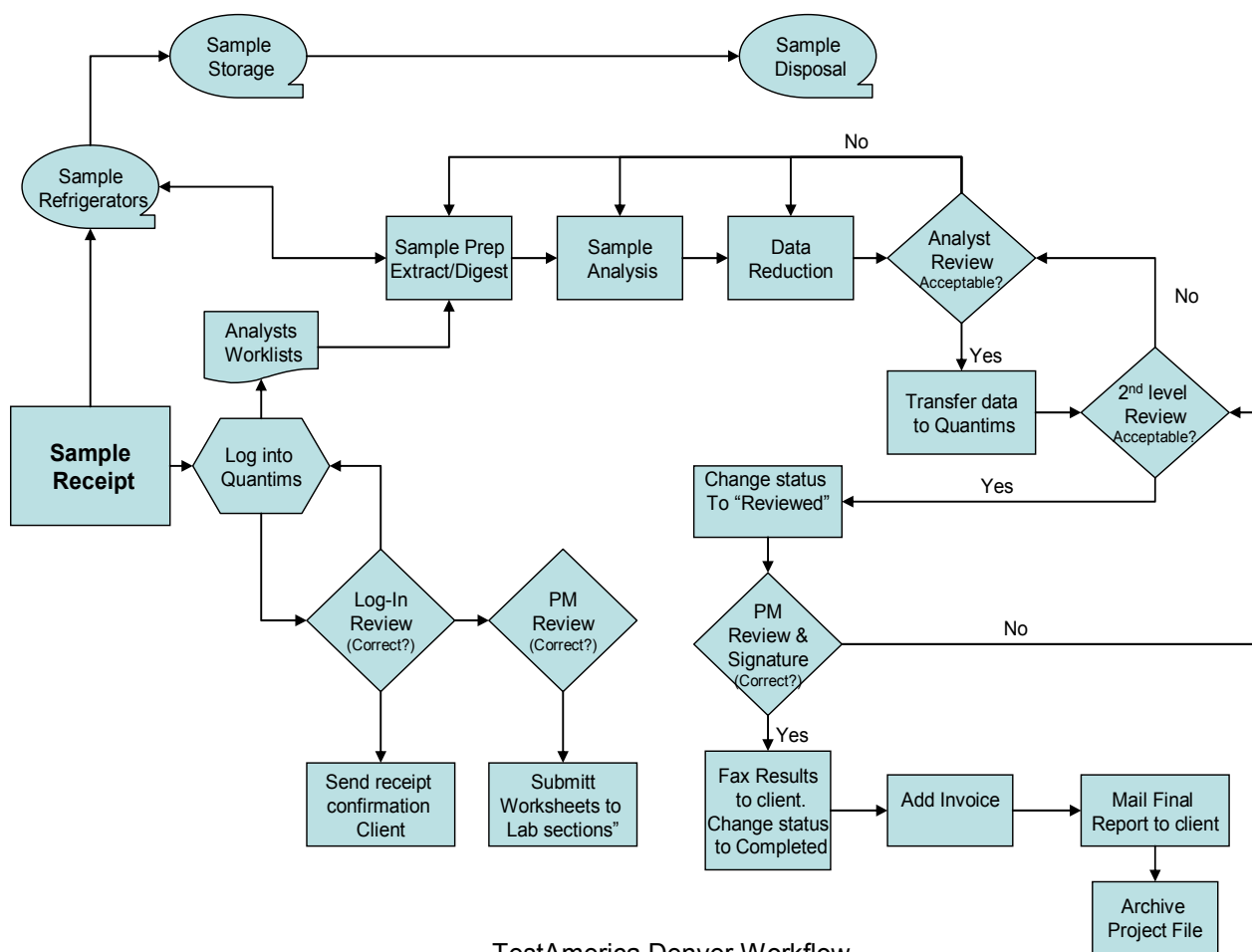
Submitted by _____ Date _____

9 _____ Certification/Approval from Regulatory Agency where available.

QA Review / Acceptance _____ Date _____

Figure 20-3.

Work Flow



TestAmerica Denver Workflow

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 method SOPs, in SOP DV-QA-024P for federal programs, and in Appendix 4. 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 TestAmerica Denver 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.

21.2.2 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. Qualified personnel must also perform maintenance when there is evidence of degradation of peak resolution, a shift in the calibration curve, loss of sensitivity, or failure to continually meet one of the quality control criteria.

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

21.2.2.2 High purity gases, reagents, and spare parts are kept on hand to minimize repair time and optimize instrument performance.

21.2.3 Table 21-2 summarizes the schedule for routine maintenance. It is the responsibility of each Department Manager 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.)

21.2.4 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.

21.2.4.1 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, lamps, tubing, valves, columns, detectors, cleaning and adjustments.

21.2.4.2 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. CCV run on 'date' was acceptable, or instrument recalibrated on 'date' with acceptable verification, etc.).

21.2.4.3 When maintenance or repair is performed by an outside agency, service receipts detailing the service performed can be affixed into the logbooks adjacent to pages describing the maintenance performed. This stapled in page must be signed across the page entered and the logbook so that it is clear that a page is missing if only half a signature is found in the logbook.

21.2.5 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).
- Required maintenance is listed in the maintenance logbooks, as well as any maintenance performed.

21.2.6 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 analyses (refer to Sections 12 and 13).

21.2.7 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.

If an instrument is sent out for service or transferred to another facility, it must be recalibrated and verified (including new initial MDL study) 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. These include but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, field sampling devices, temperature measuring devices, thermal/pressure sample preparation 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 raw data records associated with the support equipment are retained to document instrument performance.

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 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). 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 annually by an outside calibration laboratory to NIST standards.

All balances are serviced annually by a qualified service representative, who supplies the laboratory with a certificate that identifies traceability of the calibration to the NIST standards.

All of this information is recorded in logs, and the recalibration/recertification certificates are kept on file. Refer to SOP DV-QA-0014, *Balance Calibration Check*.

21.3.2 pH, Conductivity, and Turbidity Meters

The pH meters used in the laboratory are accurate to ± 0.1 pH units, and have a scale readability of at least 0.05 pH units. The meters automatically compensate for the temperature, and are calibrated with at least two working range buffer solutions before each use.

Conductivity meters are also calibrated before each use with a known standard to demonstrate the meters do not exceed an error of 1% or one umhos/cm.

Turbidity meters are also calibrated before each use. All of this information is documented in logs.

Consult pH and Conductivity, and Turbidity SOPs for further information.

21.3.3 Thermometers

All thermometers are calibrated on an annual basis with a NIST-traceable thermometer. IR thermometers, electronic thermometers, digital probes and thermocouples are calibrated quarterly refer to SOP DV-QA-0001, *Thermometer Calibration Procedure*.

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. More information on this subject can be found in SOP DV-QA-0001, *Thermometer Calibration Procedure*.

21.3.4 Refrigerators/Freezer Units, Waterbaths, Ovens and Incubators

The temperatures of all refrigerator units and freezers used for sample and standard storage are monitored each working day on a continual basis. Refer to SOP DV-QA-0012, *Monitoring Refrigerator Temperature and Power Failure Contingency Plan*.

Ovens, waterbaths and 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 $> 0^{\circ}\text{C}$ and $\leq 6^{\circ}\text{C}$.

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 posted on or near the device.

21.3.5 Autopipettors, Dilutors, and Syringes

Mechanical volumetric dispensing devices including burettes (except Class A Glassware) are checked for accuracy at least quarterly.

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. Any device not regularly verified can not be used for any quantitative measurements. Refer to SOP DV-QA-0008, *Calibration and Verification of Mechanical Pipettes*.

21.3.6 Autoclaves

TestAmerica Denver uses an autoclave for sterilization of microbiological equipment and used media only. All information regarding the autoclave is maintained in the Autoclave, Coliform lot,

and Monthly check logbook. The information recorded includes the date, contents, maximum temperature, total run time and the analyst's initials.

Demonstration of sterilization of the autoclave is performed each time of use with a Diack sterilization monitor, a maximum reading thermometer, and temperature sensitive tape. On a monthly basis, spore strips are used for the determination of effective sterilization.

The autoclaves timing device is checked on a monthly basis against a clock/watch and the actual time elapsed is documented.

Any maintenance that is performed on the autoclave (internally or by service contract) is recorded in the maintenance section of the check logbook.

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, response, type of calibration (Avg RF, curve, or other calculations that may be used to reduce instrument responses to concentration.)

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 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 (refer to Section 13).

Note: Instruments are calibrated initially and as needed after that and at least annually.

21.4.1 CALIBRATION STANDARDS

Calibration standards are prepared using the procedures indicated in the Reagents and Standards section of the determinative method SOP. However, the general procedures are described below.

21.4.1.1 For each analyte and surrogate (if applicable) of interest, prepare calibration standards at the minimum number of concentrations as stated in the analytical methods. If a reference or mandated method does not specify the number of calibration standards, the minimum number is three, not including blanks or a zero standard. All of the standard solutions are prepared using Class A volumetric

glassware, calibrated pipettes, and/or microsyringes and appropriate laboratory quality solvents and stock standards.

- 21.4.1.2** Standards for instrument calibration are obtained from a variety of sources. All standards are traceable to NIST whenever possible. Dilution standards are prepared from stock standards purchased from commercial suppliers. TestAmerica Denver uses Veritas Standards Log software for standards tracking. It is maintained for each department, containing concentration, 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.
- 21.4.1.3** The lowest concentration calibration standard that is analyzed during an initial calibration must be at or below the stated reporting limit for the method based on the final volume of extract (or sample).
- 21.4.1.4** The other concentrations define the working range of the instrument/method or correspond to the expected range of concentrations found in actual samples that are also within the working range of the instrument/method. Results of samples not bracketed by initial instrument calibration standards (within calibration range to 3 significant figures) must be reported as having less certainty, e.g., defined qualifiers or flags (additional information may be included in the case narrative). The lowest calibration standard must be at or below the reporting limit.
- 21.4.1.5** Given the number of target compounds addressed by some of the organic methods, it may be necessary to prepare several sets of calibration standards, each set consisting of the appropriate number of solutions at different concentrations. The initial calibration will then involve the analysis of each of these sets of the appropriate number of standards.
- 21.4.1.6** All initial calibrations are verified with a standard obtained from a second source and traceable to a national standard, when available (or vendor certified different lot if a second source is not available). For unique situations, such as Disodium Iminodiacetate (IDA) analysis where no other source or lot is available, a standard made by a different analyst would be considered a second source. This verification occurs immediately after the calibration curve has been analyzed, and before the analysis of any samples.

21.4.2 CALIBRATION FOR ORGANIC METHODS (GC, HPLC, GC/MS)

- 21.4.2.1** Many of the organic analytical methods utilize an internal standard calibration (GCMS and some GC). Because of the complex nature of the multipeak chromatograms produced by the method, some instruments necessitate the use of external standard calibration (most GC and HPLC). Surrogate compounds are included in the calibration processes for all appropriate organic analyses. For more details on the calibration types listed below, refer to SOP No. CA-Q-S-005, Calibration Curves.

21.4.2.2 Once the operating parameters have been established according to the method, each instrument is calibrated for the appropriate method. The analyst prepares five or more standard solutions at various concentrations containing all of the analytes of interest, internal standards, and surrogates that are appropriate for the method. Note: There are a several EPA methods that have different requirements and are exceptions (e.g. EPA 547) where a minimum of 3 calibration standards are prepared and analyzed.

21.4.2.3 The standard solutions are introduced into the instrument in the same manner as samples are; whether it be by direct injection, by headspace analysis, or by purge and trap. The calibration factor (CF) for methods that use external standards, and the response factor (RF) for methods that use internal standards are calculated for the five standards.

- External standard calibration involves comparison of instrument responses from the sample to the responses from the target compounds in the calibration standards. Sample peak areas (or peak heights) are compared to peak areas (or heights) of the standards. The ratio of the response to the amount of analyte in the calibration standard is defined as the Calibration factor (CF).
- Internal standard calibration involves the comparison of instrument responses from the target compounds in the sample to the responses of specific standards added to the sample or sample extract prior to injection. The ratio of the peak area (or height) of the target compound in the sample or sample extract to the peak area (or height) of the internal standard in the sample or sample extract is compared to a similar ratio derived for each calibration standard. The ratio is termed the response factor (RF), and may also be known as a relative response factor in other methods.

In many cases, internal standards are recommended. These recommended internal standards are often brominated, fluorinated, or stable isotopically labeled analogs of specific target compounds, or are closely related compounds whose presence in environmental samples is highly unlikely. The use of specific internal standards is available in the method SOP.

Whichever internal standards are employed, the analyst needs to demonstrate that the measurement of the internal standard is not affected by method analytes and surrogates or by matrix interferences. In general, internal standard calibration is not as useful for GC and HPLC methods with non-MS detectors because of the inability to chromatographically resolve many internal standards from the target compounds. The use of MS detectors makes internal standard calibration practical because the masses of the internal standards can be resolved from those of the target compounds even when chromatographic resolution cannot be achieved.

When preparing calibration standards for use with internal standard calibration, add the same amount of the internal standard solution to each calibration standard, such that the concentration of each internal standard is constant across all of the calibration standards, whereas the concentrations of the target analytes will vary. The internal standard solution will contain one or more internal standards and the concentration of the individual internal standards may differ within the spiking solution (e.g., not all internal standards need to be at the same concentration in this solution). The mass of each internal standard added to each sample extract immediately prior to injection into the instrument or to each sample prior to purging must be the same as the mass of the internal standard in each calibration standard. The volume of

the solution spiked into sample extracts should be such that minimal dilution of the extract occurs (e.g., 10 uL of solution added to a 1 mL final extract results in only a negligible 1% change in the final extract volume which can be ignored in the calculations).

An ideal internal standard concentration would yield a response factor of 1 for each analyte. However, this is not practical when dealing with more than a few target analytes. Therefore, as a general rule, the amount of internal standard should produce an instrument response (e.g., area counts) that is no more than 100 times that produced by the lowest concentration of the least responsive target analyte associated with the internal standard. This should result in a minimum response factor of approximately 0.01 for the least responsive target compound. Refer to SOP No. CA-Q-S-005, Calibration Curves, for specific calculations.

21.4.2.4 Policies regarding the use of calibration standard results for creating the calibration curve are as follows:

- A low calibration standard may be excluded from the calibration if the signal-to-noise ratio or spectral criteria are not suitable. The reporting level must be elevated to be the lowest calibration standard used for calibration.
- The upper calibration standard may be excluded if it saturates the detector or is obviously becoming non-linear. Any sample exceeding the upper standard used in the calibration must be diluted and re-analyzed.
- Mid-calibration standards may not be excluded unless an obvious reason is found, i.e., cracked vial, incorrectly made, etc. The failed standard should be re-run immediately and inserted into the initial calibration. If not useful, recalibration is required.

21.4.2.5 Percent RSD Corrective Action

Given the potentially large numbers of analytes that may be analyzed in some methods, it is likely that some analytes may exceed the acceptance limit for the RSD for a given calibration. In those instances, the following steps are recommended, but not required.

21.4.2.5.1 The first step is generally to check the instrument operating conditions. This option will apply in those instances where a linear instrument response is expected. It may involve some trade-offs to optimize performance across all target analytes. For instance, changes to the operating conditions necessary to achieve linearity for problem compounds may cause the RSD for other compounds to increase, but as long as all analytes meet the RSD limits for linearity, the calibration is acceptable.

21.4.2.5.2 If the RSD for any analyte is greater than the acceptance criteria in the applicable analytical method or SOP, the analyst may wish to review the results (area counts, calibration or response factors, and RSD) for those analytes to ensure that the problem is not associated with just one of the initial calibration standards. If the problem appears to be associated with a single standard, that one standard may be reanalyzed and the RSD recalculated. Replacing the standard may be necessary in some cases.

21.4.2.5.3 A third alternative is to narrow the calibration range by replacing one or more of the calibration standards with standards that cover a narrower range. If linearity can be achieved using a narrower calibration range, document the calibration linearity, and proceed with analyses. The changes to the upper end of the calibration range will affect the need to dilute samples above the range, while changes to the lower end will affect the overall sensitivity of the method. Consider the regulatory limits or action levels associated with the target analytes when adjusting the lower end of the range.

Note: When the purpose of the analysis is to demonstrate compliance with a specific regulatory limit or action level, the laboratory must ensure that the method quantitation limit is at least as low as the regulatory limit or action level.

21.4.2.6 Alternatively, the least squares regression may be used to determine linearity. A five point line must result in a correlation coefficient (r) of 0.990 or better using the least squares method to be considered acceptable. In many cases it may be preferred that the curves be forced through zero (not to be confused with including the origin as an additional data point, which is not allowed). See SOP DV-QA-024P for requirements for federal programs.

Note: EPA method 8000B does not allow forcing through zero however the agency has reevaluated this position and has since changed this stance to allow forcing through zero. In addition, from EPA Method 8000C: "However, the use of a linear regression or forcing the regression through zero may NOT be used as a rationale for reporting results below the calibration range demonstrated by the analysis of the standards.").

21.4.2.7 Instead of a linear curve model (either Average RF or least squares regression), a second order curve (Quadratic) may be used (and preferred) as long as it contains at least six data points. As a rule of thumb, if there is a consistent trend in RFs (or CFs) in the calibration curve, either up or down, then quadratic curve fit may be indicated as the preferred calibration routine for that analyte. The coefficient of determination (COD or r^2) for the quadratic curve must be at least 0.99 for it to be considered acceptable. For more details on the calculations see Calibration Curve SOP CA-Q-S-005. Some limitations on the use of Quadratic Curve fits:

21.4.2.7.1 Care **MUST** be exercised to assure that the results from this equation are real, positive, and fit the range of the initial calibration.

21.4.2.7.2 They **may not** be used to mask instrument problems that can be corrected by maintenance. (Not to be used where the analyte is normally found to be linear in a properly maintained instrument).

21.4.2.7.3 They **may not** be used to compensate for detector saturation. If it is suspected that the detector is being saturated at the high end of the curve, remove the higher concentration standards from the curve and try a 1st order fit or average RF.

21.4.3 Calibration for Inorganic Analyses

EPA Method 7000 from EPA SW-846 is a general introduction to the quality control requirements for metals analysis. For inorganic methods, quality control measures set out in the individual methods and in the *Standard Methods for the Examination of Water and Wastewater* (20th Edition) may also be included. Standard Operating Procedures for the analysis and the quality control documentation measures are kept in the analyst group's reference binders, as well as posted on the network at L:\QA\Read\SOPs\ESOPs.

In general, inorganic instrumentation is calibrated with external standards. Some exceptions would be Inductively Coupled Plasma (ICP), Inductively Coupled Plasma Mass Spec (ICPMS), and Ion Chromatography Mass Spec (ICMS). These analyses may use an internal standard to compensate for viscosity or other matrix effects. While the calibration procedures are much the same for inorganics as they are for organics, CF's or RF's are not used. The calibration model in 21.4.2.6 is generally used for most methods, however in some instances the model from section 21.4.2.7 may be used. A correlation coefficient (r) of 0.995 or greater must be used to accept a calibration curve generated for an inorganic procedure. Correlation coefficients are determined by hand-held scientific calculators or by computer programs and documented as part of the calibration raw data. Coefficients of calibration curves used for quantitation must be documented as part of the raw data. Curves are not allowed to be stored in calculator memories and must be written on the raw data for the purposes of data validation.

21.4.3.1 "Calibrations" for titrimetric analyses are performed by standardizing the titrants against a primary standard solution. See specific methods in *Standard Methods for the Examination of Water and Wastewater* (20th Edition) for more information.

21.4.3.2 Spreadsheets that are used for general chemistry calculations must have all cells containing calculations locked to prevent accidental changes to the calculations.

21.4.3.3 Instrument technologies (e.g. ICP) with validated techniques from the instrument manufacturer or other methods using a zero point and single point calibration require the following:

21.4.3.3.1 The instrument is calibrated using a zero point and a single point calibration standard.

21.4.3.3.2 The linear range is established by analyzing a series of standards, one at the reporting limit (RL).

21.4.3.3.3 Sample results within the established linear range do not need to be qualified.

21.4.3.3.4 The zero point and single standard is run daily with each analytical batch.

21.4.3.3.5 A standard at the RL is analyzed daily with each analytical batch and must meet established acceptance criteria.

21.4.3.3.6 The linearity is verified at a frequency established by the manufacturer or method. See SOP DV-MT-0012, *ICP Analysis for Trace Metals by Methods 6010 and 200.7*.

21.4.4 Calibration Verification

The calibration relationship established during the initial calibration must be verified at periodic intervals as specified in the laboratory method SOPs in accordance with the referenced analytical methods and NELAC (2003) standard, Section 5.5.5.10. The process of calibration verification applies to both external standard and internal standard calibration techniques, as well as to linear and non-linear calibration models.

Note: The process of calibration verification referred to is fundamentally different from the approach called "calibration" in some methods. As described in those methods, the calibration factors or response factors calculated during calibration are used to update the calibration factors or response factors used for sample quantitation. This approach, while employed in other EPA programs, amounts to a daily single-point calibration, and is not appropriate nor permitted in SW-846 chromatographic procedures for trace environmental analyses.

21.4.4.1 Generally, the initial calibrations must be verified at the beginning of each 12-hour analytical shift during which samples are analyzed. (Some methods may specify more or less frequent verifications). The 12-hour analytical shift begins with the injection of the calibration verification standard (or the MS tuning standard in MS methods). The shift ends after the completion of the analysis of the last sample or standard that can be injected within 12 hours of the beginning of the shift.

21.4.4.2 A continuing instrument calibration verification (CCV) must be repeated at the beginning and, for methods that have quantitation by external calibration models, at the end of each analytical batch. Some methods have more frequent CCV requirements see specific SOPs. Most Inorganic methods require the CCV to be analyzed after every 10 samples.

21.4.4.3 The acceptance limits for calibration verifications can be found in each method SOP. As a rule of thumb: GCMS $\pm 20\%$, GC and HPLC $\pm 15\%$, Inorganics: ± 10 or 15% . Actual methods may have wider or tighter limits; see the method SOP for specifics.

21.4.4.4 If the response (or calculated concentration) for an analyte is within the acceptance limits of the response obtained during the initial calibration, then the initial calibration is considered still valid, and the analyst may continue to use the CF, RF or % drift values from the initial calibration to quantitate sample results.

21.4.4.5 If the response (or calculated concentration) for any analyte varies from the mean response obtained during the initial calibration by more than the acceptance criteria, then the initial calibration relationship may no longer be valid. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptance criteria, then either the laboratory has to demonstrate performance after corrective action with two consecutive successful calibration verifications, or a new initial instrument calibration must be performed. However, sample data associated with an unacceptable calibration verification may be reported as qualified data under the following special conditions:

21.4.4.5.1 When the acceptance criteria for the calibration verification are exceeded high, i.e., high bias, and there are associated samples that are non-detects, then those non-detects may be reported. Otherwise, the samples affected by the

unacceptable calibration verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.

21.4.4.5.2 When the acceptance criteria for the calibration verification are exceeded low, i.e., low bias, those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise, the samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted. Alternatively, for some methods a reporting limit standard may be analyzed to demonstrate that the laboratory can still support non-detects at their reporting limit specific details for utilizing this option are described in SOP DV-QA-27P, *Standardized CCV Criteria for GC and HPLC*.

21.4.4.6 Verification of Linear Calibrations

Calibration verification for linear calibrations involves the calculation of the percent drift or the percent difference of the instrument response between the initial calibration and each subsequent analysis of the verification standard. Use the equations below to calculate % Drift or % Difference, depending on the procedure specified in the method SOP. Verification standards are evaluated based on the % Difference from the average CF or RF of the initial calibration or based on % Drift or % Recovery if a linear or quadratic curve is used.

The Percent Difference is calculated as follows:

$$\% \text{ Difference} = \frac{(\text{CF(v) or RF(v)}) - (\text{Avg. CF or RF})}{(\text{Avg. CF or RF})} \times 100$$

Where: CF(v) or RF(v) = CF or RF from verification standard
Avg. CF or RF = Average CF or RF from Initial Calibration.

The Percent Drift is calculated as follows:

$$\% \text{ Drift} = \frac{\text{Result} - \text{True Value}}{\text{True Value}} \times 100$$

The Percent Recovery is calculated as follows:

$$\% \text{ Recovery} = \frac{\text{Result}}{\text{True Value}} \times 100$$

21.4.4.7 Verification of a Non-Linear Calibration

Calibration verification of a non-linear calibration is performed using the percent drift or percent recovery calculations described in 21.4.4.6 above.

Regardless of whether a linear or non-linear calibration model is used, if initial verification criterion is not met, then no sample analyses may take place until the calibration has been verified or a new initial calibration is performed that meets the specifications listed in the method SOPs. If the calibration cannot be verified after the analysis of a single verification standard, then adjust the instrument operating conditions and/or perform instrument maintenance, and analyze another aliquot of the verification standard. If the calibration cannot be verified with the second standard, then a new initial calibration is performed.

All target analytes and surrogates, including those reported as non-detects, must be included in periodic calibration verifications for purposes of retention time confirmation and to demonstrate that calibration verification criteria are being met.

All samples must be bracketed by periodic analyses of standards that meet the QC acceptance criteria (e.g., calibration and retention time). The frequency is found in the determinative methods or SOPs.

Note: If an internal standard calibration is being used (basically GCMS) then bracketing standards are not required, only daily verifications are needed. The results from these verification standards must meet the calibration verification criteria and the retention time criteria (if applicable).

21.5 POLICY ON TENTATIVELY IDENTIFIED COMPOUNDS (TICS) – GC/MS ANALYSIS

For samples containing components not associated with the calibration standards, a library search may be made for the purpose of tentative identification. The necessity to perform this type of identification will be determined by the purpose of the analyses being conducted. Data system library search routines should not use normalization routines that would misrepresent the library or unknown spectra when compared to each other.

Note: If the TIC compound is not part of the client target analyte list but is calibrated by the laboratory and is both qualitatively and/or quantitatively identifiable, it will not be reported as a TIC. If the compound is reported on the same form as true TICs, it must be qualified and/or narrated that the reported compound is qualitatively and quantitatively (if verification in control) reported compared to a known standard that is in control (where applicable).

For example, the RCRA permit or waste delisting requirements may require the reporting of non-target analytes. Only after visual comparison of sample spectra with the nearest library searches may the analyst assign a tentative identification.

21.5.1 Use the following guidelines for making tentative identifications

21.5.1.1 Relative intensities of major ions in the reference spectrum (ions greater than 10% of the most abundant ion) should be present in the sample spectrum.

21.5.1.2 The relative intensities of the major ions should agree within $\pm 20\%$. (Example: For an ion with an abundance of 50% in the standard spectrum, the corresponding sample ion abundance must be between 30 and 70%).

- 21.5.1.3** Molecular ions present in the reference spectrum should be present in the sample spectrum.
- 21.5.1.4** Ions present in the sample spectrum but not in the reference spectrum should be reviewed for possible background contamination or presence of coeluting compounds.
- 21.5.1.5** Ions present in the reference spectrum but not in the sample spectrum should be reviewed for possible subtraction from the sample spectrum because of background contamination or coeluting peaks. Data system library reduction programs can sometimes create these discrepancies.

The concentration of any non-target analytes identified in the sample (see above) should be estimated. The same formulae as calibrated analytes should be used with the following modifications: The areas A_x and A_{is} should be from the total ion chromatograms, and the RF for the compound should be assumed to be 1.

The resulting concentration should be reported indicating: (1) that the value is an estimate, and (2) which internal standard was used to determine concentration. Use the nearest internal standard free of interferences.

Note: The above guidelines above are from EPA SW846 III edition, method 8260B. For general reporting if TICs are requested, the ten (10), largest non-target analyte peaks whose area count exceeds 10% of the nearest internal standard will be termed "Tentatively Identified Compounds" (TICs). More or fewer TICs may be identified based on client requirements.

21.5.2 TIC Reporting Limits

In general Reporting limits cannot be specified because of the unknown nature of the TIC. Any reporting limit that is reported can only be evaluated as an estimate as the quantitation is based on the assumption that the TIC responds exactly as the IS responds which is most likely not the case. In general, it is not recommended to set a Reporting limit at too low of a concentration as it gives a false impression.

21.6 POLICY ON GC/MS TUNING

Prior to any GCMS analytical sequence, including calibration, the instrument parameters for the tune and subsequent sample analyses within that sequence must be set.

Prior to tuning/auto-tuning the mass spec, the parameters may be adjusted within the specifications set by the manufacturer or the analytical method. These generally don't need any adjustment but it may be required based on the current instrument performance. If the tune verification does not pass it may be necessary to clean the source or perform additional maintenance. Any maintenance is documented in the maintenance log.

- 21.6.1** The concentration of the BFB or DFTPP must be at or below the concentrations that are referenced in the analytical methods. Part of the purpose of the tune is to demonstrate

sensitivity and analyzing solutions at higher concentrations does not support this purpose. Tune failures may be due to saturation and a lower BFB/DFTPP concentration may be warranted.

21.6.2 Tune evaluations usually utilize the "Autofind" function and are set up to look at the apex +/- 1 scan and average the three scans. Background correction is required prior to the start of the peak but no more than 20 scans before. Background correction cannot include any part of the target peak.

21.6.3 Other Options or if Auto Tune Fails:

21.6.3.1 Sometimes the instrument does not always correctly identify the apex on some peaks when the peak is not perfectly shaped. In this case, manually identify and average the apex peak +/- 1 scan and background correct as in 21.6.4 above. This is consistent with EPA 8260 and 8270.

21.6.3.2 Or the scan across the peak at one half peak height may be averaged and background corrected. This is consistent with Standard Methods 6200, EPA 624 and EPA 625.

21.6.3.3 Adjustments such as adjustments to the repeller and ion focus lenses, adjusting the EM Voltage, etc. may be made prior to tune verification as long as all of the subsequent injections in the 12 hour tune cycle are analyzed under the same MS tune settings and it is documented in the run sequence log and/or maintenance log that an adjustment was made. Excessive adjusting (more than 2 tries) without clear documentation is not allowed. Necessary maintenance is performed and documented in instrument log.

21.6.3.4 A single scan at the Apex (only) may also be used for the evaluation of the tune. For SW 846 and EPA 600 series methods, background correction is still required.

21.6.3.5 Cleaning the source or other maintenance may be performed and then follow steps for tune evaluation above. Note: If significant maintenance was performed, see methods 8000B or 8000C then the instrument may require recalibration prior to proceeding.

21.6.4 Tune evaluation printouts must include the chromatogram and spectra as well as the Tune evaluation information. In addition, the verifications must be sent directly to the printer or pdf file (no screen prints for DFTPP or BFB tunes). This ability should be built into the instrument software.

21.6.5 All MS tune settings must remain constant between running the tune check and all other samples. It is recommended that a separate tune method not be used, however a separate method may be used as long as the MS conditions between the methods are the same as the sample analysis method and tracked so any changes that are made to the analysis method are also made to the tune method.

Table 21-1.

TestAmerica Denver Equipment and Instrumentation

Instrument Type	Manufacturer	Model	Purchase Date	Auto-sampler	Method Performed
ICP	Thermo Fischer (025) S/N 20062004	ICP 6500	2006	Yes	6010B, 200.7
	Thermo Fischer (026) S/N 20063207	ICP 6500	2006	Yes	6010B, 200.7
ICP/MS	Agilent ICP-MS (024) S/N JP51201530	7500 ce	2006	Yes	6020, 200.8
	Perkin Elmer SCIEX (004) S/N 305970360	ELAN 6000	1996	Yes	6020, 200.8
Mercury Analyzer	Cetac CVAA (023) S/N 030504QTA	M-7500	2005	Yes	7470, 7471A, 245.1, 245.2
	Perkin Elmer (019) S/N 4025	FIMS	1996	Yes	7471A, 7470, 245.1, 245.2
Ion Chromatograph	Dionex (IC3) S/N 98040510	DX-120	1997	Yes	300.0, 9056
	Dionex (IC4) S/N 056537	N/A	2000	Yes	Hydrazine, MMH, UDMH
	Dionex (IC5) S/N 0106180	N/A	2002	Yes	300.0, 314.0, 9056
	Dionex (IC6) S/N 03100162	ICS 2000	2003	Yes	300.0, 9056
	Dionex (IC7) S/N 03100161	ICS 2000	2003	Yes	300.0, 314.0, 9056
TOC	LECO (LEC) S/N 3097	C632 (Solid)	2007	Yes	415.1, 9060
	Shimadzu (SHI3) S/N H52104301585	TOC-V _{CPN}	2005	Yes	415.1, 9060
	Shimadzu (SHI2) S/N 414445340	TOC-VCSH	2004	Yes	415.1, 9060
TKN Digestion System	Tecator System 2040 S/N 662	1000-3454	1985	No	351.2, 351.3

Instrument Type	Manufacturer	Model	Purchase Date	Auto-sampler	Method Performed
TOX	MCI S/N 43F30588	TSX-10	1987	No	9020B, 9021, 9023
	Thermo Euroglass S/N 993752	1200	1997	Yes	9020B, 9021, 9023
	Thermo Euroglas S/N 993728	ECS 1200	2004	Yes	9020B, 9021, 9023
PH Meter	Corning S/N 5707	140	1987	No	9040B, 9045C, 150.1
Dissolved Oxygen Meter	YSI (BOD2)	5100	2002	No	405.1
	YSI S/N 02F0863	5000		No	405.1
UV/VIS	Milton Roy (301) S/N 3800107006	Spectronic 301	1985	No	7196A, 353.2, 354.1, 376.2, 9065, 410.1, 410.4,
	Alpkem (Alp1) S/N 908893427	A002393	1997	Yes	325.2, CN, Phenol
	Alpkem (Alp2) S/N 917893398	A002393	1997	Yes	353.2, NH ₃ /TKN, 351.2, 351.3
	Konelab S/N P0518697	Model 20	2003	Yes	365.3, 375.4
	Astoria Pacific Analyzer S/N 200052	Astoria 2	2005	Yes	351.2, 353.2, 365.1
Ion Analyzer	Orion Research S/N PX94A	EA940	1985	No	340.2, RedOx Potential
Autotitrator (pH, Alkalinity, Conductance)	Man-Tech (AT2)	PC – Titrate PC-1000	2000	Yes	9040B, 9045C, 150.1, 2320B, 310.1, 310.2, 2510B, 9050A, 120.1
Turbidimeter	HF Scientific	Micro 100	2001	No	180.1
Automated Distillation Apparatus	Westco S/N 1028	483-W001-01 Easy Dist	1997	No	4500-CN-E, 9012A, 335.1, 335.3
COD	HACH S/N 1105524	DRB 200		No	410.4
	Intermatic		2004	No	410.4

Instrument Type	Manufacturer	Model	Purchase Date	Auto-sampler	Method Performed
GC/MS Semivolatiles	Hewlett-Packard (B) S/N US00007283	6890 – GC 5973 – MSD	1999	Yes	8270C, 625
	Hewlett-Packard (D) S/N US00007319	6890 – GC 5973 – MSD	1996	Yes	8270C, 625
	Hewlett-Packard (F) S/N US00036181	6890 – GC 5973 – MSD	1996	Yes	8270C SIM
	Agilent Technologies (K) S/N CN10332028	6890N – GC 5973 – MSD	2003	Yes	8270C, 8270C SIM, 625
	Agilent Technologies (G2) S/N CN10421078	6890N – GC 5973 – MSD	2004	Yes	8270C Best Practice
	Hewlett-Packard (G4) S/N CN10438087	6890N – GC 5973 – MSD	2004	Yes	8270C Best Practice
	Hewlett-Packard (Q) (S/N US0000021949	6890 – GC 5973 – MSD	2001	Yes	8270C, 625
	Hewlett-Packard (Y) S/N US00007291	6890 – GC 5973 – MSD	1996	Yes	8270C, 625
GC/MS Volatiles	Agilent Technologies (C) S/N US00007315	6890N – GC 5973 – MSD	2002	Yes	8260B
	Hewlett-Packard (E) S/N 3336A60699	5890II – GC 5972 – MSD	1997	Yes	8260B-Water
	Hewlett-Packard (H) S/N 3336A60700	5890II – GC 5972 – MSD	1994	Yes	8260B-Waters
	Hewlett Packard (P) S/N US00007321	6890N - GC 5973 – MSD	1999	Yes	8260B
	Hewlett-Packard (G) S/N 3336A56276	5890 - GC 5972 - MSD	1996	Yes	8260B
	Hewlett-Packard (J) S/N 3336A60701	5890II – GC 5972 – MSD	1994	Yes	8260B
	Hewlett-Packard (R1) S/N 3336A52245	5890II - GC 5972 – MSD	1994	Yes	8260B/524
	Hewlett-Packard (R2) S/N 336A53965	5890II - GC 5972 – MSD	1995	Yes	8260B
	Hewlett-Packard (S) S/N 3336A60702	5890II – GC 5972 – MSD	1994	Yes	8260B/624
	Hewlett-Packard (Z) S/N 3336A60013	5890II – GC 5972 – MSD	1996	Yes	8260B-Waters, 524
	Agilent Technologies (GC/MS1) S/N CN10420009	6890N – GC 5973 – MSD	2004	Yes	8260B Waters

Instrument Type	Manufacturer	Model	Purchase Date	Auto-sampler	Method Performed
GC Volatiles	Hewlett-Packard (B) S/N 3019A28634	5890II PID / FID	1990	Yes	8021 GRO
	Hewlett-Packard (H) S/N 2750A16573	5890A Dual PID Single FID	1988	Yes	8015, 8021B Aromatics, 8021B GRO
	Hewlett-Packard (K) S/N 2843A19497	5890A Dual PID Single FID	1988	Yes	8015, 8021B Aromatics, 8021B GRO
	Hewlett-Packard (L) S/N 2336A00164	5890A FID	1988	Yes	8015B GRO
	Hewlett-Packard (P) S/N 2518A05337	5890A Dual PID Single FID	1990	Yes	8015B, 8021B Aromatic, 8021B GRO
	Agilent Technologies (S-1) S/N US10341120	6890 Dual PID/ Dual ELCD	2003	Yes	8021B

Instrument Type	Manufacturer	Model	Purchase Date	Auto-sampler	Method Performed
GC Semivolatiles	Hewlett-Packard (C) S/N US00029514	6890 Dual ECD	1999	Yes	608, 8081A
	Hewlett-Packard (E) S/N 3121A35858	5890II Dual ECD	1992	Yes	504.1, 8011
	Hewlett-Packard (M) S/N US00024143	6890 Dual ECD	1999	Yes	615, 8151A
	Agilent Technologies (P1) S/N US10418019	6890N Dual ECD	2004	Yes	8081A
	Agilent Technologies (P2) S/N US10418024	6890N Dual ECD	2004	Yes	8081A
	Agilent Technologies (P3) S/N US10418023	6890N Dual ECD	2004	Yes	8082
	Hewlett-Packard (R) S/N 3336A55030	5890II Dual ECD	1994	Yes	608, 8081A
	Hewlett-Packard (U) S/N US00063217	5890II Single FID	1999	Yes	8015B DRO
	Hewlett-Packard (W) S/N 3126A36250	5890II Dual ECD	1990	Yes	8082
	Hewlett-Packard (Z2) S/N 2623A08097	5890 Dual FID	1990	Yes	8015B DRO
HPLC	Hewlett-Packard (G) S/N DE91609974 (Quat Pump)	1100 Multiple wavelength UV/ Fluorescence detectors	1999	Yes	8310, 8330
	Hewlett-Packard (Q) S/N DE11114412 (Quat Pump)	1100 Multiple wavelength UV/ Fluorescence detectors	2001	Yes	8310, 8330
	Agilent Technologies (X3) S/N DE33224964 (Quat Pump)	1100 Multiple wavelength UV/ Fluorescence detectors	2004	Yes	8330

Instrument Type	Manufacturer	Model	Purchase Date	Auto-sampler	Method Performed
HPLC/MS/MS	Micromass/Waters 2790 HPLC Inlet (LCMS1) plus Dionex DX600 Inlet S/N VB118	Quattro Ultima	2000	Yes	8321A, 6860
	Micromass/Waters Acquity UPLC Inlet (LCMS3) plus Dionex DX600 Inlet S/N VAA188	Quattro Premier	2004	Yes	8321A
	Micromass/Shimadzu 10 Avp HPLC Inlet (LCMS2) plus Dionex DX600 Inlet S/N VB304	Quattro Ultima	2001	Yes	8321A
	Micromass/Waters 2695 HPLC Inlet (LCMS4) plus Dionex DX600 Inlet S/N QAA632	Quattro Micro	2006	Yes	8321A
GCMS	Agilent Technologies (GCMS3) S/N CN10438076	6890N-GC 5973-MSD	2004	Yes	Custom
CI/MS/MS	Varian (CIMS1) S/N 1200-680	1200L	2004	Yes	Low Level NDMA

Table 21-2.

Example: Schedule of Routine Instrument Maintenance

Instrument	Procedure	Frequency
Cetac and Perkin Elmer Mercury Analyzers	<ul style="list-style-type: none"> • Check silica gel in drying tube • Change Lamp • Clean cell and aspirator in aqua regia • Check pump tubing and pump flow • Check Waste Container • Fill reductant bottle with 10% Stannous Chloride and check acid reagent 	As needed As needed Monthly Daily Daily Daily
ICP	<ul style="list-style-type: none"> • Check pump tubing • Fill Argon humidifier with water • Check fluid level in waste container • Clean or replace air filters • Check torch for residue • Check nebulizer flow • Clean nebulizer and drain chamber • Fill rinse solution/ IS solution • Replace capillary tubing/sipper probe • Check internal fluid reservoir • Change internal cooling fluid 	Daily Weekly Daily As needed Daily Daily As needed Daily As needed Monthly Yearly
ICP MS	<ul style="list-style-type: none"> • Change pump tubing • Check level of tuning solution • Check waste container • Load printer with paper • Check air filters • Replace coolant on chiller • Clean or change nebulizer • Clean or replace torch • Replace capillary tubing • Change oil in vacuum pumps • Remove and clean cones 	Daily Daily Daily Daily Monthly Bi-annually As needed As needed As needed As needed As needed
UV-Vis Spectrophotometer	<ul style="list-style-type: none"> • Clean ambient flow cell • Precision check/alignment of flow cell • Wavelength verification check 	As required As required Semi-annually
Colorimetric Analyzer	<ul style="list-style-type: none"> • Clean detector • Clean filters • Check tubing • Clean sample probe shaft • Clean pump, diluter, and XYZ sampler. • Lubricate pump roller 	Daily Daily Daily Daily Monthly Semi-annually

Instrument	Procedure	Frequency
Ion Chromatograph	<ul style="list-style-type: none"> • Check plumbing for leaks • Check gases • Check pump pressure • Check eluent level • Check conductivity meter • De-gas pump head when flow is erratic • Change analytical columns and bed supports guard • Check and replace any damaged/dis-colored tubing • Clean conductivity cell • Lubricate left hand position 	Daily Daily Daily Daily Daily As needed As needed As needed As needed As needed
Total Organic Halide Analyzer	<ul style="list-style-type: none"> • Check electrodes/polish if needed • Replace dehydrating fluid /electrolyte fluid • Clean quartz boat • Perform cell performance check • At the end of each day of use, wash out the absorption module, empty the electrolyte and fill chamber with DI water, empty dehydrator tube • Clean or replace pyrolysis tube • Clean titration cell • Replace reference electrode fluid • Change quartz wool • Replace o-rings and seals 	Daily Daily Daily Daily Daily As needed As needed As needed As needed As needed
Hewlett Packard GC/MS	<ul style="list-style-type: none"> • Check inlet pressure • Check temperature of inlet, detector, verify temperature program • Check Septa and clean injection port • Check carrier gas supply • Check tune parameters • Check oil levels in mechanical pumps and the diffusion pump if the vacuum is insufficient • Replace electron multiplier • Clean Source • Replace filaments • Change rough pump oil and exhaust filters • Relubricate the turbomolecular pump-bearing wick 	Daily Daily Daily Daily Daily As needed As needed As needed As needed Annually Annually
Gas Chromatograph	<ul style="list-style-type: none"> • Check carrier gas supply • Check temperatures of inlet, detectors, verify temperature program • Check septa clean injection port or replace injection port liner and cut column if needed • Reactivate carrier gas drying agents • Replace or repair flow controllers if constant flow cannot be maintained 	Daily Daily As needed As needed As needed

Instrument	Procedure	Frequency
Electron Capture Detector (ECD)	<ul style="list-style-type: none"> Detector wipe test (Ni-63) Detector cleaning 	Semi-annually As needed
Flame Ionization Detector (FID)	<ul style="list-style-type: none"> Detector cleaning 	As needed
Nitrogen Phosphorus Detector (NPD)	<ul style="list-style-type: none"> Replace bead Replace ceramic rings 	As needed As needed
Photoionization Detector (PID)	<ul style="list-style-type: none"> Change O-rings Clean lamp window 	As needed As needed
HPLC	<ul style="list-style-type: none"> Check level of eluent vessels Check gas supply Change pump seals Change the column frit Change fuses in power supply Filter all samples Change autosampler rotor or oil autosampler slides Change or backflush columns 	Daily Daily Semi-annually or as required As needed As needed Daily As needed As needed
APCI/ESI LC/MS/MS	<ul style="list-style-type: none"> Check solvent reservoirs Verify that pump is primed and operating pulse free Verify temperatures for capillary heater/vaporizer heater Verify pressure of manifold/fore-pump Verify that corona and multiplier are functional Clean Lenses Clean skimmer Replace column Oil autosampler Change autosampler filters Replace sample inlet tube Replace fused silica tubing at ESI interface Replace rough pump oil Replace turbo pump oil Vaccum system components including fans and fan covers 	Daily Daily Daily Daily As needed As needed As needed As needed As needed As needed As needed Semi-annually Annually Annually
Balances	<ul style="list-style-type: none"> Class "S" traceable weight check Clean pan and check if level Field service 	Daily, when used Daily At least Annually
Sonicator	<ul style="list-style-type: none"> Inspect probe for etching/pitting Tune sonicator assembly Dissassemble and clean probe tips 	Daily Weekly As needed
Conductivity Meter	<ul style="list-style-type: none"> Standardize with KCL Conductivity cell cleaning Check probes and cables 	Daily As needed As needed

Instrument	Procedure	Frequency
Flash Point Tester	<ul style="list-style-type: none"> • Check stirrer • Check tubing • Check gas supply • Check thermometer against NIST thermometer 	Daily Daily Daily Daily, when used
Digestion Block	<ul style="list-style-type: none"> • Check with NIST thermometer 	Annually
Turbidimeter	<ul style="list-style-type: none"> • Check light bulb • Inspect cells • Clean housing 	Daily, when used Monthly Monthly
Deionized/Distilled Water	<ul style="list-style-type: none"> • Conductivity check • System cleaning • Replace cartridge & large mixed bed resins 	Daily As needed As needed
Drying Ovens	<ul style="list-style-type: none"> • Temperature monitoring • Temperature adjustments 	Daily As required
Refrigerators/ Freezers	<ul style="list-style-type: none"> • Temperature monitoring • Temperature adjustment • Defrosting/cleaning 	Daily As required As required
pH/Specific Ion Meter	<ul style="list-style-type: none"> • Calibration/check slope • Clean electrode 	Daily As required
BOD Incubator	<ul style="list-style-type: none"> • Temperature monitoring • Coil and incubator cleaning 	Daily Monthly
Centrifuge	<ul style="list-style-type: none"> • Check brushes and bearings 	Every 6 months or as needed
Water baths	<ul style="list-style-type: none"> • Temperature monitoring • Water replaced 	Daily Monthly or as needed

Table 21-3.

Periodic Calibration

Instrument	Type of Calibration/ Number of Standards	Frequency	Acceptance Limits	Corrective Action
Analytical Balance	Accuracy determined using A2LA-accredited NIST weights. Minimum of 3 weights bracketing the weight of interest. Inspected and calibrated by A2LA accredited person annually.	Daily	$\pm 0.2\%$	Clean, check level, insure lack of drafts, and that unit is warmed up, recheck. If fails, call service.
Top Loading Balance	Accuracy determined using A2LA-accredited NIST weights. Minimum of 2 weights bracketing the weight of interest. Inspected and calibrated by A2LA accredited person annually.	Daily	$\pm 0.5\%$	Clean. Replace.
A2LA- accredited NIST Weights	Accuracy determined by accredited weights and measurement laboratory.	1 year	As per certificate.	Replace.
NIST- Traceable Thermomet er	Accuracy determined by A2LA-accredited weights and measurement laboratory.	5 years	As per certificate.	Replace.
Thermomet er	Against NIST-traceable thermometer	Yearly at appropriate temperature range for intended use	$\pm 1.2^{\circ}\text{C}$	Replace
Minimum- Maximum Thermometer s	Against NIST-traceable thermometer	Yearly	$\pm 1.5^{\circ}\text{C}$	Replace

Instrument	Type of Calibration/ Number of Standards	Frequency	Acceptance Limits	Corrective Action
InfraRed Temperature Guns	Against NIST-traceable thermometer	Quarterly at appropriate temperature range for intended use.	$\pm 1.5^{\circ}\text{C}$	Repair/replace
Dial-type Thermometer s	Against NIST-traceable thermometer	Quarterly at appropriate temperature range for intended use.	$\pm 1.5^{\circ}\text{C}$	Replace
Refrigerator	Temperature checked using NIST-traceable thermometer.	Daily. If out of range, check again in two hours.	$2.7 \pm 1.7^{\circ}\text{C}$	Adjust. Repair. While waiting for repair, seal door, attach "Out of Service" sign, move items to functional unit. Notify supervisor.
Freezer	Temperature checked using NIST-traceable thermometer	Daily. If out of range, check again in two hours.	$(-10)-(-20)^{\circ}\text{C}$	Adjust. Repair. While waiting for repair, seal door, attach "Out of Service" sign, move items to functional unit. Notify supervisor.
Oven	Temperature checked using NIST-traceable thermometer.	When in use.	$104 \pm 1^{\circ}\text{C}$ (drying) $180 \pm 2^{\circ}\text{C}$ (TDS)	Adjust. Replace.
Incubator	Temperature checked using NIST-traceable thermometer.	When in use. For microbi- ology, twice daily when in use.	BOD: $20 \pm 1.0^{\circ}\text{C}$ Micro: $35 \pm 0.5^{\circ}\text{C}$	Adjust. Replace.
Water Bath	Temperature checked using NIST-traceable thermometer.	When in use.	$\pm 2^{\circ}\text{C}$	Adjust. Replace.
Volumetric Dispensing Devices (Eppendorf ® pipette, automatic dilutor or dispensing devices)	One delivery by weight. Using DI water, dispense into tared vessel. Record weight with device ID number.	Monthly	$\pm 2\%$ Calculate accuracy by dividing weight by stated volume times 100 for percent.	Adjust. Replace.

Instrument	Type of Calibration/ Number of Standards	Frequency	Acceptance Limits	Corrective Action
Glass Microliter Syringes	None	Accuracy must be initially de- monstrated if syringe was not received with a certifi-cate attesting to established accuracy.	$\pm 2\%$	Not applicable.
Conductivity Meter	Cell impedance calibrated with three KCl standards.	Each use.	$r \geq 0.99$	Recalibrate.
Deionized Water	Check in-line conductivity meter on system with conductivity meter in Inorganics Department.	Weekly	$<10 \mu\text{mhos}/\text{cm}^2$	Record on log. Report discrepancies to QA Director.

Table 21-3
Preventive Maintenance Procedures
For Laboratory Equipment

Instrument/ Equipment Type	Maintenance	Frequency
Gas Chromatograph	Replace Gas line dryers and filters	As needed*
	Replace Gas cylinders	As needed*
	Check or adjust column gas flow and/or detector make-up flow	As needed*
	Replace Injection port Septa	Daily*
	Replace Injection port liners/re-silicone liners	GC(MSVOA); GC/MS SVOC, Daily*
	Replace injection port liner o-ring	GC, As needed; GC/MS, Daily*
	Replace inlet seal and ring	GC, As needed, GC/MS, Daily*
	Replace column ferrules	GC, As needed; *
	Clip column (injector and detector end)	GC, As needed; GC/MS, Daily*
	Replace syringes on autosamplers	As needed*
	Replace heated-zones heaters and sensors	As needed*
	Replace inlet assembly	As needed*
	Empty solvent rinse and solvent waste vials (on autosampler tower)	Daily or as needed
	Replace column	As needed*
Flame Ionization Detector (FID)	Clean/replace jet	As needed*
	Clean collector	As needed*
	Check and/or adjust gas flows	As needed*
Photoionization Detector (PID)	Clean window	As needed*
	Replace o-ring seat	As needed*
	Replace Lamp	As needed*
	Check and/or adjust gas flows	As needed*
	Adjust Lamp power supply intensity	As needed*
Mass Spectrometer (MS)	Clean source, replace source parts, replace filaments	As needed*
	Clean analyzer	As needed*
	Replace electron multiplier	As needed*
	Clean or replace glass jet separator, replace transfer line from jet separator to MS	As needed*
	Change rough pump oil	After each source cleaning
	Refill calibration compound (PFTBA) vial	As needed
Purge and Trap Equipment	Refill rinse water supply/Empty rinse water waste	Weekly or as needed
	Refill spiking solutions vials	As needed
	Rinse sparge tubes	Daily
	Clean or replace 6-port valve	As needed*
	Replace Transfer lines (from Autosampler to LSC and from LSC to GC)	As needed*
	Adjust gas flows and pressures	As needed
	Perform leak check	As needed

Table 21-3
Preventive Maintenance Procedures
For Laboratory Equipment
(cont.)

Instrument/ Equipment Type	Maintenance	Frequency
Inductively Coupled Plasma, Atomic Emission Spectrometer (ICP-AES)	Replace Peristaltic pump tubing	As needed*
	Clean autosampler, change tubing	As needed*
	Clean nebulizer and torch assembly	As needed*
	Replace nitrogen and argon tanks	As needed*
	Refill rinse water receptacle	Daily
	Empty waste receptacle	Daily
	Check for internal standard and sample flow through peristaltic pump tubing	As often as possible
	Replace internal standard solution receptacle	As needed
	Operate and check vents	Daily
	Perform Hg alignment	Daily*
	Check water level and water filter on recirculating-cooling unit, refill and replace filter	Check daily, refill and replace as needed
	Check purge windows	Daily, replace as needed
	Replace nebulizer and o-rings	As needed*
	Replace torch	As needed*
	Drain air compressor	Weekly
	Replace mixing chambers	As needed*
	Clean or replace air filters	Weekly
	Check pneumatic filters	Weekly, replace as needed
High Pressure Liquid Chromatography (HPLC)	Perform wave calibration (UV and Vis)	Quarterly*
	Calibrate Detector	Quarterly*
	Replace pre-column filter	As needed*
	Refill Solvent reservoirs	Daily or as needed
	Reverse column and rinse with solvents	Daily or as needed*
	Replace column	As needed*
	Clean solvent reservoir filters	As needed*
	Replace ball-valve cartridges on high pressure pump	As needed*
pH Meters	Replace DAD flow cell windows	As needed*
	Check system solvent pressure	Daily
	Clean or replace electrode	As needed
	Refill electrode electrolyte	As needed

Table 21-3
Preventive Maintenance Procedures
For Laboratory Equipment
(cont.)

Instrument/ Equipment Type	Maintenance	Frequency
Balance	Clean pan and platform	After each use
	Check Level bubble	Daily
	Check calibration	Daily
	Cleaning and calibration by authorized service	Annually
Conductivity Meter	Clean probe	As needed
Dissolved Oxygen Meter	Replace membrane	As needed
	Clean probe	As needed
ZHE vessels	Replace o-rings and screens	As needed
ZHE and TCLP Tumblers	Check Rotation Rate	Yearly
Spectrophotometers	Clean and check tubing	As needed
Burettes and Pipets	Clean and check calibration	Monthly
Thermometers	Check calibration	Annually, Quarterly for Digitals and IR Thermometer*
Ovens	Check and/or adjust temperature, record temperature on log sheet	Daily
Refrigerators and Freezers	Check and/or adjust temperature, record temperature on log sheet	Daily
	Defrost freezers	As needed
OI Alpkem/Astoria, Flow Injection Analyzer	Replace tubes on autodilutor	As needed*
	Clean autosample surfaces	As needed
	Spray silicone on cloth and rub on pump rollers	As needed
	Clean or replace o-rings and ports on valves	As needed*
	Clean union and T's on manifold and replace o-rings on manifold	As needed
	Dry and clean detector surfaces	As needed
	Replace flow cell o-rings and flares	As needed*
	Replace manifold tubing	As needed*
	Adjust pump timing	As needed
APCI/ESI LC/MS/MS	Change filters in Autosampler	As needed*
	Change Pump Seals	As needed*
	Rinse Capillary with MeOH	As needed*
	Rinse and clean corona needle	As needed*
	Replace fused silica tubing at ESI interface	As needed*
	Replace sample inlet tube in APCI	As needed*
	Clean lenses	As needed*

*Date and maintenance performed are recorded in Maintenance Log of the instrument/equipment

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), at a minimum, 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 in 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.

Calibration laboratory's policy for achieving measurement traceability is defined and includes the subsequent elements of uncertainty.

The uncertainty calculations of the calibration laboratory are supported by uncertainty budgets and are represented by expanded uncertainties typically using a coverage factor of $k=2$ to approximate the 95% confidence level. This explanation accompanies the measurement result and the associated uncertainty.

The tolerance uncertainty ratio (TUR) is calculated using the expanded uncertainty of the measurement, not the collective uncertainty of the measurement standards. A statement to this effect accompanies the TUR along with the coverage factor and confidence level.

The calibration report or certificate submitted to TestAmerica Denver contains, in a well designed format, a traceability statement, the conditions under which the calibrations were made in the context of any potential influence, a compliance statement with an identified metrological specification and the pertinent clauses, a clearly identified record of the quantities and functional test results before and after re-calibration, and no recommendation on the calibration interval. Opinions and interpretations of results are presented along with the basis upon which they were made and identified as such. The report may be submitted by facsimile or other electronic means as long as the requirements of the International Standard are achieved. If significant amendments are made to a calibration certificate, a supplemental certificate for the serial-number-specified piece of equipment is so identified. When a new certificate is offered, it uniquely identifies and references the one it replaces. All calibration reports are filed in the QA Office.

The calibration laboratory supports in-house calibration systems: documented procedures for in-house calibrations, evidence by a report, certificate, or sticker, for an appropriate amount of time; training records of calibration personnel; certificates from accreditation services demonstrating traceability to national or international standards of measurement; procedures for evaluating measurement uncertainty; timely and documented recalibration of reference standards. When subcontracting to a calibration laboratory, TestAmerica Denver does not use a firm who subcontracts the work.

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. Balance calibrations are checked each day of use. All mercury thermometers are calibrated annually

against a traceable reference thermometer. Temperature readings of ovens, refrigerators, and incubators are checked on each day of use.

22.3 REFERENCE STANDARDS / MATERIALS

Reference standards/materials, where commercially available, are traceable to certified reference materials. Commercially prepared standard materials are purchased from vendors accredited by A2LA, NVLAP, and ISO/IEC with an accompanying Certificate of Analysis that documents the standard purity. 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). 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 regularly 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. For unique situations, such as IDA analysis where no other source or lot is available, a standard made by a different analyst would be considered a second source. The appropriate Quality Control (QC) criteria for specific standards are defined in laboratory SOPs. In most cases, the analysis of an Initial Calibration Verification (ICV) or LCS (where there is no sample preparation) is used as the second source confirmation. These checks are generally performed as an integral part of the analysis method (e.g. calibration checks, laboratory control samples).

All standards and materials must be stored and handled according to method or manufacturer's requirements in order to prevent contamination or deterioration. Refer to Table 9-1 in Section 9 for general storage requirements and SOP DV-QA-0015 for additional storage information. 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. The lots for most of the common solvents and acids are tested for acceptability prior to company wide purchase. Refer to SOP No. CA-Q-S-001, Solvent and Acid Lot Testing and Approval.

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 by the appropriate group until they are permanently archived by QA. 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 and SOP DV-QA-0015, Verification and Storage of Calibration Standards.

Commercial materials purchased for preparation of calibration solutions, spike solutions, etc., are usually accompanied with an assay certificate or the purity is noted on the label. If the assay purity is 96% or better, the weight provided by the vendor may be used without correction. If the assay purity is less than 96% a correction will be made to concentrations applied to solutions prepared from the stock commercial material.

22.4.1 All standards, reagents, and reference materials must be labeled in an unambiguous manner. Standards are logged into the laboratory's Standards software, and are assigned a unique identification number. The following information is typically recorded in the electronic database within the Standards program.

- Standard ID
- Description of Standard
- Department
- Preparer's name
- Final volume and number of vials prepared
- Solvent type and lot number
- Preparation Date
- Expiration Date
- Standard source type (stock or daughter)
- Standard type (spike, surrogate, other)
- Parent standard ID (if applicable)
- Parent Standard Analyte Concentration (if applicable)
- Parent Standard Amount used (if applicable)
- Component Analytes
- 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. These records also include method of preparation, date of preparation, expiration date and preparer's name or initials. 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 – assigned in the Standards log software.
- Special Health/Safety warnings if applicable

22.4.3 In addition, the following information may be helpful:

- Date of receipt for commercially purchased items or date of preparation for laboratory prepared items
- Date opened (for multi-use containers, if applicable)
- Description of standard (if different from manufacturer's label or if standard was prepared in the laboratory)
- Concentration (if applicable)
- Initials of analyst preparing standard or opening container

All containers of prepared reagents must include a preparation date, expiration 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; and 3) according to requirements in SOP DV-QA-0015, Verification and Storage of Calibration Standards.

SECTION 23.0

SAMPLING (NELAC 5.5.7)

23.1 OVERVIEW

TestAmerica Denver does not provide sampling services. The laboratory's responsibility in the sample collection process lies in supplying the sampler with the necessary coolers, reagent water, sample containers, preservatives, sample labels, custody seals, COC forms, ice, and packing materials required to properly preserve, pack, and ship samples to the laboratory. On occasion, the lab will supply personnel to assist with the duties mentioned above. In that case, the laboratory staff must adhere to the site specific health and safety plan as provided by the client.

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. Any certificates of cleanliness that are provided by the supplier are maintained at the laboratory.

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 ACS (Certified VOA Free) or equivalent
- Methanol – Purge and Trap grade
- Nitric Acid – Instra-Analyzed or equivalent
- Sodium Bisulfate – ACS Grade or equivalent
- Sodium Hydroxide – Instra-Analyzed or equivalent
- Sulfuric Acid – Instra-Analyzed or equivalent
- Sodium Thiosulfate – ACS Grade or equivalent

23.2.2 Preparing Container Orders

When new containers arrive at the laboratory, the date of receipt is recorded on the packing list received with them for retained documentation. Periodically, containers are evaluated for cleanliness based upon their intended parameter sample analysis. Upon request, the containers are then sent to clients for use in collecting samples. The shipping date, type and number of containers are maintained on file by the lab. Shipping personnel insure that container stock is rotated so that "first in" is "first out." When a client requests containers, a client services representative creates a container request in LIMS; it is then stored permanently in LIMS with a unique container order number. Copies of the container request are printed for the shipping department. One copy goes to the client with the containers; one copy is filed in the shipping department.

The laboratory also provides EnCore, TerraCore or other soil sampling devices when requested.

If containers are provided directly to the client from the manufacturer or from other sources, the laboratory will not be responsible for any of the above records.

23.3 FIELD QUALITY CONTROL (QC)

Common field quality control samples are defined in the following paragraphs. The frequency of field quality control samples should be specified in the site specific Quality Assurance Project Plan (QAPP) or by the client. TestAmerica provides trip blanks for VOC analysis with the sample containers for all volatile organic analyses. Blanks generated in the field will be analyzed along with the field samples (exception soil samples where the blank is aqueous).

23.3.1 Equipment Blank / Rinsate Blank - The equipment blank, sometimes referred to as a rinsate blank, is a sample of the water used to decontaminate sampling equipment. The source water should be as free of target analytes as possible. An aliquot of this water is poured over or through the sample collection device after decontamination, collected in a sample container, preserved with appropriate reagents, and returned to the laboratory. This serves as a check on sampling device cleanliness, and will also be affected by the site and sample handling conditions evaluated by the other types of blanks. The sampling time for the equipment blank should begin when the equipment is rinsed and the water is collected.

23.3.2 Field Blank - The field blank is water that is as free of target analytes as possible and from the same source as the equipment blank. The water is poured into a sampling container at the sampling site, preserved with the appropriate reagents, and returned to the laboratory. This serves as a check on reagent and environmental contamination. The sampling time for the field blank should be when the blank is prepared in the field.

23.3.3 Trip Blank - The trip blank pertains to volatile analysis only. This serves as a check on sample contamination originating from sample transport, sample container contamination, shipping and storage, or from certain site conditions. Trip blanks are often referred to as travel blanks. They are prepared using pre-cleaned sample containers. They are filled with organic-free water (the source of the organic free water is the same source of water used to prepare volatile standards, method blanks, LCS and sample dilutions), sealed and taken into the field with the empty containers which will be used for sampling. The recommended frequency is one trip blank per cooler (in duplicate or triplicate), per volatiles method. Unless otherwise specified, the sampling time for the trip blank is the time of receipt at the laboratory (When the "Trip" ends).

23.3.4 Field Duplicates - Field duplicates are replicate samples collected from the same sampling point or location during a field collection event. This control sample is used to demonstrate the ability of both the sampling and analytical process to generate data of acceptable precision.

23.4 DEFINITION OF HOLDING TIME

The date and time of sampling documented on the chain-of-custody (COC) form establishes the day and time zero. As a general rule, when the maximum allowable holding time is expressed in "days" (e.g 14 days, 28 days), the holding time is based on calendar day measured. Holding times expressed in "hours" (e.g. 6 hours, 24 hours, etc.) are measured from date and time zero. The first day of holding time ends twenty-four hours after sampling. Holding times for analysis include any necessary reanalysis. However there are some programs that determine holding time compliance based on the

date and specific time of analysis compared to the time of sampling regardless of how long the holding time is.

23.4.1 Semi-Volatile - Holding times for sample preparation for semi-volatile organics are measured from the sampling date (and time where applicable) until the day (and time where applicable) solvent contacts the sample. Holding times for analysis are measured from the date (and time where applicable) of initiation of extraction to the time of injection into the gas chromatograph.

23.4.2 Volatiles - Holding times for volatile organics are measured from the date (and time where applicable) of sampling to the date and time of injection into the gas chromatograph.

23.4.3 Inorganics - For inorganic and metals analysis, the preparation/digestion/distillation must be started within the maximum holding time as measured from the sampling date (and time where applicable).

23.5 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 Tables 23-1 to 23-3) 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.

23.6 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.

Refer to SOPs DV-QA-0023, *Subsampling* and SOPs DV-OP-0013 and DV-OP-0014.

23.6.1 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; the final results can either be reported separately or combined mathematically, weighting the individual phase results by volume. One exception to this procedure is the situation addressed in the TCLP and SPLP methods for wastes containing free liquids. However, if the leachate and final filtrate are not miscible, it is necessary to combine mathematically the concentrations of the two (or more) solutions by volume.

Tables 23-1 to 23-3 detail holding times, preservation and container requirements, and sample volumes for SDWA and NPDES methods. The sample volumes are intended to be a minimal amount to perform the method, the containers that are used may be of larger size.

Note: the holding times are program specific and different programs may have different holding times for equivalent methods (e.g., there are difference in Holding times for many Organic analytes between SDWA and NPDES. RCRA methods may also be different.)

Table 23-1.

Inorganic Sample Containers, Preservatives, and Holding Times

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3), (7)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method	Requirements
Acidity	Water	100 mL	2310 B	250 mL plastic or glass, Cool, 4°C, 14 days	---	Not Applicable
	Solid ⁽⁵⁾	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Alkalinity	Water	100 mL	2320B	250 mL plastic or glass, Cool, 4°C, 14 days	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Ammonia	Water	400 mL	350.1	500 mL plastic or glass, Cool, 4°C H ₂ SO ₄ to pH < 2, 28 days	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Biochemical Oxygen Demand (BOD)	Water	200 mL	5210 B	1000 mL plastic or glass, Cool, 4°C 48 hours	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Bromide	Water	100 mL	300.0 ⁽⁷⁾	250 mL plastic or glass, No preservative required, 28 days	9056	Cool, 4°C, analyze ASAP after collection
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not	---	Not Applicable	---	Not Applicable

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3), (7)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method	Requirements
		Applicable				
Chemical Oxygen Demand (COD) Chloride	Water	100 mL	410.4	250 mL glass or plastic, Cool, 4°C, H ₂ SO ₄ to pH < 2, 28 days	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
	Water	50 mL	300.0 ⁽⁷⁾ 4500-Cl C,E	250 mL plastic or glass, No preservative required, 28 days	9056	Method 9056: Cool, 4°C, analyze ASAP after collection.
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Chromium (Cr ⁺⁶)	Water	100 mL	3500 Cr-D	Method 218.4: 200 mL plastic or glass, Cool, 4°C, 24 hours Method 3500 Cr-D: 200 mL quartz, TFE, or polypropylene HNO ₃ to pH <2 Cool, 4°C Analyze ASAP after collection	7196A	200 mL plastic or glass, Cool, 4°C, 24 hours
	Solid	Not Applicable	---	Not Applicable	7196A	250 mL plastic or glass, 30 days to digestion, 96 hours after digestion
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable

Table 23-1.

Inorganic Sample Containers, Preservatives, and Holding Times – con't

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3), (7)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method	Requirements
Color	Water	100 mL	2120 B	250 mL plastic or glass, Cool, 4°C, 48 hours	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Conductivity	Water	100 mL	120.1	200 mL glass or plastic, Cool, 4°C, 28 days	9050A	200 mL glass or plastic, Cool, 4°C, 24 hours
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Cyanide (Amenable)	Water	IL	335.4	1 liter plastic or glass, NaOH to pH >12 0.6g ascorbic acid ⁽⁶⁾ Cool, 4°C, 14 days unless sulfide is present. Then maximum holding time is 24 hours	9010B/ 9012A	1 liter plastic or glass, NaOH to pH >12 0.6g ascorbic acid ⁽⁶⁾ Cool, 4°C, 14 days
	Solid	50g	---	Not Applicable	9010B/ 9012A	Not Specified
	Waste	50g	---	Not Applicable	9010B/ 9012A	Not Specified
Cyanide (Total)	Water	IL	335.4	1 liter plastic or glass, NaOH to pH >12 0.6g ascorbic acid ⁽⁶⁾ Cool, 4°C, 14 days unless sulfide is present. Then maximum holding time is 24 hours	9010B/ 9012A	1 liter plastic or glass, NaOH to pH >12 0.6g ascorbic acid ⁽⁶⁾ Cool, 4°C, 14 days
	Solid	50g	--	Not Applicable	9010B 9012A	8 or 16 oz glass Teflon-lined lids, Cool, 4°C, 14 days

Table 23-1.

Inorganic Sample Containers, Preservatives, and Holding Times – con't

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3), (7)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method	Requirements
Cyanide (Total) (continued)	Waste	50g	--	Not Applicable	9010B/ 9012A	8 or 16 oz glass Teflon-lined lids, Cool, 4°C
Flashpoint (Ignitability)	Liquid	Not Applicable	---	Not Applicable	1010	No requirements, 250 mL amber glass, Cool, 4°C is recommended
	Solid	Not Applicable	--	Not Applicable	---	Not Applicable
	Waste	Not Applicable	--	Not Applicable	---	Not Applicable
Fluoride	Water	300 mL	300.0 ⁽⁷⁾ 4500-F C, C-97	500 mL plastic, No preservation required, 28 days	9056	Cool, 4°C, analyze ASAP after collection
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Hardness (Total)	Water	50 mL	2340B	250 mL glass or plastic, HNO ₃ to pH < 2, 6 months	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Iron (Ferrous)	Water	100 mL	3500-Fe D	1 liter glass or polyethylene container, 6 months This test should be performed in the field.	-	Not Applicable
	Solid	Not Applicable	-	Not Applicable	-	Not Applicable
	Waste	Not Applicable	-	Not Applicable	-	Not Applicable

Table 23-1.

Inorganic Sample Containers, Preservatives, and Holding Times – con't

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3), (7)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method	Requirements
Methylene Blue Active Substances (MBAS) (Surfactant)	Water	100 mL	5540-C-00	250 mL plastic or glass, Cool, 4°C, 48 hours	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Nitrate	Water	100 mL	300.0 ⁽⁷⁾ 353.2	Method 300.0: 250 mL plastic or glass, Cool, 4°C, 48 hours. Method 352.1: 250 mL plastic or glass, Cool, 4°C, 48 hours.	9056	Method 9056: Cool, 4°C, analyze ASAP after collection Method 9210: Cool, 4°C Preserve by adding 1 mL of 1M boric acid solution per 100 mL of sample
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	9210	Not Specified
Hydrazines	Water	100 mL	---	Preserve at lab to pH =2 within 48 hours of collection. Hold time 28 days.	---	Preserve at lab to pH =2 within 48 hours of collection. Hold time 28 days.
	Solid	10 grams	---	4 oz jar Cool, 4°C	---	4 oz jar Cool, 4°C
Nitrite	Water	50 mL	300.0 ⁽⁷⁾ 353.2	250 mL plastic or glass Cool, 4°C, 48 hours	9056	Cool, 4°C, analyze ASAP after collection
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable

Table 23-1.

Inorganic Sample Containers, Preservatives, and Holding Times – con't

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3), (7)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method	Requirements
Nitrate-Nitrite	Water	100 mL	4500-NO3 F	250 mL plastic or glass, H ₂ SO ₄ to pH < 2, 28 days	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Ortho-phosphate	Water	50 mL	300.0 ⁽⁷⁾ 365.3	100 mL plastic or glass, Filter on site Cool, 4°C, 48 hours	9056	Cool, 4°C, analyze ASAP collection
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
pH	Water	50 mL	150.1 4500-H ⁺ B	100 mL plastic or glass. Analyze immediately. This test should be performed in the field.	9040B	100 mL plastic or glass. Analyze immediately. This test should be performed in the field. ⁽⁸⁾
	Solid	Not Applicable	---	Not Applicable	9045C	4 oz glass or plastic, Cool, 4°C, Analyze as soon as possible. ⁽⁸⁾
	Waste	Not Applicable	---	Not Applicable	9045C	4 oz glass or plastic, Cool, 4°C, Analyze as soon as possible. ⁽⁸⁾
Phenolics	Water	100 mL	420.4	500 mL glass, Cool, 4°C, H ₂ SO ₄ to pH < 2, 28 days	9066	1 liter glass recommended, Cool, 4°C, H ₂ SO ₄ to pH < 4, 28 days
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	9065	Not Specified

Table 23-1.

Inorganic Sample Containers, Preservatives, and Holding Times – con't

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3), (7)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method	Requirements
Phosphate	Water	50 mL	365.3	Not Applicable	9056	Cool, 4°C, analyze ASAP collection
	Solid	Not Applicable	---	Not Applicable	9056	Not Applicable
	Waste	Not Applicable	---	Not Applicable	9056	Not Applicable
Phosphorus (Total)	Water	50 mL	365.3	100 mL plastic or glass, H ₂ SO ₄ to pH < 2, 28 days	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Reactivity (Cyanide and Sulfide)	Liquid	10 g	---	Not Applicable	Chapter 7 Section 7.3.3.2 and 7.3.4.2	10 oz amber glass, Cool, 4°C, no headspace, analyze as soon as possible.
	Solid	10 g	---	Not Applicable	Chapter 7 Section 7.3.3.2 & 7.3.4.2	10 oz amber glass, Cool, 4°C, no headspace, analyze as soon as possible.
	Waste	10 g	---	Not Applicable	Chapter 7 Section 7.3.3.2 and 7.3.4.2	10 oz amber glass, Cool, 4°C, no headspace, analyze as soon as possible.
Settleable Solids	Water	1000 mL	2540 F	1000 mL plastic or glass, Cool, 4°C, 48 hours	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Specific Conductance	Water	50 mL	2510 B	250 mL plastic or glass, Cool, 4°C, 24 hours	9050A	250 mL plastic or glass, Cool, 4°C, 28 days

Analytical Parameters		Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3), (7)}		RCRA (SW846) ^{(3), (4)}	
	Matrix		Method	Requirements	Method	Requirements
Specific Conductance – Con't	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Sulfate (SO ₄)	Water	100 mL	300.0 ⁽⁷⁾ 375.2	100 mL plastic or glass, Cool, 4°C, 28 days	9056 9038	Method 9056: Cool, 4°C, analyze ASAP collection Method 9038: 200 mL plastic or glass, Cool, 4°C, 28 days
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	100 mL	---	Not Applicable	9038	200 mL plastic or glass, Cool, 4°C, 28 days
Sulfide	Water	100 mL	4500-S2 D-00	500 mL plastic or glass, Cool, 4°C, Add 2 mL zinc acetate plus NaOH to pH > 9, 7 days	9030B/9034	500 mL plastic, no headspace, Cool, 4°C, Add 4 drops of 2N zinc acetate per 100 mL of sample, adjust the pH to > 9 with 6 N NaOH solution, 7 days
	Solid	50 g	---	Not Applicable	9030B 9034	Cool, 4°C, fill surface of solid with 2N Zinc acetate until moistened, store headspace-free
	Waste	50 g	---	Not Applicable	9030B 9034	Cool, 4°C, fill surface of solid with 2N Zinc acetate until moistened, store headspace-free

Table 23-1.

Inorganic Sample Containers, Preservatives, and Holding Times – con't

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3), (7)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method	Requirements
Sulfite (SO ₃)	Water	100 mL	4500-SO3 B-00	100 mL plastic or glass, No preservative required, analyze immediately This test should be performed in the field.	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Total Dissolved Solids (Filterable)	Water	100 mL	2540 C	250 mL plastic or glass, Cool, 4°C, 7 days	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Total Kjeldahl Nitrogen (TKN)	Water	500 mL	4500-N	500 mL plastic or glass, Cool, 4°C, H ₂ SO ₄ to pH < 2, 28 days	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Total Organic Carbon (TOC)	Water	100 mL	5310-B,C,D	100 mL plastic or glass, Cool, 4°C, H ₂ SO ₄ to pH < 2, 28 days	9060	100 mL glass or 40 mL VOA vials, Cool, 4°C, H ₂ SO ₄ or HCl to pH < 2, 28 days
	Solid	Not Applicable	---	Not Applicable	9060	Not Specified
	Waste	Not Applicable	---	Not Applicable	9060	Not Specified

Table 23-1.

Inorganic Sample Containers, Preservatives, and Holding Times – con't

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3), (7)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method	Requirements
Total Organic Halides (TOX)	Water	100 mL	---	Method 5320B: 500 mL amber glass, Teflon®-lined lid, Cool, 4°C, HNO ₃ to pH <2, no headspace, 14 days Method 450.1: 500 mL amber glass, Teflon®-lined lid, Cool, 4°C, HNO ₃ to pH <2, no headspace, 28 days	9020B	500 mL amber glass, Teflon®-lined lid, Cool, 4°C, H ₂ SO ₄ to pH < 2, no headspace, 28 days
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Total Solids	Water	100 mL	2540 B	250 mL plastic or glass, Cool, 4°C, 7 days	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Total Suspended Solids (Nonfilterable)	Water	100 mL	2540 D	250 mL plastic or glass, Cool, 4°C, 7 days	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable
Turbidity	Water	50 mL	180.1	250 mL plastic or glass, Cool, 4°C, 48 hours	---	Not Applicable
	Solid	Not Applicable	---	Not Applicable	---	Not Applicable
	Waste	Not Applicable	---	Not Applicable	---	Not Applicable

Table 23-1.

Inorganic Sample Containers, Preservatives, and Holding Times – con't

Analytical		Minimum Sample	NPDES^{(2), (3), (7)}		RCRA (SW846)^{(3), (4)}	
Parameters	Matrix	Size⁽¹⁾	Method	Requirements	Method	Requirements
Volatile Solids	Water	100 mL	160.4	250 mL plastic or glass, Cool, 4°C, 7 days ---	Not Applicable	Water
Water Content	Solid	NA	---	Not Applicable	---	Not Applicable
	Waste	NA	---	Not Applicable	---	Not Applicable
	Water	NA	---	Not Applicable	---	Not Applicable
	Solid	10 g	---	Refer to specific method used	---	Refer to specific method used
Metals (excludes Hg)	Waste	10 g	---	Refer to specific method used	---	Refer to specific method used
	Water	100 mL	200 series	1 liter glass or polyethylene container, HNO ₃ to pH ≤ 2, 6 months	6010B, 6020	1 liter glass or polyethylene container, HNO ₃ to pH ≤ 2, 6 months
	Solid	200 g	200 series	8 or 16 oz glass or polyethylene container storage at 4 °C	6010B, 6020	8 or 16 oz glass or polyethylene container, storage at 4°C, 6 months
Mercury (CVAA)	Waste	200 g	200 series	Not Applicable	6010B, 6020	8 or 16 oz glass or polyethylene container, storage at 4°C, 6 months
	Water	100 mL	245.1	1 liter glass or polyethylene container, HNO ₃ to pH ≤ 2, 28 days	7470A	1 liter glass or polyethylene container, HNO ₃ to pH ≤ 2, 28 days
	Solid	200 g	245.5	8 or 16 oz glass or polyethylene container, Cool, 4°C, 28 days	7471A	8 or 16 oz glass or polyethylene container, Cool, 4°C, 28 days (CORP-MT-0007)
	Waste	200 g	--	Not Applicable	7471A	8 or 16 oz glass or polyethylene container, Cool, 4°C, 28 days (CORP-MT-0007)

Footnotes

- (1) Minimum sample size indicates sample amount needed for a single analysis. Matrix spikes or duplicates will require an additional sample amount of at least this amount for each additional QC sample aliquot required.
- (2) National Pollutant Discharge Elimination System - MCAWW, March 1983.
- (3) Holding times are calculated from date of collection.
- (4) Resource Conservation and Recovery Act, Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, (SW-846), Third Edition, September 1986. Contains Final Update I (July 1992), Final Update IIA, (August 1993), Final Update II (September 1994), Final Update IIB (January 1995), and Final Update III (December 1996).
- (5) Solid matrix type includes soil, sediment, sludge and other solid materials not classified as waste.
- (6) Samples to be analyzed for cyanide should be field-tested for residual chlorine. If residual chlorine is detected, ascorbic acid should be added.
- (7) Method not listed in 40 CFR Part 136.
- (8) If not done in the field (ASAP) per the method and requested by client, analyze in lab within 48 hours.

Table 23-2

Organic Sample Containers, Preservatives, and Holding Times

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method ⁽⁶⁾	Requirements
Aromatic Volatiles	Water	40 mL	602	40 mL glass, VOA vial (in triplicate) with Teflon®-lined septa without headspace, Cool, 4°C, Add sodium thiosulfate if residual chlorine, 7 days with pH > 2, 14 days with pH ≤ 2	8021B	40 mL glass, VOA vial (in triplicate) with Teflon®-lined septa without headspace, Cool, 4°C, Add sodium thiosulfate if residual chlorine, 1:1 HCl to pH ≤ 2, 14 days with pH ≤ 2
	Solid ⁽⁵⁾	5 g or 25 g	--	Not Applicable	8021B	4 or 8 oz glass with Teflon®-lined lid, Cool 4 °C, 14 days. Field preserved with sodium bisulfate solution for low level analysis, or with methanol for medium level analysis. Soil sample can also be taken by using the EnCore™ sampler and preserved in the lab within 48 hours of sampling. Maximum holding time for Encore Sampler is 48 hours (before the sample is added to methanol or sodium bisulfate).Cool, 4°C (See Note 12 Page 136 for holding time.)
	Waste	5 g or 25 g	--	Not Applicable	8021B	4 or 8 oz glass with Teflon®-lined lid, Cool 4 °C, 14 days. Field preserved with sodium bisulfate solution for low level analysis, or with methanol for medium level analysis.

Table 23-2

Organic Sample Containers, Preservatives, and Holding Times – con't

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	Method	NPDES ^{(2), (3)}		RCRA (SW846) ^{(3), (4)}
				Requirements	Method ⁽⁶⁾	Requirements
Aromatic Volatiles (continued)	Waste	5 g or 25 g	--	Not Applicable	8021B	Soil sample can also be taken by using the EnCore™ sampler and preserved in the lab within 48 hours of sampling. Maximum holding time for Encore Sampler is 48 hours (before the sample is added to methanol or sodium bisulfate). Cool, 4°C. (See Note 12 Page 136 for holding time.)
Halogenated Volatiles By GC	Water	40 mL	601	Not Applicable	8021B	40 mL glass, VOA vial (in triplicate) with Teflon®-lined septa without headspace, Cool, 4°C, Add sodium thiosulfate if residual chlorine, 1:1 HCl to pH ≤ 2, 14 days
	Solid ⁽⁵⁾	5 g or 25 g	601		8021B	4 or 8 oz glass with Teflon®-lined lid, Cool 4 °C, 14 days. Field preserved with sodium bisulfate solution for low level analysis, or with methanol for medium level analysis. Soil sample can also be taken by using the EnCore™ sampler and preserved in the lab within 48 hours of sampling. Maximum holding time for Encore Sampler is 48 hours (before the sample is added to methanol or sodium bisulfate). Cool, 4°C. (See Note 12 Page 136 for holding time.)

Table 23-2

Organic Sample Containers, Preservatives, and Holding Times – con't

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method ⁽⁶⁾	Requirements
Nitrosamines	Water	1L	607 ⁽¹⁰⁾	1 liter amber glass with Teflon®-lined lid, Sodium thiosulfate or ascorbic acid if residual chlorine present, Cool, 4°C, Extraction, 7 days Analysis, 40 days after extraction	8070A	1 liter amber glass with Teflon®-lined lid. If residual chlorine present, add 3 mL sodium thiosulfate per gallon. Cool, 4°C, Extraction, 7 days Analysis, 40 days of the start of the extraction
Nitrosamines	Soil	30 g	--		8070A	4 or 8 oz glass widemouth with Teflon®-lined lid, Cool 4 °C, Extraction, 14 days Analysis, 40 days of the start of the extraction
Herbicides	Water	1L	615 ⁽¹⁰⁾	1 liter amber glass with Teflon®-lined lid, Sodium thiosulfate or ascorbic acid if residual chlorine present, Cool, 4°C, Extraction, 7 days Analysis, 40 days after extraction	8151A	1 liter amber glass with Teflon®-lined lid. If residual chlorine present, add 3 mL sodium thiosulfate per gallon. Cool, 4°C, Extraction, 7 days Analysis, 40 days of the start of the extraction
	Solid	50 g	--	Not Applicable	8151A	4 or 8 oz glass widemouth with Teflon®-lined lid, Cool 4 °C, Extraction, 14 days Analysis, 40 days of the start of the extraction
Nitroaromatics	Water	0.5L	--	Not Applicable	8330	1 liter amber glass with Teflon®-lined lid. If residual chlorine present, add 3 mL sodium thiosulfate per gallon. Cool, 4°C, Extraction, 7 days Analysis, 40 days of the start of the extraction
	Solid	25 g	---	Not Applicable	8330	4 or 8 oz glass widemouth with Teflon®-lined lid Cool, 4°C, Extraction, 14 days Analysis, 40 days of the start of the extraction

Table 23-2

Organic Sample Containers, Preservatives, and Holding Times – con't

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method ⁽⁶⁾	Requirements
Nitroaromatics (continued)	Waste	25 g	---	Not Applicable	8330	4 or 8 oz glass widemouth with Teflon®-lined lid Cool, 4 °C, Extraction, 14 days Analysis, 40 days of the start of the extraction
Organo-phosphorus Pesticides	Water	1L	---	Not Applicable	8141A	1 liter amber glass with Teflon®-lined lid. If residual chlorine present, add 3 mL sodium thiosulfate per gallon. Cool, 4°C, Extraction, 7 days Analysis, 40 days of the start of the extraction
	Solid	30 g	---	Not Applicable	8141A	4 or 8 oz glass widemouth with Teflon®-lined lid Cool, 4°C, Extraction, 14 days Analysis, 40 days of the start of the extraction
	Waste	30 g	---	Not Applicable	8141A	4 or 8 oz glass widemouth with Teflon®-lined lid, Cool, 4°C, Extraction, 14 days Analysis, 40 days of the start of the extraction
PAHs by GC and HPLC	Water	1L	610	1 liter amber glass with Teflon®-lined lid, Adjust pH to 5-9 if extraction not to be done within 72 hours of sampling. Add sodium thiosulfate if residual chlorine present. Cool, 4°C, Extraction, 7 days Analysis, 40 days after extraction	8310	1 liter amber glass with Teflon®-lined lid, If residual chlorine present, add 3 mL sodium thiosulfate per gallon, Cool, 4°C, Extraction, 7 days Analysis, 40 days of the start of the extraction

Table 23-2

Organic Sample Containers, Preservatives, and Holding Times – con't

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method ⁽⁶⁾	Requirements
PAHs by GC and HPLC (continued)	Solid	30 g	---	Not Applicable	8310	4 or 8 oz glass wide mouth with Teflon®-lined lid, Cool, 4°C, Extraction, 14 days Analysis, 40 days of the start of the extraction
	Waste	30 g	---	Not Applicable	8310	4 or 8 oz glass wide mouth with Teflon®-lined lid, Cool, 4°C Extraction, 14 days Analysis, 40 days of the start of the extraction
Pesticides/ PCBs	Water	1L	608	1 liter amber glass with Teflon®-lined lid, Adjust pH to 5-9 if extraction not to be done within 72 hours of sampling. Add sodium thiosulfate if residual chlorine present and aldrin is being determined. Cool, 4°C, Extraction, 7 days Analysis, 40 days after extraction	8081A 8082	1 liter amber glass with Teflon®-lined lid, If residual chlorine present, add 3 mL 10% sodium thiosulfate per gallon, Cool, 4°C, Extraction, 7 days Analysis, 40 days of the start of the extraction
	Solid	30 g	---	Not Applicable	8081A 8082	4 or 8 oz glass wide mouth with Teflon®-lined lid, Cool, 4°C, Extraction, 14 days Analysis, 40 days of the start of the extraction
	Waste	30 g	---	Not Applicable	8081A 8082	4 or 8 oz glass wide mouth with Teflon®-lined lid, Cool, 4°C Extraction, 14 days Analysis, 40 days of the start of the extraction

Table 23-2

Organic Sample Containers, Preservatives, and Holding Times – con't

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method ⁽⁶⁾	Requirements
Petroleum Hydrocarbons/Oil and Grease	Water	1L	413.1 413.2 418.1	1 liter glass, Cool, 4°C, HCl to pH <2, 28 days	9070	1 liter glass with Cool, 4°C, HCl to pH <2, 28 days
	Solid	---	---	Not Applicable	9071A	8 oz. glass with Teflon®-lined lid, Holding Time not specified
	Waste	---	---	Not Applicable	9071A	8 oz. glass with Teflon®-lined lid, Holding Time not specified
	Water	1 L	1664 ⁽⁷⁾	1 liter glass, Cool, 0-4°C HCl or H ₂ SO ₄ to pH <2 28 days	---	---
	Solid	30 g	1664 ⁽⁷⁾	8 or 16 oz. wide mouth glass jar, Cool, 0-4°C, 28 days	---	---
	Waste	---	---	Not Applicable	---	---

TABLE 23-2

Organic Sample Containers, Preservatives, and Holding Times – Con't

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method ⁽⁶⁾	Requirements
Semivolatile s	Water	1L	625	1 liter amber glass with Teflon®-lined lid, Cool, 4°C, Extraction, 7 days Analysis, 40 days	8270C	1 liter amber glass with Teflon®-lined lid, If residual chlorine present, add 3 mL sodium thiosulfate per gallon, Cool, 4°C, Extraction, 7 days Analysis, within 40 days of extraction
	Solid	30 g	---	Not Applicable	8270C	8 or 16 oz glass wide mouth with Teflon-lined lid, Cool, 4°C, Extraction, 14 days Analysis, within 40 days of extraction
	Waste	30 g	---	Not Applicable	8270C	8 or 16 oz glass wide mouth with Teflon®-lined lid, Cool, 4°C, Extraction, 14 days Analysis, within 40 days of extraction
Volatile Organics	Water	40 mL	624	40 mL glass, VOA vial (in triplicate) with Teflon®-lined septa without headspace, Cool, 4°C, Add sodium thiosulfate if residual chlorine, 7 days with pH > 2, 14 days with pH ≤ 2 ⁽⁸⁾	8260B	40 mL glass, VOA vial (in triplicate) with Teflon®-lined septa without headspace, Cool, 4°C, Add sodium thiosulfate if residual chlorine, 1:1 HCl to pH ≤ 2, 14 days with pH ≤ 2 ⁽⁹⁾

TABLE 23-2

Organic Sample Containers, Preservatives, and Holding Times – Con't

Analytical Parameters	Matrix	Minimum Sample Size ⁽¹⁾	NPDES ^{(2), (3)}		RCRA (SW846) ^{(3), (4)}	
			Method	Requirements	Method ⁽⁶⁾	Requirements
Volatile Organics (continued)	Solid ⁽⁵⁾	5 g or 25 g	--	Not Applicable	8260B	4 or 8 oz glass with Teflon®-lined lid, Cool 4 °C, 14 days. Field preserved with sodium bisulfate solution for low level analysis, or with methanol for medium level analysis. Soil sample can also be taken by using the EnCore™ sampler and preserved in the lab within 48 hours of sampling. Maximum holding time for Encore Sampler is 48 hours (before the sample is added to methanol or sodium bisulfate). Cool, 4°C. (See Note 12 Page 136 for holding time.)
	Waste	5 g or 25 g	--	Not Applicable	8260B	4 or 8 oz glass with Teflon®-lined lid, Cool 4 °C, 14 days. Field preserved with sodium bisulfate solution for low level analysis, or with methanol for medium level analysis. Soil sample can also be taken by using the EnCore™ sampler and preserved in the lab within 48 hours of sampling. Maximum holding time for Encore Sampler is 48 hours (before the sample is added to methanol or sodium bisulfate). Cool, 4°C. (See Note 12 Page 136 for holding time.)

TABLE 23-2
Organic Sample Containers, Preservatives, and Holding Times Footnotes

Footnotes

- (1) Minimum sample size indicates sample amount needed for a single analysis. Matrix spikes or duplicates will require an additional sample amount of at least this amount for each additional QC sample aliquot required.
- (2) National Pollutant Discharge Elimination System - 40 CFR Part 136, Appendix A.
- (3) Holding times are calculated from the date of collection.
- (4) Resource Conservation and Recovery Act, Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, Third Edition, September 1986. Contains Final Update I (July 1992), Final Update IIA (August 1993), Final Update II (September 1994), Final Update IIB (January 1995), and Final Update III (December 1996).
- (5) Solid matrix type includes soil, sediment, sludge or other solids not classified as waste.
- (6) Only one determination method is listed when separate methods are required for preparation and analysis.
- (7) **Method 1664 was promulgated by the EPA with an effective date of June 14, 1999.**
- (8) **For acrolein and acrylonitrile the pH should be adjusted to 4-5. This pH adjustment is not required if acrolein is not measured. Samples requiring analysis of acrolein that received no pH adjustment must be analyzed within three days of sampling.**
- (9) **For acrolein and acrylonitrile the pH should be adjusted to 4-5.**
- (10) Method not listed in 40 CFR Part 136.
- (11) Should only be used in the presence of residual chlorine.
- (12) Depending on regulatory programs, EnCore™ samplers may be preserved for up to 14 days from sampling by freezing at -5 to -12°C until analysis. Alternatively the EnCore™ sample may be transferred to a 40-ml VOA vial and preserved by freezing at -5 to -12°C until analysis. Some regulatory agencies may require 4 or 8 oz glass with Teflon®-lined lid, Cool 4°C, 14 days. This technique is not recommended, but will be supported where required. (Preservation and holding times are subject to client specifications.)

TABLE 23-3
Sample Containers, Preservatives, and Holding Times for TCLP⁽¹⁾ and SPLP⁽²⁾

Analytical Parameters	Matrix	Minimum Sample Size ⁽³⁾	TCLP Method 1311 and SPLP Method 1312 Requirements	
			From Field Collection to TCLP/SPLP Extraction	From TCLP/SPLP Extraction to Analysis
Mercury	Liquid Solid Waste	1L	1L glass, Cool, 4°C, 28 days	Glass or polyethylene 28 days
Metals (except mercury)	Liquid Solid Waste	1L	1L glass, Cool, 4°C, 180 days	Glass or polyethylene 180 days
Semivolatiles	Liquid Solid Waste	1L	1L glass, Cool 4°C, 14 days	1L glass Extraction of leachate within 7 days of TCLP extraction, Analyze extract within 40 days
Volatiles	Liquid Solid Waste	6 oz	4 oz glass, Cool 4°C, 14 days	40 mL glass, 14 days

Footnotes

⁽¹⁾ TCLP = Toxicity Characteristic Leaching Procedure

⁽²⁾ SPLP = Synthetic Precipitation Leaching Procedure

⁽³⁾ Smaller sample size is adequate for solid samples or individual fractions. A combined volume of 32 oz. is recommended for semivolatiles and metals. A separate 4 oz. container should always be used for the volatile fraction. Volatile fractions should be stored with minimal headspace.

SECTION 24

HANDLING OF SAMPLES (NELAC 5.5.8)

Sample management procedures at TestAmerica Denver 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.

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. The COC is usually kept in the sealed sample cooler. The receipt from the courier is stored in log-in by date; it lists all receipts each date.

24.1.2 Legal / Evidentiary Chain-of-Custody

All samples are tracked through the sample utility software program "STU" to ensure internal chain of custody and cradle to grave tracking of each sample container. 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 an internal COC for analysts to fill out and sample disposal record from STU (Figures 24-3 and 24-4) will be included in the data package.

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. Refer to SOP DV-QA-0003, *Sample Management and Chain of Custody*.

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 Condition Upon Receipt Anomaly Form (CUR Figure 24-6) 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 (see Figure 24-5):

- 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.
- 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 (see Section 23).
- Damage or signs of contamination to sample container. Volatile vials are also inspected for headspace

24.2.1.2 Using the infrared temperature gun, check and record the temperature of the samples (use temperature blanks if present) to verify appropriate thermal preservation. Record the temperature on both the chain of custody (Figure 24-1) and the sample receiving checklist (Figure 24-5).

- Samples shall be deemed acceptable if arrival temperature is just above freezing and less than or equal to 6.0° C, or $\geq -20^{\circ}$ C if shipped frozen (encores). 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 CUR (Figure 24-6).
- 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 Verify sample preservation as specified in the test method. Check for correct pH as specified in the test method. The results are documented on the CUR form (Figure 24-5). In the case of volatiles it is recorded after analysis on the instrument run log. Chlorine is checked on samples requiring extractable organics, BOD, TOX, cyanide, fluoride, ammonia, TKN, CBOD and Nitrate; presence or absence is recorded. The need for a residual chlorine check is noted on the sample receiving checklist by the project manager during the cooler greeting process.

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 refrigerators or 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 Only department of transportation (DOT) trained staff may receive samples, so it is imperative that samples are dropped during normal working hours, or special arrangements are made with the project manager. If an attempt is made to drop

samples after hours without arrangements to have DOT trained staff available, the laboratory staff will be unable to accept them.

24.2.1.8 Any deviations from the checks described in Section 24.2.1 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 to proceed with sample analysis that does not meet sample acceptance criteria.

Note: North Carolina requires that they be notified when samples are processed that do not meet sample acceptance criteria.

24.2.2 Sample Log-in

All samples that are received by the laboratory are logged into the LIMS and the Sample Transfer Utility program (STU) 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. Within each job, each sampling point (or 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 an 6-digit workorder number 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)

24.3 SAMPLE ACCEPTANCE POLICY

The laboratory has a written sample acceptance policy (Figure 24-5) that clearly outlines the circumstances under which samples shall be accepted or rejected. These include:

- Cooler seals intact;
- a COC filled out completely;
- samples must be properly labeled;
- proper sample containers with adequate volume for the analysis and necessary QC;
- samples must be preserved according to the requirements of the requested analytical method;
- sample holding times must be adhered to;
- all samples submitted for water/solid Volatile Organic analyses must have a Trip Blank submitted at the same time;
- the project manager will be notified if any sample is received in damaged condition.

Data from samples which do not meet these criteria are flagged and the nature of the variation from policy is defined. A copy of the sample acceptance policy is provided to each client prior to shipment of samples.

24.4 SAMPLE STORAGE

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 refrigerators suitable for the sample matrix, except metals sample containers which may be stored unrefrigerated. In addition, samples to be analyzed for volatile organic parameters are stored in separate refrigerators designated for volatile organic parameters only. Samples are never to be stored with reagents, standards or materials that may create contamination.

To ensure the integrity of the samples during storage, refrigerator blanks are maintained in the volatile sample refrigerators and analyzed every two weeks.

Analysts and technicians retrieve the sample container allocated to their analysis from the designated refrigerator, document the transfer of containers in STU and place them on carts, analyze the sample, and return the remaining sample to the refrigerator from which it originally came, documenting the return in STU. Empty containers are stored in the sample archive area until disposal, this transfer is documented in STU. All samples are kept in the refrigerators until the project is invoiced. At this time, the samples will be retained for an additional thirty days, either in the refrigerators, or in the sample archive area. Special arrangements may be made to store samples for longer periods of time. This extended holding period allows additional metal analyses to be performed on the archived sample and assists clients in dealing with legal matters or regulatory issues. Upon disposal, the drum number used for disposal is logged into STU.

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 refrigerator and laboratory areas unless accompanied by an employee of TestAmerica.

24.5 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 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 analyst will notify login staff so the hazardous sample is properly labeled as such. The sample itself is clearly marked with a label reading "HAZARDOUS", "PCBs" or "FOREIGN SOIL". All hazardous samples are either returned to the client or disposed of appropriately through a hazardous waste disposal firm. All foreign soil samples are sent out for incineration by a USDA-approved waste disposal facility, refer to SOP DV-QA-0019, *Quarantine Soils Procedure* for more detail.

24.6 SAMPLE SHIPPING

In the event that the laboratory needs to ship samples, the samples are placed in a cooler with enough ice to ensure the samples remain just above freezing and at or below 6.0°C during transit. The samples are carefully surrounded by packing material to avoid breakage (yet maintain appropriate temperature). A trip blank is enclosed for those samples requiring water/solid volatile organic analyses. The chain-of-custody form is signed by the sample control technician and attached to the shipping paperwork. Samples are generally shipped overnight express or hand-delivered by a TestAmerica courier to maintain sample integrity. All personnel involved with shipping and receiving samples must be trained to maintain the proper chain-of-custody documentation and to keep the samples intact and on ice. The Environmental, Health and Safety Manual contains additional shipping requirements.

24.7 SAMPLE DISPOSAL

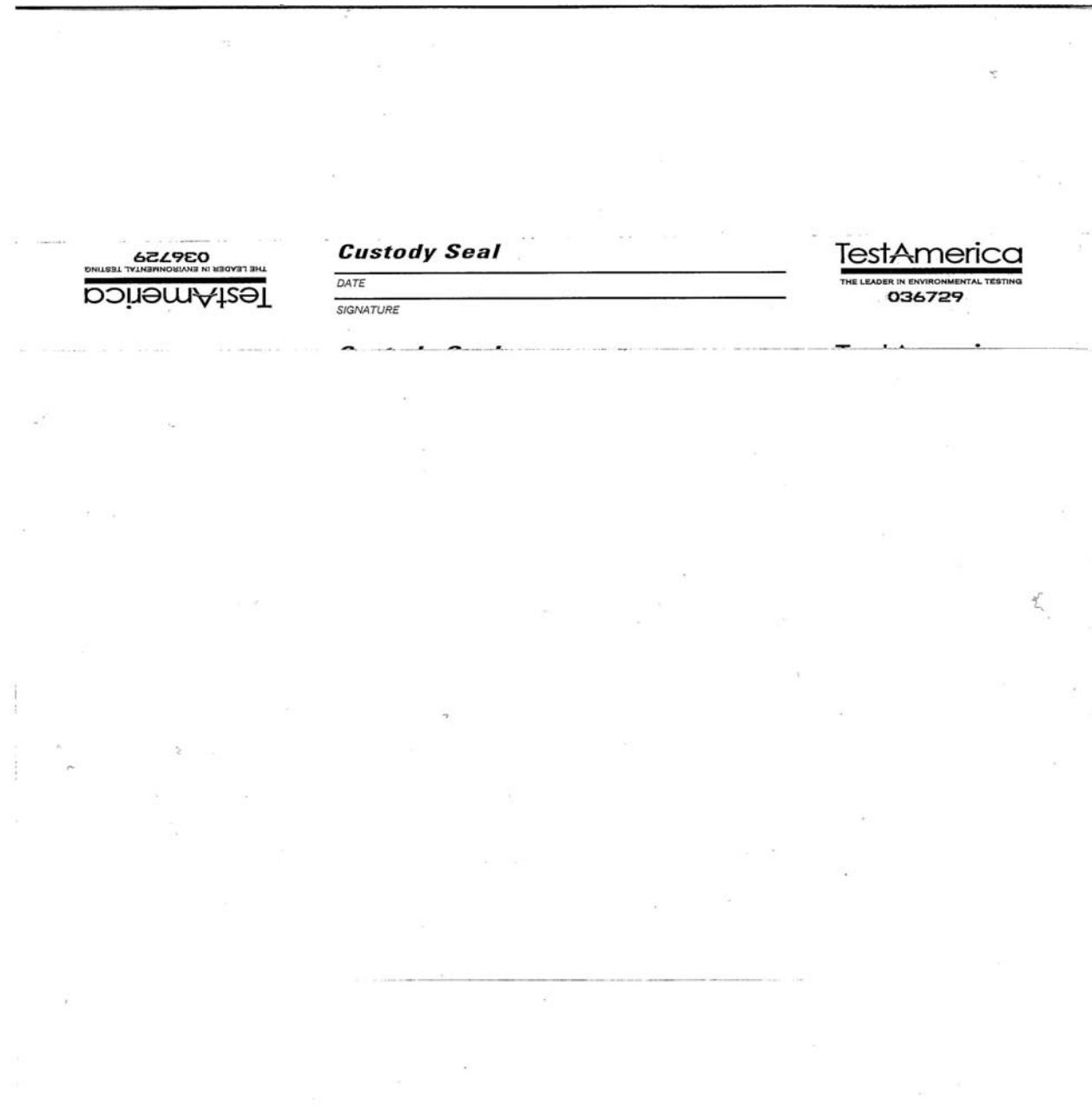
Samples should be retained for a minimum of 30 days after the project report is sent, however, provisions may be made for earlier disposal of samples once the holding time is exceeded. Some samples are required to be held for longer periods based on regulatory or client requirements (e.g., 60 days after project report is sent). The laboratory must follow the longer sample retention requirements where required by regulation or client agreement. 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: *DV-HS-0005, Excess Sample Material Management*). 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 weeks 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.

All documentation and correspondence concerning the disposal of samples is kept on file. The STU software allows tracking for each sample container from the time of sample receipt through the disposal process, including such detail as the identifying number of the waste drum used for disposal. 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 Hazardous Waste Manifest will be prepared to document the

disposal of each drum, see Figure 24-7 for labeling of drums for disposal. Additional detail is in SOP DV-HS-0004, *Hazardous Waste Manifesting*.

Figure 24-2.

Example: Custody Seal



Example: Internal Chain of Custody

Internal Chain-of-Custody *TestAmerica Denver*[illegible]

Satellite Area Sample Transfers								
Satellite Area	Sample Numbers	Transfer Date	Storage Location	Received by	2 nd Transfer Date	2 nd Storage Location	Archive Date	Archived By
Aquatic Toxicology								
Metals (aqueous, non-AFCEE)								
GC Volatiles	Water							
	Solid							
MS Volatiles	Water							
	Solid							

C=Consumed, B=Broken, T=Transfer, LA=Liter Amber, LP=Liter Poly, MDP=Multiple Day Preparation

Figure 24-4.
Example: Disposal Record

TestAmerica

THE LEADER IN ENVIRONMENTAL TESTING

Sample Transfer Audit Report

Test America - Denver
4355 Yarrow Street
Arvada, CO 80002

LotID	ClientSampleID	ContainerID	EventID	ClientName	ClientCd	Quote	TransferType	TransferTime	UserName	StorageLoc	DrumNewLoc	ContType
D7J230212-001	TF2-MMV-01	J9L8B-001	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-001	TF2-MMV-01	J9L8B-001	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-001	TF2-MMV-01	J9L8B-002	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-001	TF2-MMV-01	J9L8B-002	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-001	TF2-MMV-01	J9L8B-003	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-001	TF2-MMV-01	J9L8B-003	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-002	TF2-MMV-02	J9L8B-001	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-002	TF2-MMV-02	J9L8B-001	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-002	TF2-MMV-02	J9L8B-002	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-002	TF2-MMV-02	J9L8B-002	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-002	TF2-MMV-02	J9L8B-003	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-002	TF2-MMV-02	J9L8B-003	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-003	TF2-MMV-03	J9L8B-001	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-003	TF2-MMV-03	J9L8B-001	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-003	TF2-MMV-03	J9L8B-002	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-003	TF2-MMV-03	J9L8B-002	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-003	TF2-MMV-03	J9L8B-003	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-003	TF2-MMV-03	J9L8B-003	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-004	TF2-MMV-06	J9L8B-001	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-004	TF2-MMV-06	J9L8B-001	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-004	TF2-MMV-06	J9L8B-002	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-004	TF2-MMV-06	J9L8B-002	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-004	TF2-MMV-06	J9L8B-003	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-004	TF2-MMV-06	J9L8B-003	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-005	TF2-MMV-10	J9L8B-001	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-005	TF2-MMV-10	J9L8B-001	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-005	TF2-MMV-10	J9L8B-002	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-005	TF2-MMV-10	J9L8B-002	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-005	TF2-MMV-10	J9L8B-003	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-005	TF2-MMV-10	J9L8B-003	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-006	TF2-MMV-11M	J9L8B-001	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-006	TF2-MMV-11M	J9L8B-001	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-006	TF2-MMV-11M	J9L8B-002	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-006	TF2-MMV-11M	J9L8B-002	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-006	TF2-MMV-11M	J9L8B-003	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	
D7J230212-006	TF2-MMV-11M	J9L8B-003	57366		40687	55443	Relocate	12/05/2007 14:11	Chavez, Lawrence NF		AC9	
D7J230212-006	TF2-MMV-11M	J9L8B-004	51414		40687	55443	Relocate	10/23/2007 13:07	Bindel, Aaron	NF	NA	

2/12/2007 18:50

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12/12/2007 18:50

Figure 24-5. Sample Receiving Checklist Page 1

Lot #: _____ Date/Time Received: _____

Company Name & Sampling Site: _____

PM to Complete This Section: *Yes* *No*
Residual chlorine check required: ☐ ☐ Quarantined : ☐ ☐

Quote #:

Special Instructions:

Time Zone:
• EDT/EST • CDT/CST • MDT/MST • PDT/PST • OTHER

Unpacking Checks:

Cooler #(s): _____			
Temperatures (°C): _____			
<i>N/A</i>	<i>Yes</i>	<i>No</i>	<i>Initials</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. Cooler seals intact? (N/A if hand delivered) If no, document on CUR. _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. Chain of custody present? If no, document on CUR.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. Bottles broken and/or are leaking? If yes, document on CUR.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Multiphasic samples obvious? If yes, document on CUR.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5. Proper container & preservatives used? (ref. Attachment D of SOP# DEN-QA-0003) If no, document on CUR.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. pH of all samples checked and meet requirements? If no, document on CUR.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. Sufficient volume provided for all analysis requested? (ref. Attachment D of SOP# DEN-QA-0003) If no, document on CUR, and contact PM before proceeding.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8. Did chain of custody agree with labels ID and samples received? If no, document on CUR.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Were VOA samples without headspace? If no, document on CUR.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10. Were VOA vials preserved? Preservative <input type="checkbox"/> HCl <input type="checkbox"/> 4±2°C <input type="checkbox"/> Sodium Thiosulfate <input type="checkbox"/> Ascorbic Acid
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11. Did samples require preservation with sodium thiosulfate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12. If yes to #11, did the samples contain residual chlorine? If yes, document on CUR.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13. Sediment present in dissolved/filtered bottles? If yes, document on CUR.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14. Is sufficient volume provided for client requested MS, MSD or matrix duplicates? If no, document on CUR, and contact PM before proceeding.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15. Receipt date(s) > 48 hours past the collection date(s)? If yes, notify PA/PM.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16. Are analyses with short holding times requested?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17. Was a quick Turn Around (TAT) requested?

Figure 24-5. Sample Receiving Checklist Page 2

Lot # _____

Login Checks:

Initials

N/A Yes No

- ☐ ☐ 18. Sufficient volume provided for all analysis requested? (ref. Attachment D of SOP# DEN-QA-0003) If no, document on CUR, and contact PM before proceeding.
- ☐ ☐ ☐ 19. Is sufficient volume provided for client requested MS, MSD or matrix duplicates? If no, document on CUR, and contact PM before proceeding.
- ☐ ☐ 20. Did the chain of custody includes "received by" and "relinquished" by signatures, dates, and times?
- ☐ ☐ ☐ 21. Were special log in instructions read and followed?
- ☐ ☐ ☐ 22. Were AFCEE metals logged for refrigerated storage?
- ☐ ☐ 23. Were tests logged checked against the COC? Which samples were confirmed? _____
- ☐ ☐ ☐ 24. Was a Rush form completed for quick TAT?
- ☐ ☐ ☐ 25. Was a Short Hold form completed for any short holds?
- ☐ ☐ 26. Were special archiving instructions indicated in the General Comments? If so, what were they?
- _____

Labeling and Storage Checks:

Initials

- ☐ ☐ ☐ 28. Was the subcontract COC signed and sent with samples to bottle prep?
- ☐ ☐ 29. Were sample labels double-checked by a second person?
- ☐ ☐ ☐ 30. Were sample bottles and COC double checked for dissolved/filtered metals by a second person?
- ☐ ☐ 31. Did the sample ID, Date, and Time from label match what was logged?
- ☐ ☐ ☐ 32. Were stickers for special archiving instructions affixed to each box and to the ICOC? See #27
- ☐ ☐ ☐ 33. Were AFCEE metals stored refrigerated?

Document any problems or discrepancies and the actions taken to resolve them on a Condition Upon Receipt Anomaly Report (CUR).

FIGURE 24-6 CONDITION UPON RECEIPT ANOMALY REPORT (CUR)

TestAmerica Denver Condition Upon Receipt Anomaly Report (CUR)

Lot No : _____ Date/Time: _____
Client : _____ Initiated by: _____
Affected Samples _____ COC# _____

Client ID	Lab ID	Analyses Requested

CONDITION/ANOMALY/VARIANCE (CHECK ALL THAT APPLY):

<input type="checkbox"/> COOLERS <input type="checkbox"/> Received, No Chain of Custody (COC) <input type="checkbox"/> Not Received but COC(s) Available <input type="checkbox"/> Leaking <input type="checkbox"/> Other: _____	<input type="checkbox"/> CUSTODY SEALS (COOLER(S)/CONTAINER(S)) <input type="checkbox"/> None <input type="checkbox"/> Not Intact <input type="checkbox"/> Other: _____
<input type="checkbox"/> TEMPERATURE (greater than 6° C) <input type="checkbox"/> Cooler Temp _____ <input type="checkbox"/> Temperature Blank _____	<input type="checkbox"/> CHAIN OF CUSTODY (COCs) <input type="checkbox"/> Not relinquished by Client; No date/time Relinq. <input type="checkbox"/> Incomplete Information <input type="checkbox"/> Other: _____
<input type="checkbox"/> CONTAINERS <input type="checkbox"/> Leaking <input type="checkbox"/> Broken <input type="checkbox"/> Extra <input type="checkbox"/> Without Labels <input type="checkbox"/> VOA Vials with Headspace _____ mm <input type="checkbox"/> Other: _____	<input type="checkbox"/> CONTAINER LABELS <input type="checkbox"/> Not the same ID/info as in COC <input type="checkbox"/> Incomplete <input type="checkbox"/> ID COLLECTION <input type="checkbox"/> Time <input type="checkbox"/> Date <input type="checkbox"/> PRESERVATIVE <input type="checkbox"/> Markings/Info smeared or illegible <input type="checkbox"/> Torn <input type="checkbox"/> Other: _____
<input type="checkbox"/> SAMPLES <input type="checkbox"/> Samples <u>NOT RECEIVED</u> but listed on COC ----- <input type="checkbox"/> Samples received but <u>NOT LISTED</u> on COC <input type="checkbox"/> Logged based on Label Information <input type="checkbox"/> Logged based on info from other samples on COC <input type="checkbox"/> Logged according to Work Plan <input type="checkbox"/> Logged on HOLD UNTIL FURTHER NOTICE <input type="checkbox"/> Other: _____	<input type="checkbox"/> will be noted on COC <input type="checkbox"/> Client to send samples with new COC <input type="checkbox"/> Trip Blank received, not on COC, _____ vials received <input type="checkbox"/> Misabeled as to tests, preservatives, etc. <input type="checkbox"/> Holding time expired <input type="checkbox"/> Improper container used <input type="checkbox"/> Not preserved / Improper preservative used <input type="checkbox"/> Improper pH _____ <input type="checkbox"/> Lab to preserve sample <input type="checkbox"/> Insufficient quantities for analysis

Comments: _____

Corrective Action:

- ☐ Client Informed: verbally on: _____ By: _____ : In writing on: _____ By: _____
☐ Sample(s) processed "as is". _____
☐ Sample(s) on hold until: _____ If released, notify: _____

Sample Control Supervisor Review: _____ Date: _____

Project Management Review: _____ Date: _____

FIGURE 24-7 Labeling for Waste Disposal

Shipping Label Requirements for Waste

Waste Code	Waste Stream	Drum Type	Label information	DOT Label
A	Expired Extract Vials	Steel- Open Head	RQ WasteSolids containing Flammable Liquids, n.o.s (Hexane, Acetone, Methanol), 4.1, UN3175, PGII, (D001)	Flammable Solid, Class 4.1
B	Waste Dichlormethane	Steel- Bung Top	Waste Dichloromethane, 6.1, UN1593, PG III, (Methylene Chloride), F002	Toxic, Class 6.1
C	Flammable Solvent	Steel-Bung Top	RQ Waste Flammable Liquids, n.o.s. (Hexane, Acetone), 3, UN1993, PG II, (D001)	Flammable Liquid, Class 3
D	Sodium Sulfate	Steel-Open Head	Non DOT Regulated Material, (Sodium Sulfate)	None
E	Aqueous Alkaline	HDPE-Bung Top	RQ, Waste Corrosive Liquids, basic, Inorganic, n.o.s. (Sodium Hydroxide), 8, UN3266, PG II, (D002)	Corrosive, Class 8
F	Aqueous Acidic	HDPE-Bung Top	RQ Waste Corrosive Liquid, Acidic, Inorganic, n.o.s. (Sulfuric Acid, Hydrochloric Acid), 8, UN3264, PG II (D002)	Corrosive, Class 8
G	Aqueous Acidic	HDPE-Bung Top	Pending Characterization/Process Knowledge	Pending Characterization/process knowledge
H	Aqueous Acidic	HDPE-Bung Top	RQ Waste Corrosive Liquid, Acidic, Inorganic, n.o.s. (Sulfuric Acid, Hydrochloric Acid), 8, UN3264, PG II (D002)	Corrosive, Class 8
I	COD Vials	HDPE- Open Head	RQ Waste Sulfuric Acid Solution (Sulfuric acid, Chromium, Mercury, Silver) 8, UN1830, PG II, (D002,D007,D009,D011)	Corrosive, Class 8
J	Aqueous Acidic	HDPE-Bung Top	Pending Characterization/Process Knowledge	Pending Characterization/process knowledge
M	Miscellaneous Waste	Variable	Pending Characterization/process knowledge	Pending Characterization/process knowledge
O	Used Pump Oil	HDPE-Bung Top	Non-RCRA Regulated Material, (Pump Oil)	None
P	Solid Laboratory Waste	Steel- Open Head	Environmentally Hazardous Substances, Solid, n.o.s. 9, UN3077, PG III, (Soil, Anhydrous, Rubber Gloves)	Miscellaneous Dangerous Goods, Class 9

Shipping Label Requirements for Waste

Waste Code	Waste Stream	Drum Type	Label information	DOT Label
S	Excess Sample – Solid	Steel- Open Head	Non DOT Regulated Material, (Soil Samples)	Pending Characterization/process knowledge
W	Excess Sample – Aqueous	HDPE-Bung Top	Pending Characterization/process knowledge	Pending Characterization/process knowledge
RAD followed by the Waste Code Listed Above	Radioactive (RAD) –Could Apply to Any of the Waste Streams Listed Above	Per 49 CFR 171 –173 and TSDF	Per 49 CFR 171 –173 and TSDF	Per 49 CFR 171-173 and TSDF

Note: If characterization determines a waste is hazardous, labeling shall meet the requirements of 49 CFR 171-180. This table does not supersede 49 CFR 171-180.

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), duplicates (DUP), surrogates, Internal Standards (IS)). 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.

25.2 CONTROLS

Sample preparation or pre-treatment is commonly required before analysis. Typical preparation steps include homogenization, grinding, solvent extraction, sonication, acid digestion, distillation, reflux, 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 are used to assess preparation and analysis for possible contamination during the preparation and processing steps.

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

25.3.3 The method blank goes through all of the steps of the process (including as necessary: filtration, clean-ups, etc.).

25.3.4 The specific frequency of use for method blanks during the analytical sequence is defined in the specific standard operating procedure for each analysis. Generally it is 1 for each batch of samples; not to exceed 20 environmental samples.

25.3.5 Evaluation criteria and corrective action for method blanks is defined in the specific standard operating procedure for each analysis. Generally, corrective action is taken if the concentration of a target analyte in the blank is at or above the reporting limit.

- 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.

25.3.6 **Calibration Blanks** are prepared and analyzed along with calibration standards where applicable. They are prepared using the same reagents that are used to prepare the standards. In some analyses the calibration blank may be included in the calibration curve.

25.3.7 **Instrument Blanks** are blank reagents or reagent water that may be processed during an analytical sequence in order to assess contamination in the analytical system. In general, instrument blanks are used to differentiate between contamination caused by the analytical system and that caused by the sample handling or sample prep process. Instrument blanks may also be inserted throughout the analytical sequence to minimize the effect of carryover from samples with high analyte content.

25.3.8 **Trip Blanks** are required to be submitted by the client with each shipment of samples requiring aqueous and solid volatiles analyses. Additionally, trip blanks may be prepared and analyzed for volatile analysis of air samples, when required by the client. A trip blank is prepared by the laboratory by filling a clean container with pure deionized water that has been purged to remove any volatile compounds. Appropriate preservatives are also added to the container. The trip blank is sent with the bottle order and is intended to reflect the environment that the containers are subjected to throughout shipping and handling and help identify possible sources if contamination is found. The field sampler returns the trip blank in the cooler with the field samples. Trip Blanks are also sometimes referred to as Travel Blanks.

25.3.9 **Field Blanks** are sometimes used for specific projects by the field samplers. A field blank prepared in the field by filling a clean container with pure reagent water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA OSWER)

25.3.10 **Equipment Blanks** are also sometimes created in the field for specific projects. An equipment blank is a sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures. (NELAC)

25.3.11 **Holding Blanks**, also referred to as refrigerator or freezer blanks, are used to monitor the sample storage units for volatile organic compounds during the storage of VOA samples in the laboratory (refer to section 24.4 and SOP DV-QA-0013, *Refrigerator Blank and Trip Blank Monitoring*).

25.3.12 **Field blanks**, equipment blank and trip blanks, when received, are analyzed in the same manner as other field samples. When known, blanks should not be selected for matrix QC, as it does not provide information on the behavior of the target compounds in the field samples. Usually, the client sample ID will provide information to identify the field blanks with labels such as "FB", "EB", or "TB".

25.3.13 Negative Controls for Microbiological Methods

Microbiological Methods utilize a variety of negative controls throughout the process to ensure that false positive results are not obtained. These controls are critical to the validity of the microbiological analyses. Some of these negative controls are: Sterility checks of media are analyzed for each lot of pre-prepared media, ready-to-use media and for each batch of medium prepared by the laboratory.

- 25.3.13.1** Filtration blanks are run at the beginning and end for each sterilized filtration unit used in a filtration series.
- 25.3.13.2** Sterility checks on sample containers are performed on at least one container per lot of purchased, pre-sterilized containers. Container sterility checks are performed using non-selective growth media.
- 25.3.13.3** Sterility checks are performed on each batch of pre-prepared dilution water. All checks are performed using non-selective growth media.
- 25.3.13.4** Sterility checks are also performed on at least one filter from each new lot of membrane filters using non-selective growth media.
- 25.3.13.5** Negative culture controls demonstrate that a media does not support the growth of non-target organisms and ensures that there is not an atypical positive reaction from the target organisms. Prior to the first use of the media, each lot of pre-prepared selective media or batch of laboratory prepared selective media is analyzed with at least one known negative culture control as appropriate to the method.

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 (MD, 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 analytical SOP.

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 effects 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. 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), a calibration verification standard may be reported as the LCS.
- 25.4.1.3** Certified pre-made reference material purchased from a NIST/A2LA accredited vendor may also be used for the LCS when the material represents the sample matrix or the analyte is not easily spiked (e.g. solid matrix LCS for metals, TDS, etc.).
- 25.4.1.4** 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.).
- 25.4.1.5** The specific frequency of use for LCS during the analytical sequence is defined in the specific standard operating procedure for each analysis. It is generally 1 for each batch of samples; not to exceed 20 environmental samples.
- 25.4.1.6** If the mandated or requested test method, or project requirements, do not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample (and Matrix Spike) where applicable (e.g. no spike of pH). However, in cases where the components interfere with accurate assessment (such as simultaneously spiking chlordane, toxaphene and PCBs in Method 608), the test method has an extremely long list of components or components are incompatible, at a minimum, a representative number of the listed components (see below) shall be used to control the test method. The selected components of each spiking mix shall represent all chemistries, elution patterns and masses, permit specified analytes and other client requested components. However, the laboratory shall ensure that all reported components are used in the spike mixture within a two-year time period.
- 25.4.1.6.1** For methods that have 1-10 target analytes, spike all components.
- 25.4.1.6.2** For methods that include 11-20 target analytes, spike at least 10 or 80%, whichever is greater.
- 25.4.1.6.3** For methods with more than 20 target analytes, spike at least 16 components.
- 25.4.1.6.4** Exception: Due to analyte incompatibility in pesticides, Toxaphene and Chlordane are only spiked at client request based on specific project needs.

25.4.1.6.5 Exception: Due to analyte incompatibility between the various PCB aroclors, aroclors 1016 and 1260 are used for spiking as they cover the range of all of the aroclors. Specific aroclors may be used by request on a project specific basis.

25.4.1.7 **Accuracy Calculation:** Percent Recovery (%R) Calculation (applies to LCS, CCV, Surrogates, and Matrix Spikes.

$$\%R = \frac{AV}{TV} \times 100$$

Where: AV = Analyzed Value
TV = True Value

25.4.2 **Positive Controls for Microbiological Methods**

Prior to the first use of the media, each lot of pre-prepared media is tested with at least one pure culture of known positive reaction.

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 If the mandated or requested test method does not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample and Matrix Spike. However, in cases where the components interfere with accurate assessment (such as simultaneously spiking chlordane, toxaphene and PCBs in Method 608), the test method has an extremely long list of components or components are incompatible, a representative number of the listed components (see LCS analytes 25.4.1.6 above) may be used to control the test method. The selected components of each spiking mix shall represent all chemistries, elution patterns and masses, permit-specified analytes and other client requested components. However, the laboratory shall ensure that all reported components are used in the spike mixture within a two-year time period.

25.5.1.4 The percent recovery calculation for matrix spikes is essentially the same as the calculation shown in 25.4.1.7 except that:

$$AV = Sp - Sa$$

Where: Sp = Spike result

Sa = Sample result

25.5.2 Surrogate Spikes

25.5.2.1 Surrogate Spikes are similar to matrix spikes except the analytes are compounds with properties that mimic the analyte of interest and are unlikely to be found in environment samples.

25.5.2.2 Surrogate compounds are added to all samples, standards, and blanks, for all organic chromatography methods except when the matrix precludes its use or when a surrogate is not available. The recovery of the surrogates is compared to the acceptance limits for the specific method (also refer to Section 25.5). Poor surrogate recovery may indicate a problem with sample composition and shall be reported, with data qualifiers, to the client whose sample produced poor recovery.

25.5.3 Duplicates

25.5.3.1 For a measure of analytical precision, with each matrix-specific batch of samples processed, a matrix duplicate (MD or 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. LCSD's 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. The precision measurement is reported as "Relative Percent Difference" (RPD). Poor precision between duplicates (except LCS/LCSD) may indicate non-homogeneous matrix or sampling.

25.5.3.2 Precision Calculation (Relative Percent Difference - RPD)

$$RPD = \frac{|S - D|}{\frac{(S + D)}{2}} \times 100$$

Where: S=Sample Concentration
D=Duplicate Concentration

25.5.4 Internal Standards

25.5.4.1 In most organic analyses, internal standards are spiked into all environmental and quality control samples (including the initial calibration standards). An internal standard is also used with some metals analyses. It is typically added to sample extracts after the extraction (post-prep). The acceptance criteria in most methods are 50% to 200% of the responses in the mid-point of the corresponding calibration curve. Consult the method-specific SOPs for details on the internal standard compounds, calculations and acceptance criteria.

25.5.4.2 When the internal standard recoveries fall outside these limits, if there are not obvious chromatographic interferences, reanalyze the sample to confirm a possible matrix effect. If the recoveries confirm or there was obvious interference, results are reported from the original analysis and a qualifier is added. If the reanalysis meets internal standard recovery criteria, the second run is reported (or both are reported if requested by the client).

25.6 ACCEPTANCE CRITERIA (CONTROL LIMITS)

25.6.1 Each individual analyte in the LCS, MS, or Surrogate Spike are evaluated against the control limits as published in the test method. Where there are no established acceptance criteria, the laboratory calculates control limits with the use of control charts or, in some cases, utilizes client project specific or regulatory mandated control limits. When this occurs, the regulatory or project limits will supersede the laboratory's in-house limits.

Note: For methods, analytes and matrices with very limited data (e.g., unusual matrices not analyzed often), interim limits are established using available data or by analogy to similar methods or matrices.

25.6.2 Once control limits have been established, they are verified, reviewed, and updated if necessary on an annual basis unless the method requires more frequent updating (e.g. EPA SW846 8000 series methods). Control limits are established per method (as opposed to per instrument) regardless of the number of instruments utilized.

25.6.2.1 The lab should consider the effects of the spiking concentration control limits, and to avoid censoring of data. The acceptance criteria for recovery and precision are often a function of the spike concentration used. Therefore, caution must be used when pooling data to generate control limits.

25.6.2.2 Not only should the results all be from a similar matrix, but the spiking levels should also be approximately the same (within a factor of 2). Similarly, the matrix spike and surrogate results should all be generated using the same set of extraction, cleanup and analysis techniques. For example, results from solid samples extracted by ultrasonic extraction are not mixed with those extracted by Soxhlet.

25.6.2.3 The laboratory should try and avoid discarding data that do not meet a preconceived notion of acceptable performance. This results in a censored data set, which, when used to develop acceptance criteria, will lead to unrealistically narrow criteria. For a 99% confidence interval, 1 out of every 100 observations likely will still fall outside the limits. For methods with long analyte lists this may mean occasional failures every batch or two. While professional judgment is important in evaluating data to be used to develop acceptance criteria, specific results are not discarded simply because they do not meet one's expectations. However, data points shall be discarded if they were the result of human or mechanical error or sample concentration exceeded spike level by $> 4x$.

25.6.3 Laboratory generated % Recovery acceptance (control) limits are generally established by taking ± 3 Standard Deviations (99% confidence level) from the average recovery of a minimum of 20-30 data points (more points are preferred).

25.6.3.1 Regardless of the calculated limit, the limit should be no tighter than the Calibration Verification (ICV/CCV). (Unless the analytical method specifies a tighter limit).

25.6.3.2 In-house limits cannot be any wider than those mandated in a regulated analytical method.

25.6.3.3 The lowest acceptable recovery limit will be 10% (the analyte must be detectable). Exception: The lowest acceptable recovery limit for Benzidine will be 5% and the analyte must be detectable.

25.6.3.4 The maximum acceptable recovery limit will be 150%.

25.6.3.5 The maximum acceptable RPD limit will be 35% for waters and 40% for soils. The minimum RPD limit is 10%.

25.6.3.6 If either the high or low end of the control limit changes by $\leq 5\%$ from previous, the control chart is visually inspected and, using professional judgment, they may be left unchanged if there is no affect on laboratory ability to meet the existing limits.

25.6.3.7 The lab must be able to generate a current listing of their control limits and track when the updates are performed. In addition, the laboratory must be able to recreate historical control limits. Refer to SOP DV-QA-003P for details.

25.6.4 A LCS that is within the acceptance criteria establishes that the analytical system is in control and is used to validate the process. Samples that are analyzed with an LCS with recoveries outside of the acceptance limits may be determined as out of control and should be reanalyzed if possible. If reanalysis is not possible, then the results for all affected analytes for samples within the same batch must be qualified when reported. The internal corrective action process (see Section 13) is also initiated if an LCS exceeds the acceptance limits. Sample results may be qualified and reported without reanalysis if:

25.6.4.1 The analyte results are below the reporting limit and the LCS is above the upper control limit.

25.6.4.2 If the analytical results are above the relevant regulatory limit and the LCS is below the lower control limit.

25.6.4.3 Or, for NELAC and Department Of Defense (DOD) work, there are an allowable number of Marginal Exceedances (ME):

- <11 analytes – 0 marginal exceedances are allowed.
- 11 – 30 Analytes – 1 marginal exceedance is allowed
- 31-50 Analytes – 2 marginal exceedances are allowed
- 51-70 Analytes – 3 marginal exceedances are allowed

- 71-90 Analytes – 4 marginal exceedances are allowed
- > 90 Analytes – 5 marginal exceedances are allowed

25.6.4.3.1 Marginal exceedances are recovery exceedances between 3 SD and 4 SD from the mean recovery limit (NELAC).

25.6.4.3.2 Marginal exceedances must be random. If the same analyte exceeds the LCS control limit repeatedly, it is an indication of a systematic problem. The source of the error must be located and corrective action taken. The laboratory has a system to monitor marginal exceedances to ensure that they are random.

25.6.4.3.3 Though marginal exceedances may be allowed, the data must still be qualified to indicate it is outside of the normal limits.

25.6.5 If the MS/MSDs do not meet acceptance limits, the MS/MSD and the associated spiked sample is reported with a qualifier for those analytes that do not meet limits. If obvious preparation errors are suspected, or if requested by the client, unacceptable MS/MSDs are reprocessed and reanalyzed to prove matrix interference. A more detailed discussion of acceptance criteria and corrective action can be found in Appendix 4 and in Section 13.

25.6.6 If a surrogate standard falls outside the acceptance limits, if there is not obvious chromatographic matrix interference, reanalyze the sample to confirm a possible matrix effect. If the recoveries confirm or there was obvious chromatographic interference, results are reported from the original analysis and a qualifier is added. If the reanalysis meets surrogate recovery criteria, the second run is reported (or both are reported if requested by the client). Under certain circumstances, where all of the samples are from the same location and share similar chromatography, the reanalysis may be performed on a single sample rather than all of the samples and if the surrogate meets the recovery criteria in the reanalysis, all of the affected samples would require reanalysis.

25.7 METHOD DETECTION LIMITS (MDLs)

MDLs, calculated as described in Section 20.7, are updated or verified annually, or more often if required by the method.

25.8 ADDITIONAL PROCEDURES TO ASSURE QUALITY CONTROL

25.8.1 The laboratory has written procedures to assure the accuracy of the test method including calibration (see Section 21), use of certified reference materials (see Section 22) and use of PT samples (see Section 16).

25.8.2 A discussion regarding MDLs, Limit of Detection (LOD) and Limit of Quantitation (LOQ) can be found in Section 20.

25.8.3 Use of formulae to reduce data is discussed in the method standard operating procedures and in Section 21.

25.8.4 Selection of appropriate reagents and standards is included in Section 9 and 22.

- 25.8.5** A discussion on selectivity of the test is included in Section 5.
- 25.8.6** Constant and consistent test conditions are discussed in Section 19.
- 25.8.7** The laboratories sample acceptance policy is included in Section 24.
- 25.8.8** A listing of the type of test result correlations that are looked at during report review (e.g. Total Chromium should be greater or equal to Hexavalent Chromium) is included in Section 20.13.4.5.

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.

Review of reported data is included in Section 20.

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, 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) with a "sample results" column header.

26.2.2 The report cover page is printed on company letterhead, which includes the laboratory name, address and telephone number.

26.2.3 A unique identification of the report (e.g. lot 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: The total number of pages is indicated at the front of each report.

26.2.4 A copy of the chain of custody (COC).

- Any COCs involved with Subcontracting are included.
- Any additional addenda to the report must be treated in a similar fashion so it is a recognizable part of the report and cannot accidentally get separated from the report (eg. Sampling information).

26.2.5 The name and address of client and a project name/number, if applicable.

26.2.6 Client project manager or other contact

26.2.7 Description and unambiguous identification of the tested sample(s) including the client identification code.

26.2.8 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.

26.2.9 Date reported or date of revision, if applicable.

26.2.10 Method of analysis including method code (EPA, Standard Methods, etc).

26.2.11 Reporting limits.

26.2.12 Method detection limits (if requested)

26.2.13 Definition of Data qualifiers and reporting acronyms (e.g. ND).

26.2.14 Sample results.

26.2.15 QC data consisting of method blank, surrogate, LCS, and MS/MSD recoveries and control limits.

26.2.16 Condition of samples at receipt including temperature. This may be accomplished in a narrative or by attaching sample login sheets (Refer to Sec. 26.2.4 – Item 3 regarding additional addenda).

26.2.17 A statement to the effect that the results relate only to the items tested and the sample as received by the laboratory.

26.2.18 A statement that the report shall not be reproduced except in full, without prior express written approval by the laboratory coordinator.

26.2.19 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.

26.2.20 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. For Example:

“The results included in this report have been reviewed for compliance with the laboratory QA/QC plan and meet all requirements of NELAC. All data have been found to be compliant with laboratory protocol and any exceptions are noted below. “

26.2.21 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.

26.2.22 When Soil samples are analyzed, a specific identification as to whether soils are reported on a “wet weight” or “dry weight” basis.

26.2.23 Appropriate laboratory certification number for the state of origin of the sample, if applicable.

26.2.24 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 “partial report”, and that a complete report will follow once all of the work has been completed.

26.2.25 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

TestAmerica Denver 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 reported to the laboratory MDL, percent recovery for laboratory control samples and matrix spike samples, and the RPD 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. All faxed reports are followed by hardcopy. 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. TestAmerica Denver offers a variety of EDD formats including Environmental Restoration Information Management System (ERPIMS), New Agency Standard (NAS), Format A, Excel, SEDD, NWIS, Dbase, GISKEY, Text Files, and a number of client specific formats.

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. Refer to Appendix 7 for a list of the laboratory's standard footnotes and qualifiers.

26.4.1 Numeric results with values outside of the calibration range, either high or low are qualified as 'estimated'.

26.4.2 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.

26.4.3 Where applicable, a statement on the estimated uncertainty of measurements; information on uncertainty is needed when a client's instructions so require.

26.4.4 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.

Note: Review of data deliverable packages for submittal to regulatory authorities requires responses to non-conforming data concerning potential impact on data quality. This necessitates a limited scope of interpretation, and this work is performed by the QA Department. This is the only form of "interpretation" of data that is routinely performed by 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.

26.5 ENVIRONMENTAL TESTING OBTAINED FROM SUBCONTRACTORS

If TestAmerica Denver 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 1-800-765-0980 (or for e-mails: please notify us immediately by e-mail or by phone (1-800-765-0980) 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). Refer to SOP DV-QA-019P, *Result and Report Revisions*.

When the report is re-issued, a notation of "revised 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 revision. *For Example: Report was revised on 11/3/07 to include toluene in sample NQA1504 per client's request*

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. Based on the above comments, the laboratory will reanalyze samples at a client's request with the following caveats. Client specific arrangements for reanalysis protocols can be established.

- Homogenous samples: If a reanalysis agrees with the original result to within the RPD limits for MS/MSD or Duplicate analyses, or within ± 1 reporting limit for samples $\leq 5x$ the reporting limit, the original analysis will be reported. At the client's request, both results may be reported on the same report but not on two separate reports.
- If the reanalysis does not agree (as defined above) with the original result, then the laboratory will investigate the discrepancy and reanalyze the sample a third time for confirmation if sufficient sample is available.
- Any potential charges related to reanalysis are discussed in the contract terms and conditions or discussed at the time of the request. The client will typically be charged for reanalysis unless it is determined that the lab was in error.
- Due to the potential for increased variability, reanalysis may not be applicable to Non-homogenous, Encore, and Sodium Bisulfate preserved samples. See the Department Manager or Laboratory Director if unsure.

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) or to not raise reporting limits and report sample results as ND. 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 (e.g., COC lists 8315 but client wanted 8310). 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 _____

Work Instruction No. CA-WI-005

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

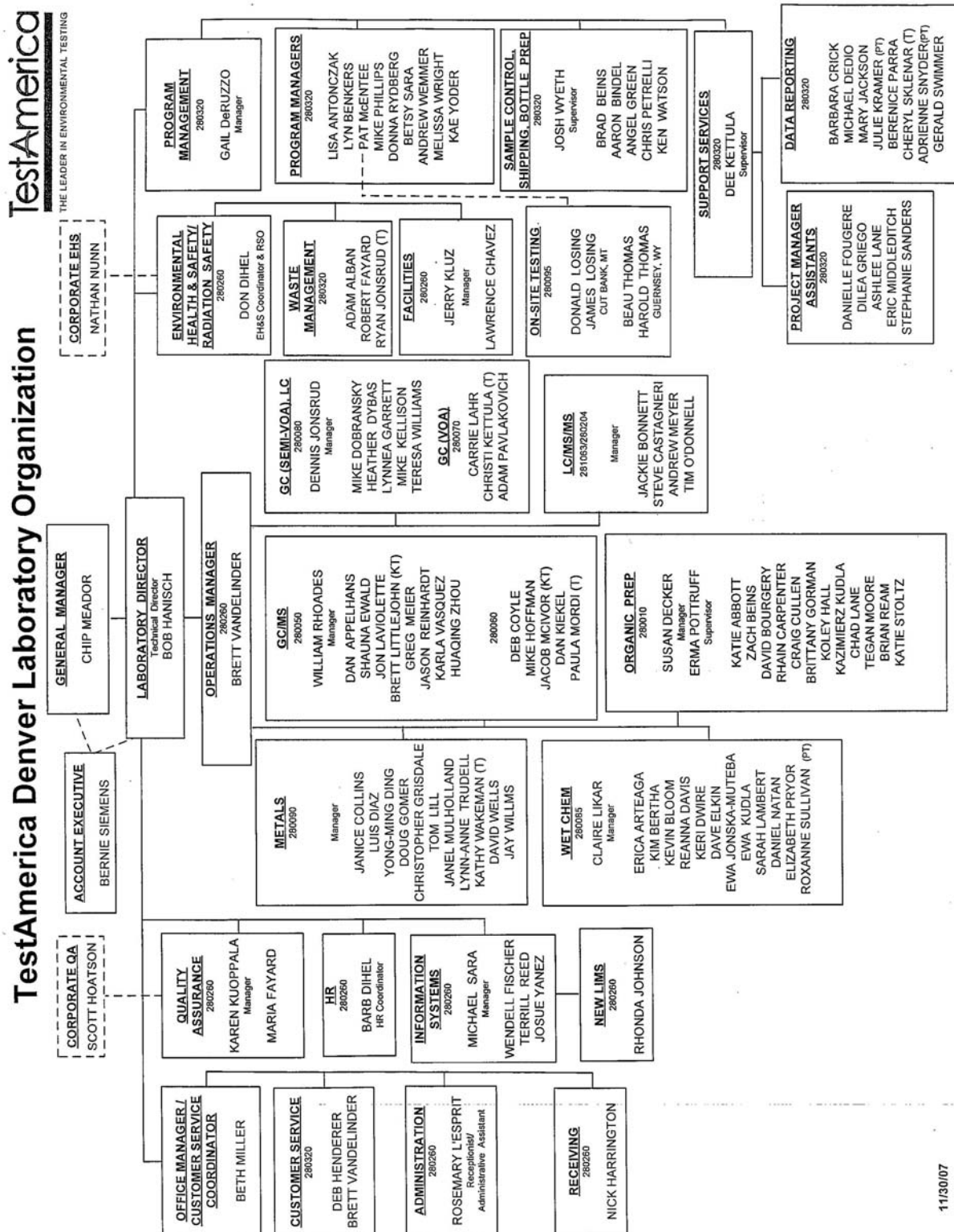
Signature

Date

Work Instruction No. CA-WI-006

Appendix 2.

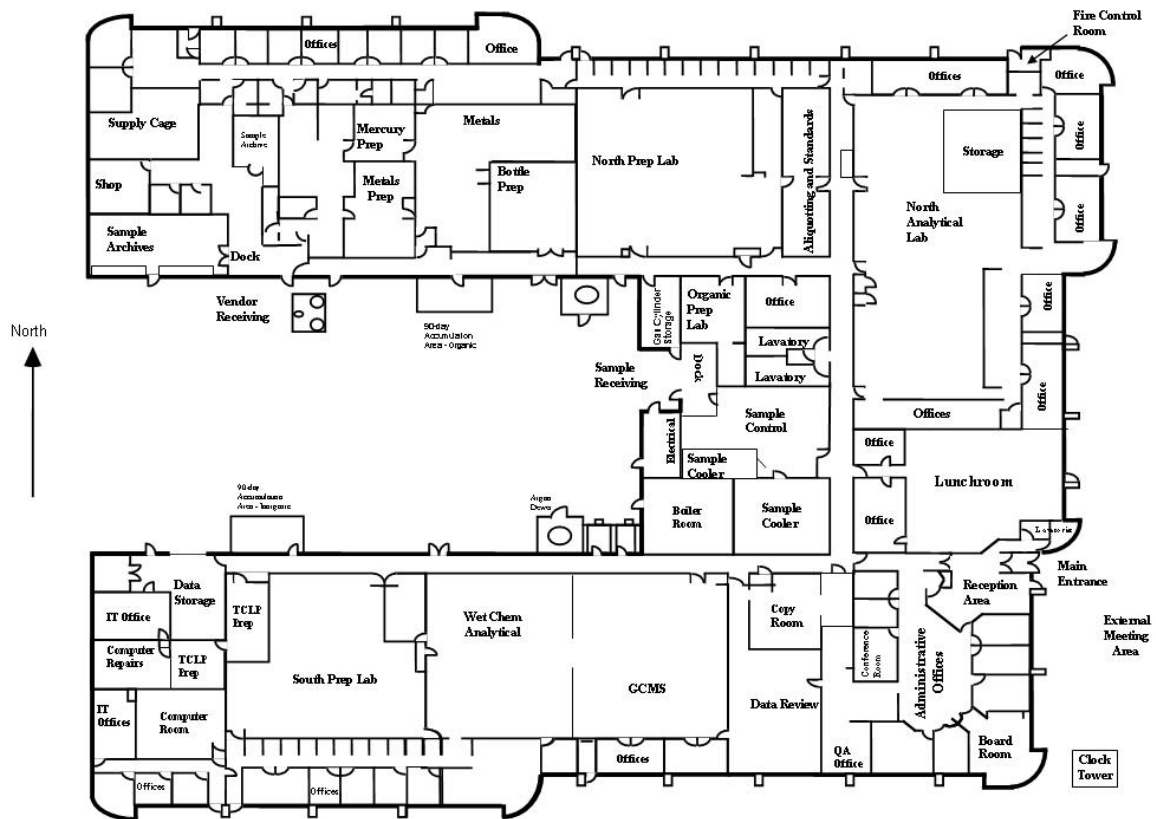
Example Laboratory Organization Chart



11/30/07

Appendix 3.

Laboratory Floor Plan



TestAmerica
Denver

**Criteria in Appendix 4 are to be used for general guidance. Method or Program specific criteria take precedence.
For methods not listed (SW6020, SW8321, SW6860, Hydrazine) refer to the analytical SOPs.**

Appendix 4: Summary of Calibration and QC Procedures for GC Organics

Method	QC Check	Frequency	Acceptance Criteria ³	Corrective Action ⁴
SW8081 SW8082 SW8141 SW8151	Minimum five-point initial calibration for all target analytes ²	Initial calibration prior to sample analysis. Perform instrument re-calibration once per year minimum.	Linear regression correlation coefficient $r^2 \geq 0.99$, $r \geq 0.995$. RSD of CF $\leq 20\%$	Correct problem then repeat initial calibration
	Initial calibration verification (ICV) must be from a 2 nd source	Once immediately following initial calibration	All target analytes within 15% of expected value	Correct problem then repeat initial calibration
	Continuing calibration verification (CCV)	Before sample analysis, after every 10 samples, and at the end of the analysis sequence	All analytes within 15% of expected value and within the RT Window ⁷ .	Correct problem then repeat initial CCV (re-calibrate if necessary) and re-analyze all samples since last successful CCV.
	Breakdown check (Endrin and DDT) ¹	Before sample analysis	Degradation $\leq 15\%$ for either Endrin or DDT.	Inlet/column maintenance; repeat breakdown check and re-analyze all samples since last successful breakdown check.
	Method blank	One per analytical prep batch, not to exceed 20 samples in a batch.	No analytes detected \geq RL	Correct problem then re-prep ⁶ and analyze method blank and all samples processed with the contaminated blank
	LCS	One per prep batch, not to exceed 20 samples in a batch.	See Control Limits in LIMS or Clouseau	Re-prep ⁶ and analyze the LCS and all samples in the affected analytical batch
	Surrogate(s)	Every sample, spike, standard, and method blank	See Control Limits in LIMS or Clouseau	Check system, re-inject, re-extract ⁶
	MS/MSD	One per batch per matrix, if insufficient sample for MS/MSD, then a LCS/LCSD will be analyzed.	See Control Limits in LIMS or Clouseau	None (LCS is used to determine if data is acceptable).
	Second-column confirmation	100% for all positive results Only applies to 8082 for specific programs (see SOP DV-QA-024P for federal program Requirements)	Same as for initial or primary column analysis	Same as for initial or primary column analysis. If the relative % difference of results between the 2 columns is greater than 40%, a comment should be placed in LIMS.
	Retention time window calculated for each analyte (see section 9 for how to calculate RTWs).	System set-up, with each new column or major instrument maintenance. Update the mid-RTW at the start of the run or daily.	Each analyte of the LCS, MS/MSD and CCV must be within the calculated RTW.	Correct the problem and re-process or re-analyze samples. If questions, see the supervisor or technical director.
	MDL verification	Quarterly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

1 --8081A only

2 – Method 8082, a five-point calibration is only analyzed for Aroclors 1016 and 1260.

3 - This is a summary of the acceptance criteria, refer to the method SOP for specific or more information.

4 - All abnormalities must be noted in a NCM.

6 - If unable to re-extract the samples because of insufficient sample volume or holding time has expired a NCM must be generated.

7 - The mean of all calibrated compounds may be used, but all compounds above the 15% must be documented in a NCM.

Appendix 4: Summary of Calibration and QC Procedures for GC Organics

Method	QC Check	Frequency	Acceptance Criteria ³	Corrective Action ⁴
EPA608 EPA615	Minimum three-point (preferably five) initial calibration for all target analytes	Initial calibration prior to sample analysis. Perform instrument re-calibration once per year minimum.	RSD of CF ≤ 10% Linear regression - correlation coefficient $r \geq 0.99$, $r \geq 0.995$.	Correct problem then repeat initial calibration
	Initial calibration verification (ICV) must be from a 2 nd source.	Immediately following initial calibration	All analytes within 15% of expected value	Correct problem then repeat initial calibration
	Continuing calibration verification (CCV)	Before sample analysis, and at the end of the analysis sequence	All analytes within 15% of expected value and within the RTW.	Correct problem then repeat initial CCV (re-calibrate if necessary) and re-analyze all samples since last successful CCV.
	Breakdown check (Endrin and DDT) ¹	Before sample analysis	Degradation ≤15% for either Endrin or DDT.	Inlet/column maintenance; repeat breakdown check and re-analyze all samples since last successful breakdown check.
	Method blank	One per analytical prep batch, not to exceed 10 samples in a batch.	No analytes detected ≥ RL	Correct problem then re-prep ⁷ and analyze method blank and all samples processed with the contaminated blank
	LCS all analytes	One per prep batch, not to exceed 10 samples in a batch.	See Control Limits in LIMS or Clouseau	Re-prep ⁷ and analyze the LCS and all samples in the affected analytical batch
	Surrogate(s)	Every sample, spiked sample, standard, and method blank	See Control Limits in LIMS or Clouseau	Check system, re-inject, re-extract ⁷
	MS	One per batch per matrix, 10%, if insufficient sample for MS, then an additional LCS will be analyzed.	See Control Limits in LIMS or Clouseau	All target compounds should be reported, and any compounds that are outside criteria must be within criteria in the LCS.
	Second-column confirmation	100% for all positive results	Same as for initial or primary column analysis	Same as for initial or primary column analysis. If the relative % difference of results between the 2 columns is greater than 40%, a comment should be placed in LIMS.
	Retention time window calculated for each analyte (see section 9 for how to calculate RTWs).	System set-up, with each new column or major instrument maintenance. Update the mid-RTW at the start of the run or as needed.	Each analyte of the LCS, MS/MSD and CCV must be within the calculated RTW.	Correct the problem and re-process or re-analyze samples. If questions, see the supervisor or technical director.
	MDL verification	Minimum yearly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

3 - This is a summary of the acceptance criteria, refer to the method SOP for specific or more information.

4 - All abnormalities must be documented in a NCM.

6 - Report all target compounds identified in the method blank above the MDL.

7 - If unable to re-extract the samples because of insufficient sample volume or holding time has expired, then a NCM must be generated

Appendix 4: Summary of Calibration and QC Procedures for GC/MS Organics

Method	QC Check	Frequency	Acceptance Criteria ²	Corrective Action ³
SW8260 SW8270	Check of mass spectral ion intensities ¹ , i.e., Tune	Prior to initial calibration or Continuing calibration verification, every 12 hours	Refer to criteria listed in the method SOP for Tune criteria, including DDT, Benzidine and Pentachlorophenol requirements for 8270.	Retune the instrument and verify (instrument maintenance may be needed).
SW8260	Minimum five-point initial calibration for all target analytes	Initial calibration prior to sample analysis. Perform instrument re-calibration once per year minimum.	SPCCs average RF ≥ 0.30 or 0.1 depending on the compound and %RSD for RFs for CCCs $\leq 30\%$ and all other target analytes %RSD for RF $\leq 15\%$.	Correct problem then repeat initial calibration
SW8270			SPCCs average RF ≥ 0.050 and %RSD for RFs for CCCs $\leq 30\%$ and all other target analytes %RSD for RF $\leq 15\%$.	Correct problem then repeat initial calibration
			option (if %RSD is $> 15\%$)—linear regression $r^2 \geq 0.99$, $r \geq 0.995$.	If the calibration is not considered linear by either %RSD or linear regression, then correct the problem and re-calibrate.
SW8260 SW8270	Initial calibration verification (ICV) must be from a 2 nd source.	Immediately following five-point initial calibration	All analytes within 25% of expected value	Correct problem then repeat initial calibration
	Relative Retention time window	Each sample	Relative retention time (RRT) of the analyte within 0.06 RRT units of the RRT of the internal standard	Correct problem then reprocess or re-analyze all samples analyzed since the last retention time check
SW8260	Continuing calibration verification (CCV) Continuing calibration check	Daily, before sample analysis and every 12 hours of analysis time	SPCCs average RF ≥ 0.30 or 0.1 depending on the compound; and	Correct problem then repeat initial calibration and re-analyze all samples since last successful CCV.
SW8270			SPCCs average RF ≥ 0.050 ; and	
SW8260 SW8270			CCCs: $\leq 20\%$ difference (when using RFs) or drift (when using least squares regression). All other target compounds $\leq 20\%$, up to 5 non-CCC target compounds, may fail this requirement provided the % difference is $\leq 40\%$.	
SW8260 SW8270	Method blank	One per analytical prep batch	No analytes detected \geq RL	Correct problem then re-prep ⁵ and analyze method blank and all samples processed with the contaminated blank

Method	QC Check	Frequency	Acceptance Criteria ²	Corrective Action ³
SW8260 SW8270	Internal Standards	Every sample/standard and blank	Retention time ± 30 seconds from retention time of the mid-point std. in the CCV/ICAL (sample/standard). EICP area within -50% to +100% of ICAL mid-point std for the CCV and -50% to +100% of the prior CCV for the samples. (See federal programs SOP DV-QA-024P for program specific requirements)	Inspect mass spectrometer and GC for malfunctions; mandatory re-analysis of samples analyzed while system was malfunctioning (dilution of the sample may be required, see the supervisor or the technical director for advice).
	LCS	One per prep batch, not to exceed the 20 samples in a batch.	See Control Limits in LIMS or Clouseau	Correct problem then re-prepare ⁵ and analyze the LCS and all samples in the affected analytical batch
	MS/MSD	One per batch per matrix, if insufficient sample for MS/MSD, then a LCS/LCSD will be analyzed.	See Control Limits in LIMS or Clouseau	None (the LCS is used to evaluate to determine if the batch is acceptable).
	Surrogate(s)	Every sample, spike, standard, and blank	See Control Limits in LIMS or Clouseau	Check system, re-analyze, re-prepare ⁵
SW8260	pH check	All 8260 water samples.	pH ≤ 2 .	If the pH is > 2, then a NCM must be generated
SW8260	Residual chlorine check (North Carolina samples only)	Each sample.	Residual chlorine should be negative.	If the residual chlorine is positive, then document in a NCM.
	MDL verification	Minimum yearly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

1 – SW8260B requires BFB; SW8270C requires DFTPP

2 - This is a summary of the acceptance criteria, refer to the method SOP for specific or more information.

3 - All abnormalities must be documented in a NCM.

4 - Report all target compounds identified in the method blank above the MDL.

5 - If unable to re-prepare samples because of insufficient sample volume or the holding time has expired, then a NCM must be generated.

Appendix 4: Summary of Calibration and QC Procedures for GC/MS Organics

Method	QC Check	Frequency	Acceptance Criteria ²	Corrective Action ³
EPA624 EPA625	Check of mass spectral ion intensities ¹ (i.e. Tune)	Prior to initial calibration or Continuing calibration verification every 12 hours.	Refer to criteria listed in the method SOP for Tune requirements including DDT, Benzidine and Pentachlorophenol criteria for 625.	Retune instrument and verify instrument maintenance may be needed.
	Five- point initial calibration for all target analytes	Initial calibration prior to sample analysis. Perform instrument re-calibration once per year minimum.	%RSD < 35%, if %RSD is > 35% then linear regression is used (for linear regression $r^2 \geq$ 0.99), $r \geq 0.995$.	If the calibration is not considered linear by either %RSD or linear regression, then correct problem then repeat initial calibration
	Initial calibration verification (ICV), 20 ug/L, must be from a 2 nd source. May be the same as the LCS.	Immediately following initial calibration	See analytical SOP.	Correct problem then repeat initial calibration
	Relative Retention time window	Each sample	Retention time (RT) of the analyte within 30 seconds of the RT (± 0.25 min. RTW is used) of the target.	Correct problem then reprocess or re- analyze all samples analyzed since the last retention time check
EPA625	Continuing calibration verification (CCV)	Daily, before sample analysis and every 12 hours of analysis time.	All calibration analytes within 20% of expected value	Correct problem then repeat initial calibration and re-analyze all samples since last successful CCV.
EPA624 EPA625	Method blank	One per prep batch (not to exceed 20 samples per batch).	No analytes detected \geq RL	Correct problem then re-prep ⁵ and analyze method blank and all samples processed with the contaminated blank
	LCS for all analytes.	One per prep batch (not to exceed 10 samples per batch) or daily.	See Control Limits in LIMS or Clouseau	Correct problem then re-prep ⁵ and analyze the LCS and all samples in the affected analytical batch
	MS	One per batch of 10 per matrix, if insufficient sample for MS, then a-duplicate LCS will be analyzed.	See Control Limits in LIMS or Clouseau	All target compounds should be reported, and any compound that is outside criteria must be within criteria in the LCS.
	Surrogate(s)	Every sample, spiked sample, standard, and method blank	See Control Limits in LIMS or Clouseau	Correct problem then re-prep ⁵ and analyze sample
EPA624 EPA625	Internal Standards	Every sample/standard	Retention time ± 30 seconds from retention time of the mid-point std. in the CCV/ICAL (sample/standard). EICP area within -50% to +100% of ICAL mid-point std for the CCV and -50% to +100% of the prior CCV for the samples.	Inspect mass spectrometer and GC for malfunctions; mandatory re-analysis of samples analyzed while system was malfunctioning (dilution of the sample may be required, see the supervisor or the technical director for advice).
EPA624	pH check	All 624 samples after analysis	pH should be ≤ 2 .	If the pH is > 2, then document in a NCM.
EPA624	Residual chlorine check (North Carolina samples only)	All samples after analysis	Residual chlorine should be negative.	If the residual chlorine is positive, then document in a NCM.

Method	QC Check	Frequency	Acceptance Criteria ²	Corrective Action ³
	MDL verification	Quarterly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

1 – 624 requires BFB; 625 requires DFTPP

2 - This is summary of the acceptance criteria, refer to the method SOP for specific or more information.

3 - All abnormalities must be documented in a NCM

4 - Report all target compounds identified in the method blank above the MDL.

5 - If unable to re-prepare samples because of insufficient sample volume or holding time has expired, then generate a NCM

Appendix 4: Summary of Calibration and QC Procedures for Method SW8310

Method	QC Check	Frequency	Acceptance Criteria ¹	Corrective Action ²
SW8310	Minimum five-point initial calibration for all target analytes	Initial calibration prior to sample analysis. Perform instrument re-calibration once per year minimum.	CF RSD for each analyte $\leq 20\%$ or mean RSD for all analytes $\leq 20\%$, with all compounds above 20% commented in LIMS with each sample. linear – $r^2 \geq 0.99$, $r \geq 0.995$.	Correct problem then repeat initial calibration
	Initial calibration verification (ICV) must be from a 2 nd source.	Immediately following initial calibration	All analytes within 15% of expected value	Correct problem then repeat initial calibration
	Retention time verification	Update at start of run or daily	All standards within window	Correct problem then re-analyze all samples analyzed since the last retention time check
	Continuing calibration verification (CCV)	Before sample analysis, after every 10 samples, and at the end of the analysis sequence	All analytes within 15% of expected value	Correct problem then reprocess or repeat initial CCV and re-analyze all samples since last successful CCV.
	Method blank	One per prep batch (not to exceed more than 20 samples per batch).	No analytes detected $\geq \frac{1}{2}$ RL	Correct problem then re-prep ⁴ and analyze method blank and all samples processed with the contaminated blank
	LCS	One per prep batch (not to exceed more than 20 samples per batch).	See Control Limits in LIMS or Clouseau	Correct problem then re-prep ⁴ and analyze the LCS and all samples in the affected analytical batch
	Surrogate	Every sample, spike, standard, and method blank	See Control Limits in LIMS or Clouseau	Check system, re-inject, re-extract ⁴
	MS/MSD	One per batch per matrix, if insufficient sample for MS/MSD, then a LCS/LCSD will be analyzed.	See Control Limits in LIMS or Clouseau	None (LCS is used to determine if the batch is acceptable).
	Confirmation	100% for all positive results (use response of both detectors)	Same as for initial or primary analysis. Comment LIMS if >40% difference in compound response between detectors.	Same as for initial or primary analysis.
	MDL verification	Quarterly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

1 - This is a summary of the acceptance criteria, refer to the method SOP for specific information or more information.

2 - All abnormalities must be documented in a NCM.

3 - Report all target compounds identified in the method blank above the MDL.

4- If unable to re-extract because of insufficient sample volume or the holding time has expired, then a NCM must be generated.

Appendix 4: Summary of Calibration and QC Procedures for Method EPA610 (HPLC)

Method	QC Check	Frequency	Acceptance Criteria ¹	Corrective Action ²
EPA610 (HPLC)	Minimum five-point initial calibration for all target analytes	Initial calibration prior to sample analysis. Perform instrument re-calibration once per year minimum.	RSD of CF of each analyte <10%, $r^2 \geq 0.99$, $r \geq 0.995$, or linear regression.	Correct problem then repeat initial calibration
	Initial calibration verification (ICV) must be from a 2 nd source.	Immediately following initial calibration	All analytes within 15% of expected value	Correct problem then repeat initial calibration
	Retention time verification	Update at start of run or daily	All standards within window	Correct problem then reprocess or re-analyze all samples analyzed since the last retention time check
	Continuing calibration verification (CCV)	Before sample analysis and at the end of the analysis sequence	All analytes within 15% of expected value	Correct problem then repeat initial CCV and re-analyze all samples since last successful CCV.
	Method blank	One per prep batch (not to exceed more than 10 samples per batch).	No analytes detected $\geq \frac{1}{2}$ RL or MDL, whichever is greater ³	Correct problem then re-prep ⁴ and analyze method blank and all samples processed with the contaminated blank
	LCS for all analytes	One per prep batch (not to exceed more than 10 samples per batch).	See Control Limits in LIMS or Clouseau	Correct problem then re-prep ⁴ and analyze the LCS and all samples in the affected analytical batch
	Surrogate	Every sample, spiked sample, standard, and method blank	See Control Limits in LIMS or Clouseau	Check system, re-inject, re-extract ⁴
	MS	One per batch per matrix, if insufficient sample for MS, then an additional LCS will be analyzed.	See Control Limits in LIMS or Clouseau	All target compounds should be reported, and any compound that is outside criteria must be within criteria in the LCS.
	Confirmation	100% for all positive results (use response of both detectors)	Same as for initial or primary analysis. Comment LIMS if >40% difference in compound response between detectors.	Same as for initial or primary analysis
	MDL verification	Quarterly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

1 - This is a summary of the acceptance criteria, refer to the method SOP for specific information or more information.

2 - All abnormalities must be noted in a NCM.

3 - Report all target compounds identified in the method blank above the MDL.

4- If unable to re-extract because of insufficient sample volume or the holding time has expired, then a NCM must be generated.

Appendix 4: Summary of Calibration and QC Procedures for Method SW8330

Method	QC Check	Frequency	Acceptance Criteria ¹	Corrective Action ²
SW8330	Five-point initial calibration for all target analytes	Initial calibration prior to sample analysis. Perform instrument re-calibration once per year minimum.	RSD of CF of each analyte $\leq 20\%$ or mean RSD for all analytes $\leq 20\%$, with all compounds above 20% commented in LIMS with each sample. linear – $r^2 \geq 0.99$, $r \geq 0.995$	Correct problem then repeat initial calibration
	Initial calibration verification (ICV) must be from a 2 nd source.	Immediately following initial calibration	All analytes within 15% of expected value	Correct problem then repeat initial calibration
	Retention time verification	Update at start of run or daily	All standards within RT window	Correct problem then reprocess or re-analyze all samples analyzed since the last retention time check
	Continuing calibration verification (CCV)	Before sample analysis, after every 10 samples, and at the end of the analysis sequence	All analytes within 15% of expected value	Correct problem then repeat initial CCV and re-analyze all samples since last successful CCV.
	Method blank	One per prep batch not to exceed more than 20 samples per batch.	No analytes detected $\geq \frac{1}{2}$ RL	Correct problem then re-prep ⁴ and analyze method blank and all samples processed with the contaminated blank
	LCS	One per prep batch (not to exceed more than 20 samples per batch).	See Control Limits in LIMS or Clouseau	Correct problem then re-prep ⁴ and analyze the LCS and all samples in the affected analytical batch
	Surrogate	Every sample, spike, standard, and blank	See Control Limits in LIMS or Clouseau	Check system, re-inject, re-extract ⁴
	MS/MSD	One per batch per matrix	See Control Limits in LIMS or Clouseau	None (LCS is used to determine if the batch is acceptable).
	Confirmation	100% for all positive results; 2 nd column (lunacolumn) confirmation	Same as for initial or primary analysis. Comment LIMS if $>40\%$ difference in compound response between detectors.	Same as for initial or primary analysis
	MDL verification	Minimum yearly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

1 - This is a summary of the acceptance criteria, refer to the method SOP for specific or more information.

2 - All abnormalities must be documented in a NCM.

3 - Report all target compounds identified in the method blank above the MDL.

4 - If unable to re-extract sample because of insufficient sample volume or expired holding time, then a NCM must be generated.

Appendix 4: Summary of Calibration and QC Procedures for GC Organics

Method	QC Check	Frequency	Acceptance Criteria ¹	Corrective Action ²
EPA504.1 SW8011	Five-point initial calibration for all target analytes (calibration standards should be prepped as the samples).	Initial calibration prior to sample analysis. Perform instrument re-calibration once per year minimum.	RSD of CF of each analyte $\leq 20\%$ RSD of CF < 10% for Method 8011 Linear – $r^2 \geq 0.99$, $r \geq 0.995$	Correct problem then repeat initial calibration
	Initial calibration verification (ICV) must be from a 2 nd source.	Immediately following initial calibration	All analytes within 15% of expected value	Correct problem then repeat initial calibration
	Continuing calibration verification (CCV)	Before sample analysis, after every 10 samples, and at the end of the analysis sequence	All analytes within 15% of expected value and within the RTW.	Correct problem then repeat initial CCV (re-calibrate if necessary) and re-analyze all samples since last successful CCV.
	Method blank	One per analytical prep batch, not to exceed 20 samples in a batch.	No analytes detected \geq RL	Correct problem then re-prepare ⁴ and analyze method blank and all samples processed with the contaminated blank
	LCS	One per prep batch, not to exceed 20 samples in a batch.	See Control Limits Manual	Re-prepare ⁴ and analyze the LCS and all samples in the affected analytical batch
	Surrogate	Every sample, spike, standard, and method blank	See Control Limits Manual	Check system, re-inject, re-extract ⁴
	MS/MSD	One per batch per matrix, if insufficient sample for MS/MSD, then a LCS/LCSD will be analyzed.	See Control Limits Manual	None (LCS is used to determine if data is acceptable).
	Second-column confirmation	100% for all positive results	Same as for initial or primary column analysis	Same as for initial or primary column analysis. If the relative % difference of results between the 2 columns is greater than 40%, a comment should be placed in LIMS.
	Retention time window calculated for each analyte (see section 9 for how to calculate RTW's).	System set-up, with each new column or major instrument maintenance. Update the mid-RTW as the start of the run or daily.	Each analyte of the LCS, MS/MSD and CCV must be within the calculated RTW.	Correct the problem and re-process or re-analyze samples. For questions, see the supervisor or technical director.
	MDL check standard	Each week that samples are analyzed.	Detected	Correct problem and re-analyze samples.

1 - This is a summary of the acceptance criteria, refer to the method SOP for specific or more information.

2 - All abnormalities must be documented in a NCM.

3 - Report all target compounds identified in the method blank above the MDL.

4 - If unable to re-extract the samples because of insufficient sample volume or holding time has expired, then a NCM must be generated.

Appendix 4: Summary of Calibration and QC Procedures for GC Organics

Method	QC Check	Frequency	Acceptance Criteria ¹	Corrective Action ²
SW8021 SW8015 ⁵	Five-point initial calibration for all target analytes	Initial calibration prior to sample analysis. Perform instrument re-calibration once per year minimum.	RSD of CF \leq 20% Linear – least squares regression $r^2 \geq 0.99$, $r \geq 0.995$	Correct problem then repeat initial calibration
	Initial calibration verification (ICV), must be from a 2 nd source.	Immediately following five-point initial calibration	All analytes within 15% of expected value	Correct problem then repeat initial calibration
	LCS for all analytes must be from a 2 nd source.	One per prep batch, not to exceed 20 samples in a batch.	See Control Limits Manual	Re- ⁴ and analyze the LCS and all samples in the affected analytical batch
	Continuing calibration verification (CCV)	Before sample analysis, after every 10 samples, and at the end of the analysis sequence	All analytes within 15% of expected value and within the RTW.	Correct problem then repeat initial CCV (re-calibrate if necessary) and re-analyze all samples since last successful CCV.
	Method blank	One per analytical prep batch, not to exceed 20 samples in a batch.	No analytes detected \geq RL	Correct problem then re- ⁴ and analyze method blank and all samples processed with the contaminated blank
	Surrogate	Every sample, spiked sample, standard, and method blank	See Control Limits Manual	Check system, re-analyze, re- ⁴
	MS/MSD	One per batch per matrix, if insufficient sample for MS/MSD, then a LCS/LCSD will be analyzed.	See Control Limits Manual	None (LCS is used to determine if data is acceptable).
	GC/MS confirmation.	At the clients request or analyst judgment.		
	Retention time window calculated for each analyte (see section 9 for how to calculate RTWs).	System set-up, with each new column or major instrument maintenance. Update the mid-RTW as the start of the run or daily.	Each analyte of the LCS, MS/MSD and CCV must be within the calculated RTW.	Correct the problem and re-process or re-analyze samples. For questions, see the supervisor or technical director.
8021	pH Check	All water samples after analysis.	pH should be less than 2.	If pH is > 2 , then place a comment on the benchsheet and in LIMS.
8021	Residual chlorine check (North Carolina samples only)	All water samples after analysis.	Residual chlorine should be negative.	If residual chlorine is positive, document in a NCM.
	MDL verification	Quarterly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

1 - This is a summary of the acceptance criteria, refer to the method SOP for specific or more information. 2 - All abnormalities must be documented in a NCM.

3 - Report all target compounds identified in the method blank above the MDL.

4 - If unable to re-⁴ the samples because of insufficient sample volume or holding time has expired, then a NCM must be generated.

5 - For GRO and DRO, see state specific SOP/Method for acceptance criteria. If there is not a specific method for that state, then follow the acceptance criteria in this table.

Appendix 4: Summary of Calibration and QC Procedures for GC Organics

Method	QC Check	Frequency	Acceptance Criteria ¹	Corrective Action ²
EPA601 EPA602	Minimum three-point (preferably five) initial calibration for all target analytes	Initial calibration prior to sample analysis. Perform instrument re-calibration once per year minimum.	RSD of CF < 10% RSD of RF < 10% $r^2 \geq 0.99$, $r \geq 0.995$	Correct problem then repeat initial calibration
	Initial calibration verification (ICV), 20 ug/L, must be from a 2 nd source. May be the same as the LCS.	Once immediately following initial calibration	Reference 601/602 table in Section 5 ("Q" in EPA method).	Correct problem then repeat initial calibration
	LCS for all analytes	One per prep batch, not to exceed 10 samples in a batch.	See Control Limits Manual	Re-prep ⁴ and analyze the LCS and all samples in the affected analytical batch
	Method blank	One per analytical prep batch, not to exceed 10 samples in a batch.	No analytes detected \geq RL	Correct problem then re-prep ⁴ and analyze method blank and all samples processed with the contaminated blank
	Surrogate(s)	Every sample, spiked sample, standard, and method blank	See Control Limits in LIMS or Clouseau	Check system, re-analyze, re-prep ⁴
	MS	One per batch of 10 per matrix, if insufficient sample for MS, then an additional LCS will be analyzed.	See Control Limits in LIMS or Clouseau	All target compounds should be reported, and any compound that is outside criteria must be within criteria in the LCS.
	GC/MS confirmation.	At clients request or analyst judgment.		
	Retention time window calculated for each analyte (see section 9 for how to calculate RTWs).	System set-up, with each new column or major instrument maintenance. Update the mid-RTW as the start of the run (or as needed).	Each analyte of the LCS, MS/MSD and CCV must be within the calculated RTW.	Correct the problem and re-process or re-analyze samples. For questions, see the supervisor or technical director.
	pH check	All samples after analysis.	pH should be ≤ 2 .	If pH is > 2, then place a comment on the benchsheet, in the PIPE database, and in LIMS.
	Residual chlorine check (North Carolina samples only)	All samples after analysis.	Residual chlorine should be negative.	If residual chlorine is positive, document in a NCM.
	MDL verification	Quarterly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

1 – This is a summary of the acceptance criteria, refer to the method SOP for specific or more information. 2 – All abnormalities must be noted on the data, the benchsheet, in the PIPE database, and in LIMS.

3 – Report all target compounds identified in the method blank above the MDL.

4 – If unable to re-prepare the samples because of insufficient sample volume or holding time has expired, then a NCM must be generated.

Appendix 4: Summary of Calibration and QC Procedures for Method SW6010

Method	QC Check	Frequency	Acceptance Criteria	Corrective Action
SW6010	Initial calibration (minimum 1 standard and a blank)	Daily initial calibration prior to sample analysis.	N/A	N/A
	Second-source calibration verification (ICV)	Daily after initial calibration	All analytes within 10% of expected value	Correct problem then repeat initial calibration
	Calibration blank (CB)	After every continuing calibration verification	Must be <3 times the IDL or the average of 3 CB must be <3 times the IDL.	Correct problem then analyze calibration blank and previous 10 samples
	Continuing calibration verification (CCV)	Before sample analysis, after every 10 samples, and at the end of the analysis sequence	All analytes within 10% of expected value and RSD of replicate integrations <5%	Repeat calibration and re-analyze all samples since last successful calibration
	Method blank	One per prep batch	No analytes detected \geq RL	Correct problem then re-prepare and analyze method blank and all samples processed with the contaminated blank
	Interference check solution (ICS)	At the beginning of an analytical run	Within 20% of expected value	Terminate analysis; correct problem; re-analyze ICS; re-analyze all affected samples
	LCS	One per prep batch	See Control Limits in LIMS or Clouseau	Correct problem then re-prepare and analyze the LCS and all samples in the affected analytical batch
	MS/MSD	One per batch per matrix	See Control Limits in LIMS or Clouseau	None
	MDL verification	Quarterly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.
	Dilution test	Each new sample matrix	1:5 dilution must agree within 10% of the original determination	Perform post digestion spike addition
	Post digestion spike addition	When dilution test fails	Recovery within 25% of expected results	Correct problem then re-analyze post digestion spike addition

1 – Report all targets identified in the method blank above the MDL.

Appendix 4: Summary of Calibration and QC Procedures for Method SW7196

Method	QC Check	Frequency	Acceptance Criteria	Corrective Action
SW7196	Initial calibration (minimum three standards and a blank)	Initial calibration prior to sample analysis.	$r^2 \geq 0.99$, $r \geq 0.995$ for linear regression	Correct problem then repeat initial calibration
	Second-source calibration verification (ICV)	Immediately following initial calibration	All analytes within 10% of expected value	Correct problem then repeat initial calibration
	Continuing calibration verification (CCV)	Beginning and after every 10 samples and at the end of the analysis sequence	All analytes within 20% of expected value	Correct problem then repeat initial calibration and re-analyze all samples since last successful calibration
	Verification check to ensure lack of reducing condition and/or interference	Once for every sample matrix analyzed	Spike recovery between 85-115%	If check indicates interference, dilute and re-analyze sample persistent interference indicates the need to use and alternate method
	Method blank	One per prep batch	No analytes detected \geq RL	Correct problem then re-prepare and analyze method blank and all samples processed with the contaminated blank
	MS/MSD	One per 20 samples per matrix	See Control Limits in LIMS or Clouseau	none
	LCS	One per batch	See Control Limits in LIMS or Clouseau	Re-prepare, re-analyze all affected samples.
	MDL verification	Quarterly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

1 - Report all targets identified in the method blank above the MDL.

Appendix 4: Summary of Calibration and QC Procedures for Method SW7470/SW7471

Method	QC Check	Frequency	Acceptance Criteria	Corrective Action
SW7470 SW7471	Initial calibration (minimum 5 standards and a blank)	Daily initial calibration prior to sample analysis. Perform instrument re-calibration once per year minimum.	$r^2 \geq 0.99$, $r \geq 0.995$ for linear regression	Correct problem then repeat initial calibration. If calibration fails again, re-digest the entire digestion batch.
	Second-source calibration verification (ICV)	Immediately following initial daily calibration	Analytes within 10% of expected value	Correct problem then repeat initial calibration. If calibration fails again, re-digest the entire digestion batch.
	Calibration blank	Once per initial daily calibration	No analytes detected \geq MDL	Correct problem then re-digest and re-analyze calibration and entire digestion batch
	Continuing calibration verification (CCV)	Before sample analysis, after every 10 samples, and at the end of the analysis sequence	Analytes within 20% of expected value	Correct problem then repeat all QC and samples since last successful calibration. If the CCV fails again upon reanalysis, reprep the entire digestion batch.
	Method blank	One per prep batch	No analytes detected \geq RL	Correct problem then re-prep and analyze method blank, all samples, and QC processed with the contaminated blank
	LCS	One per prep batch	See Control Limits in LIMS or Clouseau	Correct problem then re-prep and analyze the LCS, all samples, and QC in the affected analytical batch
	Dilution test; five-fold dilution test	Each preparatory batch	Five times dilution sample result must be $\pm 10\%$ of the undiluted sample result	Perform post digestion spike addition
	Recovery test	When dilution test fails	Recovery within 85-115% of expected results	Dilute the sample; re-analyze post digestion spike addition
	MS/MSD	One per batch per matrix	See Control Limits in LIMS or Clouseau	None
	MDL verification	Minimum yearly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

1 - Report all targets identified in the method blank above the MDL.

Appendix 4: Summary of Calibration and QC Procedures for Method SW9010/SW9012/SW9014

Method	QC Check	Frequency	Acceptance Criteria	Corrective Action
SW9010 SW9012 SW9014	Initial calibration (six standards and a calibration blank)	Initial daily calibration prior to sample analysis. Perform instrument re-calibration once per year minimum.	$r^2 \geq 0.99$, $r \geq 0.995$ for linear regression	Correct problem then repeat initial calibration
	Distilled standards (one high and one low)	Once per calibration	Analytes within 10% of true value	Correct problem then repeat distilled standards
	Second-source calibration verification (ICV)	Immediately following initial daily calibration	Analytes within 15% of expected value	Correct problem then repeat initial calibration
	Continuing calibration verification (CCV)	Beginning and after every 10 samples and at the end of the analysis sequence	Analytes within 15% of expected value	Correct problem then repeat initial Continuing calibration verification and re-analyze all samples since last successful Continuing calibration verification
	Method blank	One per prep batch	No analytes detected \geq RL	Correct problem then re-prep and analyze method blank and all samples processed with the contaminated blank
	LCS	One per batch per matrix	See Control Limits in LIMS or Clouseau	Re-prep, re-run affected samples
	MS/MSD	One per batch per matrix	See Control Limits in LIMS or Clouseau	None
	MDL verification	Quarterly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

Appendix 4: Summary of Calibration and QC Procedures for Mercury

Method	QC Check	Frequency	Acceptance Criteria	Corrective Action
EPA245.1	Initial calibration (minimum 5 standards and a blank)	Daily initial calibration prior to sample analysis. Perform instrument re-calibration once per year minimum.	$r^2 \geq 0.99$, $r \geq 0.995$ for linear regression	Correct problem then repeat initial calibration
	Second-source calibration verification (ICV)	Immediately following five-point initial calibration	Analyte within 5% of expected value	Correct problem then repeat initial calibration
	Calibration blank	Once per initial daily calibration	No analytes detected \geq MDL	Correct problem then re-analyze calibration blank and all samples associated with blank
	Continuing calibration verification (CCV)	Before sample analysis, after every 10 samples, and at the end of the analysis sequence	Analyte within 10% of true value	Correct problem then repeat calibration and re-analyze all samples and QC since last successful calibration
	LCS	One per prep batch	All analytes within 15% of expected value	Correct problem then re-prepare and analyze the LCS, all samples, and QC in the affected analytical batch
	Matrix Spike/Matrix Spike Duplicate	One per batch or 10 samples	All analytes within 30% of expected value	None
	Method Blank	One per batch	No analytes > RL	Reprep
	MDL verification	Minimum yearly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

1 - Report all targets identified in the method blank above the MDL.

Appendix 4: Summary of Calibration and QC Procedures for ICP Metals

Method	QC Check	Frequency	Acceptance Criteria	Corrective Action
EPA200.7	Initial calibration (minimum 1 standard and a blank)	Daily initial calibration prior to sample analysis.	N/A	N/A
	Second-source calibration verification (ICV)	Each calibration	Value of all analytes within 5% of expected value	Correct problem then repeat initial calibration
	Linear Dynamic Range	Once annually	All analytes within 10% of expected value	Calibration range lowered to meet LDR results
	Calibration blank	After every Continuing calibration verification	No analytes detected \geq MDL	Correct problem then analyze calibration blank and previous 10 samples
	Continuing calibration verification (CCV)	Before sample analysis, after every 10 samples, and at the end of the analysis sequence	All analytes within 10%	Repeat calibration and re-analyze all samples since last successful calibration
	Method blank	One per prep batch	No analytes detected \geq RL	Correct problem then re-prepare and analyze method blank and all samples processed with the contaminated blank
	Interference check solution (ICS)	At the beginning of an analytical run, daily		Terminate analysis; correct problem; re-analyze ICS; re-analyze all affected samples
	LCS	One per prep batch	All analytes within 15% of expected value	Correct problem then re-prepare and analyze the LCS and all samples in the affected analytical batch
	Dilution test	Each new sample matrix	1:5 dilution must agree within 10% of the original determination	Perform post digestion spike addition
	Post digestion spike addition	When dilution test fails	Recovery within 25% of expected results	Correct problem then re-analyze post digestion spike addition
	Matrix Spike/Matrix Spike Duplicate	One per batch of 20 samples	All analytes within 30% of expected value	None
	MDL verification	Minimum yearly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

1 - Report all targets identified in the method blank above the MDL.

Appendix 4: Summary of Calibration and QC Procedures for Gravimetric Analyses

Method	QC Check	Frequency	Acceptance Criteria	Corrective Action
SM2540 C (TDS) SM2540 D (TSS) SM2540 B (TS) EPA160.4, SM2540E* (TVS)* ASTM D5057* (Density/ Specific Gravity)*	Verification standard– single standard (if available)	Each batch	±10%	Repeat
	Method blank	Each batch	No analytes detected ≥ RL	Repeat, rerun
	Duplicate	Each batch, less than 20	±20%	None
	MDL verification	Minimum yearly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

*Analysis is performed at TestAmerica Denver but does not have any check standard available.

Appendix 4: Summary of Calibration and QC Procedures for Titrimetric Analyses

Method	QC Check	Frequency	Acceptance Criteria	Corrective Action
SM2310B: Acidity. Alkalinity. SM2320: HCO ₃ ⁻ , CO ₃ ²⁻ . SM4500-CO ₂ C: CO ₂ . SM4500SO ₃ : Sulfite 4500S ² F, 9030\9034: Sulfide SM4500CL C: Chloride 2340B or C: Hardness	Verification standard– single standard (if available)	Each batch	±10%	Repeat, check
	Method blank	Each batch	No analyte detected ≥ report limit	Repeat batch
	Duplicate	Each batch	±20%	None
	MDL verification	Minimum yearly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

Appendix 4: Summary of Calibration and QC Procedures for Spectrophotometric Analyses

Method	QC Check	Frequency	Acceptance Criteria	Corrective Action
EPA350.1: NH ₃ . EPA410.4: COD. SW7196, SM3500Cr: Cr+6 EPA335.4, 9010, 9012, SM4500CN : CN. SM4500S ⁻² D: Sulfide SM5310B,9060: TOC. SM4500NO ₂ B: Nitrite SM3500Fe D: Ferrous Iron SM4500CL E: Chloride EPA420.1, 420.4: Phenol EPA351.2: TKN EPA353.2: Nitrate, NO ₂ +NO ₃ EPA365.1: Total Phos, O-Phos ASTMD516-02: Turb. Sulfate EPA180.1: Turbidity.	Calibration curve – minimum 5 point	Initial. Perform re-calibration once per year minimum.	RSD <10%, $r^2 \geq 0.99$, $r \geq 0.995$	Recalibrate
	Independent calibration verification – mid-level, second-source required (ICV)	Immediately following initial calibration.	±10%	Recalibrate
	Continuing calibration verification (CCV)	Beginning, every 10 samples, and at end of sequence	±10%	Correct, recalibrate
	Method blank	Each use	No analyte detected ≥ report limit	Reprep, rerun
	MS/MSD	Each batch, less than 20	±20% Or: historical or client specified where applicable	None
	LCS	Each batch	± 10% Or: historical or client specified where applicable	Rerun
	MDL verification	Minimum yearly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

Appendix 4: Summary of Calibration and QC Procedures for Electrometric Analyses

Method	QC Check	Frequency	Acceptance Criteria	Corrective Action
SM5210B: BOD ¹ , CBOD ¹ . SM2510B, SW9050: Cond. SW9023: EOX. SM4500F-C: Flouride. SM4500H ⁺ B, SW9040/9045: pH. SM5310B, SW9020,9076: TOX. EPA365.3: ORP ¹	Calibration Curve – minimum of 5 standards	Initial Calibration. Perform re-calibration once per year minimum	±10%, $r^2 \geq 0.99$, $r \geq 0.995$.	Recalibrate
	Independent calibration verification (second source) (ICV)	Immediately after initial calibration	±10%	Recalibrate
	Continuing calibration verification (CCV)	Beginning, every 10 samples, and end of batch	±10%	Rerun
	Method blank NA for pH	Each batch	No analyte detected \geq report limit	Reprep
	LCS	Each batch	±10% Or: historical or client specified where applicable	Rerun batch
	MS/MSD	Each batch	± 20% Or: historical or client specified where applicable	None
	Duplicate	When spike not available	±20%	None
	MDL verification	Minimum yearly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

¹Calibration curve does not apply.

Appendix 4: Summary of Calibration and QC Procedures for Ion Chromatographic Analyses

Method	QC Check	Frequency	Acceptance Criteria	Corrective Action
EPA300 & SW9056: Bromide Chloride Chlorate Fluoride Nitrate Nitrite Sulfate.	Calibration Curve – Minimum 5-point calibration	Initial calibration. Perform instrument re-calibration once per year minimum.	RSD \pm 10%, $r^2 \geq 0.99$, $r \geq 0.995$.	Recalibrate
	Calibration verification (ICV), second source	Immediately following initial calibration	$\pm 10\%$	Recalibrate
	Continuing calibration verification (CCV)	Each use, beginning, every 10 samples, end of batch	$\pm 10\%$	Rerun affected samples
	Method blank	Each batch	No analyte detected \geq report limit	Rerun batch
	LCS	Each batch	$\pm 10\%$ Or: historical or client specified where applicable	Rerun batch
	MS/MSD ¹	Each batch	$\pm 20\%$ Or: historical or client specified where applicable	None, use LCS
	Duplicate	Each batch	$\pm 30\%$	None
	MDL verification	Minimum yearly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

¹Only applies to EPA300, SW9056.

Appendix 4: Summary of Calibration and QC Procedures for Oil & Grease Analyses

Method	QC Check	Frequency	Acceptance Criteria	Corrective Action
EPA1664 SW9070. SW9071.	Verification standard (NA for 1664)	Single standard	±10% PAR standard	Rerun
	Method blank	Each batch	No analyte detected ≥ report limit	Repeat batch
	LCS	Each batch	See Control Limits Manual	Repeat batch
	MS/MSD	Each batch	See Control Limits Manual	None, use LCS
	MDL verification	Minimum yearly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

Appendix 4: Summary of Calibration and QC Procedures for Physical Analyses

Method	QC Check	Frequency	Acceptance Criteria	Corrective Action
SW1010: Flash Point. SM2120B*: Color* SW9095*: Paint Filter*. SM2540F*: Settleable Solids*. .	Method blank	Each batch	No analyte detected \geq report limit	Repeat, rerun
	Two standards for Flash Point 1 Known for Settleable Solids Method-specific standards for Color.	Each batch	Flashpoint LCS $\pm 2^\circ$ F	Rerun batch
	Duplicate	Each batch	$\pm 20\%$	None
	MDL verification (NA for flashpoint and paint filter)	Minimum yearly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

*Analysis is performed at TestAmerica Denver but does not have any check standard available.

Appendix 4: Summary of Calibration and QC Procedures for Perchlorate

Method	QC Check	Frequency	Acceptance Criteria	Corrective Action
EPA314.1: Perchlorate	Calibration Curve – Minimum 5-point calibration	Initial calibration. Perform instrument re-calibration once per year minimum.	$r \geq 0.995$.	Recalibrate
	Calibration verification (ICV), second source	Immediately following initial calibration	$\pm 10\%$	Recalibrate
	Initial Performance Check (IPC)	Each batch	$\pm 20\%$	Recalibrate
	Initial Calibration Check Standard (ICCS)	Each batch	$\pm 25\%$	Recalibrate
	Initial Calibration Blank (ICB)	After initial calibration	No analyte detected \geq report limit	
	Continuing calibration verification (CCV)	Each use, beginning, every 10 samples, end of batch	$\pm 10\%$	Rerun affected samples
	Method blank	Each batch	No analyte detected \geq report limit	Rerun batch
	LCS	Each batch	$\pm 15\%$	Rerun batch
	MS/MSD ¹	Each batch	$\pm 20\%$ RPD 15%	Document in NCM
	MDL verification	Minimum yearly	Detectible	Re-evaluate MDL standard used and MDL; see Technical Director.

Appendix 5. 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)

Aliquot, aliquant:

A measured portion of a sample taken for analysis.

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)

arithmetic mean

The arithmetic mean (\bar{x}) is the average of a set of values. It is equal to the sum of the observed values divided by the number of observations. Also called "average".

$$\bar{X} = \frac{\sum_{i=1}^n x_i}{n}$$

where: \bar{X} = the mean

x_i = the i^{th} data value

n = number of data values

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)

Benchmarking:

A step-by-step method of improving performance by identifying and studying best practices and comparing them to industry practices.

Bias:

A systematic (consistent) error in test results. Bias is expressed as the difference between the population mean and the true or reference value, or as estimated from sample statistics, the difference between the sample average and the reference value.

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 factor (CF):

The ratio of the instrument response of an analyte to the amount injected. CFs are used in external standard calibrations.

$$CF = \frac{\text{Total Area of Peak}}{\text{Mass Injected}}$$

Calibration Method:

A defined technical procedure for performing a calibration. (NELAC)

Calibration Standard:

A substance or reference material used to calibrate an instrument (QAMS)

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)

coefficient of variation (relative standard deviation)

A measure of precision (relative dispersion). It is equal to the standard deviation (s) divided by the mean (\bar{X}) and multiplied by 100 to give a percentage value.

$$CV (RSD) = \left(\frac{s}{\bar{X}} \right) \times 100$$

collocated samples:

Independent samples collected in such a manner that they are equally representative of the variable(s) of interest at a given point in space and time. The results will indicate sampling as well as analytical variability.

Comparability:

Comparability is a measure of the confidence with which one data set can be compared to another. To ensure comparability, all laboratory analysts are required to use uniform procedures (i.e., SOPs) and a uniform set of units and calculations for analyzing and reporting environmental data.

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)

completeness

Completeness is a measure of the percentage of measurements that are judged to be valid measurements. At a minimum, the objective for completeness of data is 90% for each constituent analyzed. It is usually expressed as a percentage:

$$\% \text{ Completeness} = \frac{V}{n} \times 100$$

where: V = number of measurements judged valid

n = total number of measurements

composite

A sample composed of two or more increments.

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.

Confirmation:

Verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to:

- Second column confirmation
- Alternate wavelength
- Derivatization
- Mass spectral interpretation
- Alternative detectors or
- Additional Cleanup procedures

(NELAC)

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. (ANSI/ASQC E4-1994)

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)

correlation coefficient

The correlation coefficient (r) is a determination of how closely data "fits" a straight line. It is a number between -1 and 1 that indicates the degree of linear relationship between two sets of numbers. A correlation coefficient of +1 (usually calculated to three decimal places or 1.000) means the data falls exactly on a straight line with positive slope. A correlation coefficient of -1 (or -1.000) means the data falls exactly on a straight line with negative slope.

Data Audit:

A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are 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)

data quality objective (DQO)

Data quality objectives (DQOs) are qualitative and quantitative statements used to ensure the generation of the type, quantity, and quality of environmental data that will be appropriate for the intended application (EPA 1994). Typically, DQOs are identified during project scope and development of sampling and analysis plans. In this QA manual, however, we refer to only the analytical DQOs because laboratories generally do not have any authority over sample collection, shipment, or other field-related activities that may affect the data quality of the environmental sample before the sample is received in the laboratory. EPA has established six primary analytical DQOs for environmental studies: precision, accuracy, representativeness, completeness, comparability, and detectability.

Deficiency:

An unauthorized deviation from acceptable procedures or practices, or a defect in an item. (ASQC)

degrees of freedom

The number of independent deviations used in calculating an estimate of the standard deviation.

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 is 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)

error

The difference between an observed or measured value and its true value.

External Standard Calibration:

Calibrations for methods that do not utilize internal standards to compensate for changes in instrument conditions.

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA):

The enabling legislation under 7 U.S.C. 135 et seq., as amended, that empowers the EPA to register insecticides, fungicides, and rodenticides. (NELAC)

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 filling 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. (ANSI/ASQC E4-1994)

Internal Standard:

A known amount of standard added to a test portion of a sample and carried through the entire measurement process as a reference for evaluating and controlling the precision and bias of the applied analytical test method. (NELAC)

Internal Standard Calibration:

Calibrations for methods that utilize internal standards to compensate for changes in instrument conditions.

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)

Instrument Response:

Instrument response is normally expressed as either peak area or peak height however it may also reflect a numerical representation of some type of count on a detector (e.g. Photomultiplier tube, or Diode array detector) and is used in this document to represent all types.

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)

measurement

The process or operation of ascertaining the extent, degree, quantity, dimensions, or capability with respect to a standard.

median

The middle value of a set of data when the data set is ranked in increasing or decreasing order.

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)

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)

outlier

A result excluded from the statistical calculations due to being deemed "suspicious" when applying the "Grubbs Test" (or equivalent).

parameter

In statistical analysis, a constant or coefficient that describes some characteristic of a population (e.g., standard deviation, mean, regression coefficients). In analytical chemistry, a chemical or physical attribute of a sample that is being measured, i.e., an analyte (e.g., chemical concentration, temperature, pH, etc.).

percent difference

The difference between two values, expressed as a percent of the first value.

$$\%D = \frac{X_1 - X_2}{X_1} \times 100\%$$

where: %D = percent difference
X₁ = first value
X₂ = second value

percent recovery

A measure of accuracy determined from the comparison of a reported spike value to its true spike concentration.

$$\%R = \frac{\text{observed conc.} - \text{sample conc.}}{\text{true spike conc.}} \times 100\%$$

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 (ANSI/ASQC-E-41994)

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)

Relative percent different (RPD)

Statistic for evaluating the precision of a replicate set. For replicate results:

$$RPD = \left[\frac{|X_1 - X_2|}{\left(\frac{X_1 + X_2}{2} \right)} \right] \times 100$$

where: X_1 = first observed concentration

X_2 = second observed concentration

Relative response factor (RRF)

A measure of the relative mass spectral response of a compound compared to its internal standard. RRFs are determined by analysis of standards and are used in the calculation of concentrations of analytes in samples. Because a RRF is the comparison of two responses, it is a unitless number. RRFs are determined by the following equation:

$$RRF = \frac{A_x}{A_{IS}} \times \frac{C_{IS}}{C_x}$$

where: A = area of the characteristic ion measured

C = concentration

IS = internal standard
x = analyte of interest

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)

Reporting limit (RL)

One of two types of reporting limit conventions within STL Denver. The Reporting Limit (RL) is a uniform, STL-wide reporting limit based on an evaluation of the PQLs at STL laboratories and the expected method performance in routine water and soil matrices. Project Specific Reporting Limits (PSRLs) are reporting limits that are defined by project requirements.

Representativeness

Representativeness is the degree to which data accurately and precisely represent a characteristic of a population, a variation in a physical or chemical property at a sampling point, or an environmental condition. Data representativeness is primarily a function of sampling strategy; therefore, the sampling scheme must be designed to maximize representativeness.

Representativeness also relates to ensuring that, through sample homogeneity, the sample analysis result (concentration) is representative of the constituent concentration in the sample matrix. At each STL laboratory, every effort must be made to analyze an aliquot that is representative of the original sample, and to ensure the homogeneity of the sample before subsampling.

reproducibility

The precision, usually expressed as a standard deviation, measuring the variability among results of measurements of the same sample at different laboratories.

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 2nd 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 2nd 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.

If the mandated or requested test method does not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample and Matrix Spike. However, in cases where the components interfere with accurate assessment (such as simultaneously spiking chlordane, toxaphene and PCBs in Method 608), the test method has an extremely long list of components or components are incompatible, a representative number (at a minimum 10%) of the listed components may be used to control the test method. The selected components of each spiking mix shall represent all chemistries, elution patterns and masses permit specified analytes and other client requested components. However, the laboratory shall ensure that all reported components are used in the spike mixture within a two-year time period.. (NELAC)

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 addition

The procedure of adding known increments of the analyte of interest to a sample to cause increases in detection response to subsequently establish, by extrapolation of the plotted responses, the level of the analyte of interest present in the original sample.

Standard deviation

A measure of the dispersion about the mean of the elements in a population. The square root of the variance of a set of values:

$$s = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{X})^2}{n - 1}}$$

where: s = standard deviation

□ = sum of

X = observed values
n = number of observations

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)

Surrogate:

A substance with properties that mimic the analyte of interest. It is unlikely to be found in environment samples and is added to them for quality control purposes.

Surrogate compounds must be added to all samples, standards, and blanks, for all organic chromatography methods except when the matrix precludes its use or when a surrogate is not available. Poor surrogate recovery may indicate a problem with sample composition and shall be reported to the client whose sample produced poor recovery. (QAMS)

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:

Individual(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)

Toxic Substances Control Act (TSCA):

The enabling legislation in 15 USC 2601 et seq., (1976) that provides for testing, regulating, and screening all chemicals produced or imported into the United States for possible toxic effects prior to commercial manufacture. (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)

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.

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:

A2LA – American Association for Laboratory Accreditation
ASTM – American Society for Testing and Materials
BOD – Biological Oxygen Demand
BS – Blank Spike
BSD – Blank Spike Duplicate
CAR – Corrective Action Report
CCC – Calibration Check Compound
CCV – Calibration Verification
CF – Calibration Factor
CFR – Code of Federal Regulations
COC – Chain of Custody
COD – Chemical Oxygen Demand
CRS – Change Request Form
CUR – Condition Upon Receipt
DFTPP – Decafluorotriphenylphosphine
DOC – Demonstration of Capability
DOE – Department of Energy
DOT – Department of Transportation
DoD – Department of Defense
DQO – Data Quality Objectives
DU – Duplicate
DUP - Duplicate
EHS – Environment, Health and Safety
EPA – Environmental Protection Agency
GC - Gas Chromatography
GC/MS - Gas Chromatography/Mass Spectrometry
HDPE – High Density Polyethylene
HPLC - High Performance Liquid Chromatography
ICP - Inductively Coupled Plasma Atomic Emission Spectroscopy
ICS – Interference Check Sample
ICV – Initial Calibration Verification
IDL – Instrument Detection Limit
IH – Industrial Hygiene
IS – Internal Standard
ISO – International Organization for Standardization
LCL – Lower Control Limit
LCS – Laboratory Control Sample
LCSD – Laboratory Control Sample Duplicate
LIMS – Laboratory Information Management System
MDL – Method Detection Limit
MS – Matrix Spike
MSA – Method of Standard Additions
MSD – Matrix Spike Duplicate
MSDS - Material Safety Data Sheet
NELAC - National Environmental Laboratory Accreditation Conference
NELAP - National Environmental Laboratory Accreditation Program
NCM – Non-conformance Memo
NIST – National Institute of Standards Technology
NPDES – National Pollutant Discharge Elimination System

Acronyms con't:

PAH – Polyanuclear Aromatic Hydrocarbon
PCB – Polychlorinated biphenyl
PDS – Post Digestion Spike
PM – Project Manager
PQL – Practical Quantitation Limit
PSRL – Project Specific Reporting Limit
PT – Performance Testing
QAM – Quality Assurance Manual
QAPP – Quality Assurance Project Plan
QAS – Quality Assurance Summary
QA/QC – Quality Assurance / Quality Control
QAPP – Quality Assurance Project Plan
RCRA – Resource Conservation and Recovery Act
RF – Response Factor
RFP – Request for Proposal
RL – Reporting Limit
RPD – Relative Percent Difference
RRF – Relative Response Factor
RSD – Relative Standard Deviation
RSO – Radiation Safety Officer
SD – Standard Deviation
SDG – Sample Delivery Group
SOP - Standard Operating Procedure
SOW – Statement of Work
SPCC – System Performance Check Compound
SPLP – Synthetic Precipitation Leaching Procedure
SRM – Standard Reference Material
TCLP – Toxicity Characteristic Leaching Procedure
TIC – Tentatively Identified Compound
TAT – Turn-Around-Time
TKN – Total Kjeldahl Nitrogen
TOC – Total Organic Carbon
TOX – Total Organic Halides
UCL – Upper Control Limit
UPS – Uninterruptible Power Supply
USEPA – United States Environmental Protection Agency
VOA – Volatiles
VOC – Volatile Organic Compound
WS – Water Supply
WP – Water Pollution

Appendix 6.

Laboratory Certifications, Accreditations, Validations

TestAmerica Denver 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:

Organization	Certificate Number	Organization	Certificate Number
AFCEE	None	Nevada	CO0026
Alabama	40730	New Jersey	CO004
Alaska	UST-30	New Mexico	None
Arizona	AZ0713	North Carolina	358
Arkansas	88-0687	North Dakota	R-034
California	2513	Oklahoma	8614
Colorado	CO0026	Oregon	CO200001
Connecticut	PH-0686	Pennsylvania	68-00664
Florida	E87667	RAM License	Colorado 486-03
Georgia – DW	962	South Carolina	72002001
Georgia – NP & Soils	None	Tennessee	TN02944
Idaho	CO00026	USACE	Self Declared
Illinois	007726	USDA	S-60617
Iowa	370	Texas	T104704183
Kansas	E-10166	Utah	Quans5
Louisiana	02096	Washington	C1284
Maine	CO0002	Wisconsin	999615430
Maryland	268	West Virginia	354
Minnesota	11175AA		

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.

Claims of Accreditation Status

TestAmerica Denver 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 7. Data Qualifiers - Standard

Qualifier	Definition
*	Surrogate or Relative Percent Difference (RPD) is outside control limits.
A	Spiked analyte recovery is outside control limits.
B	Organics: Method blank contamination. The associated method blank contains the target analyte at a reportable level. Inorganics: Estimated result. Result is less than the RL
COL	More than 40% difference between the primary and confirmation detector results. The lower of the two results is reported.
DIL	The concentration is estimated or not reported due to dilution.
E	Estimated result. Result concentration exceeds the calibration range.
G	Inorganics: Elevated reporting limit. The reporting limit is elevated due to matrix interference.
J	Organics: Estimated result. Result is less than RL Inorganics: Method blank contamination. The associated method blank contains the target analyte at a reportable level.
L	Serial dilution of a digestate in the analytical batch indicates that physical and chemical interferences are present
N	Spiked analyte recovery is outside stated control limits.
NC	The recovery and/or RPD were not calculated.
ND	The analyte was not detected at the MDL concentration and with a measurable degree of confidence can be said not to be present at or above the RL concentration.
P	Relative percent difference (RPD) is outside stated control limits.
Q	Elevated reporting limit. The reporting limit is elevated due to high analyte levels.
V	General Chemistry: Elevated reporting limit due to limited sample volume.
Wa	Post digestion spike recovery fell between 40-85% due to matrix interference.
Wb	Post digestion spike recovery fell between 115-150% due to matrix interference.
I	Percent recovery is estimated since the results exceeded the calibration range.
T1	A tentatively identified compound that did not generate a spectral match of 80% or greater. Typically called "unknown"
T2	A tentatively identified compound with a spectral match of 80% or better
T3	A tentatively identified compound that was calibrated for by the lab, but not on the client target analyte list.
IC	Diluted due to high inorganic chloride.

This is not an exhaustive list of qualifiers. All qualifiers are defined on each data sheet.
Client specific qualifiers may also be used, and would also be defined on the data sheet.

Appendix 7 con't. Data Qualifiers – AFCEE 4.0

Qualifier	Definition
J	The analyte was positively identified; the quantitation is estimated due to discrepancies in meeting certain analyte-specific quality control criteria.
U	The analyte was analyzed for, but not detected. The associated numerical value is at or below the MDL.
F	The analyte was positively identified but the associated numerical value is above the MDL and below the RL.
R	The data are rejected due to deficiencies in the ability to analyze the sample and meet QC criteria.
Q	One or more quality control criteria (for example, LCS recovery, surrogate spike recovery, etc.) failed.
B	The analyte was found in an associated blank, as well as in the sample.
M	A matrix effect was present.
NC, MSB	The recovery and RPD were not calculated because the sample amount was greater than four times the spike amount.
NC, DIL	The recovery was not calculated because the sample was diluted four times or greater.
N	Inorganics: Spiked analyte recovery is outside stated control limits.
A	Organics: Spiked analyte recovery is outside stated control limits.
*	Surrogate or LCS is outside control limits.
UJ	The analyte was not detected; however, the result is estimated due to discrepancies in meeting certain analyte specific quality control criteria.

Appendix 7 con't. Data Qualifiers – DoD QSM Version 3

Qualifier	Definition
U	Undetected at the limit of detection. The associated data value is the limit of detection, adjusted by any dilution factor used in the analysis.
J	Estimated: The analyte was positively identified; the quantitation is estimated (for example, matrix interference, outside the calibration range).
B	Blank contamination: The analyte was detected in the associated method blank at a concentration greater than one-half the reporting limit.
B	Metals Forms 3, 5B and 9 (ICB, CCB, Post-Digestion Spike and Serial Dilution): Analyte was detected above the method detection limit but below the reporting limit.
Q	One or more quality control criteria (for example, LCS recovery, surrogate recovery) failed. Data usability should be carefully assessed by the project team.
A	Spiked analyte recovery is outside control limit.
MSB	The recovery and RPD were not calculated because the sample amount was greater than four times the spike amount.
NC DIL	The recovery and RPD were not calculated due to dilution.
N	Inorganics: Spiked analyte recovery is outside stated control limits.
A	Organics: Spiked analyte recovery is outside stated control limits.
*	Surrogate or LCS is outside control limits.