FACILITY SOP ATTACHMENT

SOP NUMBER: IR-QAM, Rev. 2 (06/21/13) **CHANGE FORM ID:** CF2

SOP TITLE: Quality Assurance Manual

REASON FOR ADDITION OR CHANGE (Use additional sheets if necessary):

Add procedure for client notification of SOP changes that could potentially affect reported client data

CHANGE OR ADDITION (Use additional sheets if necessary):

Add the following new paragraph immediately following the third paragraph of Section 7.3.1 (Project-Specific Quality Planning):

Whenever a new or revised technical SOP or SOP Change Form is issued, QA will notify all PMs if there are any changes that will affect how final results will be reported compared to the previous revision. QA and the PM will work together to ensure the client is properly notified of the change. Changes in a technical SOP that should be considered with regards to impact on client data include, but are not limited to:

- Increase in RL
- Deletion of target analytes from a method
- Change in method name or method reference e(e.g., 8260B to 8260C)
- Change in how target analytes are qualitatively or quantitatively determined (e.g., how peaks are identified, how integrations are performed)

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FACILITY SOP ATTACHMENT

SOP NUMBER: IR-QAM, Rev. 2 (06/21/13) **CHANGE FORM ID:** CF2

Prepared By: W. Daystrom

***APPROVED BY:**

Laboratory Director	Date 09/26/13
Quality Assurance Manager	Date 9-26-2013
Technical Manager (Chemistry)	Date 9/26/13
Technical Manager (Microbiology)	Date 9/26/13.

*Should be the same signature authorities of SOP being revised.

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FACILITY SOP ATTACHMENT

SOP NUMBER: IR-QAM, Rev. 2 (06/21/13)	**CHANGE FORM ID:** CF1

SOP TITLE: Quality Assurance Manual

REASON FOR ADDITION OR CHANGE (Use additional sheets if necessary):

Define criteria for reporting an LOD (MDL) and/or QL (RL) that have been adjusted for sample weight

CHANGE OR ADDITION (Use additional sheets if necessary):

Add the following to the end of Section 19.6.1.3 (Relationship of Limit of Detection to the Quantitation Limit):

The LOD (MDL) of the analyte shall be multiplied by a correction factor, when applicable, based on actual divided by expected sample weights. The adjusted LOD (MDL) shall not be reported if the adjustment lowers the LOD (MDL) by more than 50%.

The QL (RL) of the analyte shall be multiplied by a correction factor, when applicable, based on actual divided by expected sample weights. The adjusted QL (RL) cannot be lower than the lowest non-zero calibration level.

Prepared By: W. Daystrom

***APPROVED BY:**

Laboratory Director	Date 09/11/13
Quality Assurance Manager	Date 9-11-2013
Technical Manager (Chemistry)	Date 09/11/2013
Technical Manager (Microbiology)	Date 9/11/13.

*Should be the same signature authorities of SOP being revised.

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Quality Assurance Manual

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Quality Assurance Manual
Approval Signatories

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Technical Manager (Microbiology) – Priyuni Patel — Date: 6/21/13

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SECTION 2

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REFERENCED CORPORATE DOCUMENTS

Document Reference	Title
CA-Q-M-002	Corporate Quality Management Plan
CW-L-P-004	Ethics Policy
CW-L-S-002	Internal Investigation of Potential Data Discrepancies and Determination for Data Recall
CW-Q-S-001	Corporate Document Control & Archiving
CA-L-P-002	Contract Compliance Program
CA-L-S-002	Subcontracting Procedures
CA-C-S-001	Work Sharing Process
CW-F-S-007	Capital Expenditure Request and Controlled Purchases
CW-F-P-002	Company Wide Authorization Matrix
CW-F-P-004	Procurement and Contracts Policy
CA-Q-S-001	Solvent & Acid Lot Testing and Approval
CW-E-M-001	Environmental Health and Safety Manual
CA-T-P-001	Qualified Products List
CW-F-P-004	Procurement & Contracts Policy
CA-Q-S-004	Internal Auditing
CA-Q-S-008	Management Systems Review
CA-Q-WI-020	Instructions for Use of TestAmerica's Management Systems Review Workbook
CW-Q-S-002	Writing a Standard Operating Procedure (SOP)
CA-Q-S-006	Detection Limits
CA-Q-S-002	Acceptable Manual Integration Practices
CA-I-P-002	Electronic Reporting and Signature Policy

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REFERENCED LABORATORY DOCUMENTS

Document Reference	Title
IR-QA-DOC	Document Control & Review
IR-QA-CNTRLLIM	Control Charts and Statistical Process Control
IR-QA-TRAIN	Training and Documentation
IR-QA-MDL	Determination of Method Detection Limits
IR-IT-COMPSEC	Computer Security
IR-QA-STDCNTRL	Reagent and Standard Preparation, Control and Documentation
IR-SC-FIELD	Field Sampling
IR-QA SUBSAMP	Subsampling
IR-SC-LOGIN	Sample Login
IR-EHS-WASTE	Hazardous Waste Disposal

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SECTION 3

INTRODUCTION, SCOPE, AND APPLICABILITY

3.1 INTRODUCTION AND COMPLIANCE REFERENCES

TestAmerica Irvine's QAM is a document prepared to define the overall policies, organization objectives, and functional responsibilities for achieving TestAmerica's data quality goals. The 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 NELAC Standard, dated 2003 and with TNI Standard, dated 2009, Volume 1 Modules 2 and 4. In addition, the policies and procedures outlined in this manual are compliant with TestAmerica's CQMP (Corporate Quality Document No. CA-Q-M-002) and the various accreditation and certification programs listed in Appendix 3. The CQMP provides a summary of TestAmerica's quality and data integrity system. It contains requirements and general guidelines under which all TestAmerica facilities shall conduct their operations.

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.
- *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; Final Update IV, January 2008.*
- Federal Register, 40 CFR Parts 136, 141, 172, 173, 178, 179 and 261.
- *Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-R-05-004, January 2005)*
- *Statement of Work for Inorganics & Organics Analysis, SOM and ISM, current versions, USEPA Contract Laboratory Program Multi-media, Multi-concentration.*
- APHA, *Standard Methods for the Examination of Water and Wastewater,* 18th, 19th, 20th, 21st, 22nd, and on-line Editions.
- Toxic Substances Control Act (TSCA)

3.2 TERMS AND DEFINITIONS

A QA Program is a company-wide system designed to ensure that data produced by the laboratory 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 SOPs and QC. The TestAmerica program is

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designed to minimize systematic error, encourage constructive documented problem solving, and provide a framework for continuous improvement within the organization.

Refer to Appendix 2 for the Glossary/Acronyms.

3.3 SCOPE / FIELDS OF TESTING

The laboratory analyzes a broad range of environmental and industrial samples every month. Sample matrices vary among air, drinking water, effluent water, groundwater, hazardous waste, sludge, and soils. The QA Program contains specific procedures and methods to test samples for chemical, physical, and biological parameters. The Program also contains guidelines on maintaining documentation of analytical processes, reviewing results, servicing clients, and tracking samples through the laboratory. The technical and service requirements of all analytical requests are thoroughly evaluated before commitments are made to accept the work. Measurements are made using published reference methods or methods developed and validated by the laboratory.

The methods covered by this manual include the most frequently requested methodologies needed to provide analytical services in the United States and its territories. The specific list of test methods used by the laboratory can be found in the laboratory's QA server. The approach of this manual is to define the minimum level of QA and QC necessary to meet these requirements. All methods performed by the laboratory shall meet these criteria as appropriate. In some instances, QAPPs, project-specific 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 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 laboratory's best interest to follow the less stringent requirements.

3.4 MANAGEMENT OF THE MANUAL

3.4.1 Review Process

The template on which this manual is based is reviewed annually by Corporate Quality Management personnel to assure it remains in compliance with Section 3.1. This manual itself is reviewed annually by senior laboratory management to assure that it reflects current practices and meets the requirements of the laboratory's clients and regulators as well as the CQMP. 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 revisions of the document. All updates will be reviewed by the senior laboratory management staff. The laboratory updates and approves such changes according to the procedures in laboratory SOP No. IR-QA-DOC.

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SECTION 4

MANAGEMENT REQUIREMENTS

4.1 OVERVIEW

TestAmerica Irvine is a local operating unit of TestAmerica Laboratories, Inc. The organizational structure, responsibilities, and authorities of the corporate staff of TestAmerica Laboratories, Inc. are presented in the CQMP. The laboratory has day-to-day independent operational authority overseen by corporate officers (e.g., President, Chief Executive Officer, Corporate Quality, etc.). The laboratory's operational and support staff work under the direction of the Laboratory Director. The organizational structure for both Corporate and TestAmerica Irvine is presented in Figure 4-1.

4.2 ROLES AND RESPONSIBILITIES

In order for the QA Program to function properly, all members of the staff must clearly understand and meet their individual responsibilities as they relate to the QA Program. The following descriptions briefly define key roles and their relationship to the QA Program. All other roles are defined in the Human Resource files.

4.2.1 Additional Requirements for Laboratories

The responsibility for quality resides with every employee of the laboratory. All employees have access to the QAM, are trained to this manual, and are responsible for upholding the standards therein. Each employee 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. Role descriptions for Corporate employees are defined in the CQMP. This manual is specific to the operations of TestAmerica Irvine.

4.2.2 Laboratory Director

The Laboratory Director is responsible for the overall quality, safety, financial, technical, human resource, and service performance of the whole laboratory. The Laboratory Director provides the resources necessary to implement and maintain an effective and comprehensive QA and Data Integrity Program.

The Laboratory Director shall:

- Ensure that all tasks performed at the laboratory are conducted according to the requirements of this QAM and appropriate QAPPs (if applicable).
- Ensure 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.
- Ensure that employees are free from any commercial, financial, and other undue pressures which might adversely affect the quality of their work.

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- Ensure TestAmerica's human resource policies are adhered to and maintained.
- Ensure that sufficient numbers of qualified individuals are employed to supervise and perform the work of the laboratory.
- Communicate resource needs to Corporate Management.
- Supervise staff, set goals and objectives for both the business and the employees, and achieve the financial, business, and quality objectives of the laboratory.
- Establish the priority of sample analysis in order to meet QA and client deadlines.
- Maintain well-versed technical understanding of analytical methodology for the evaluation of laboratory operations, development of procedural improvements, investigation of nonconforming results, and implementation of corrective actions.
- Ensure that appropriate corrective actions are taken to address analyses identified as requiring such actions by internal and external performance or procedural audits. The Laboratory Director may temporarily suspend procedures that do not meet the standards set forth in the QAM or laboratory SOPs.
- Review and approve all SOPs prior to their implementation and ensure all approved SOPs are implemented and adhered to.
- Pursue and maintain appropriate laboratory certification and contract approvals.
- Ensure that client-specific reporting and QC requirements are met.

4.2.3 QA Manager or Designee

The QA Manager has responsibility and authority to ensure the continuous implementation of the Quality System.

The QA Manager reports directly to the Laboratory Director and to Corporate Quality, for advice and resources. Corporate Quality may be used as a resource in dealing with regulatory requirements, certifications, and other QA-related concerns.

The QA Manager shall:

- Serve as the focal point for QA/QC in the laboratory.
- Have functions independent from laboratory operations for which he/she has QA oversight.
- Have the final authority to accept or reject data and to stop work in progress in the event that procedures or practices compromise the validity or integrity of analytical data.

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- Communicate and monitor standards of performance to ensure that systems are in place to produce the level of quality defined in this document.
- Identify areas where corrective action is required and ensure implementation and completion of the resulting action.
- Notify laboratory management of deficiencies in the quality system and ensure corrective action is taken. Procedures that do not meet the standards set forth in the QAM or laboratory SOPs shall be investigated following the procedures outlined in Section 12 and, if deemed necessary, may be temporarily suspended during the investigation.
- Objectively monitor standards of performance in QA/QC without outside (e.g., managerial) influence.
- Maintain, improve, and evaluate the corrective action database and the corrective and preventive action systems.
- Prepare monthly reports to management.
- Maintain, approve, and implement the QAM.
- Conduct internal system and data audits to monitor laboratory conformance to the QAM, SOPs, and policies.
- Provide and document employee training regarding quality system, ethics, and client confidentiality.
- Evaluate the thoroughness and effectiveness of training.
- Review and approve documentation of analyst training records (e.g., demonstration of capability).
- Review and approve MDL studies and MDL verification, method validation studies, and statistical control limits.
- Have documented training and/or experience in QA/QC procedures and the laboratory's Quality System.
- Have a general knowledge of the analytical test methods for which data audit/review is performed (and/or have the means of getting this information when needed).
- Provide assistance in the development and approval of laboratory management documents including SOPs as well as the control, revision, and distribution thereof.
- Direct the controlled distribution of laboratory quality documents.
- Oversee laboratory participation in performance evaluation programs and regulatory certification and accreditation programs.
- Monitor and communicate to management regulatory changes that may affect the laboratory.
- Act as point of contact regarding QA matters for the laboratory, including external audits.

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- Develop suggestions and recommendations to improve quality systems.
- Comply with the 2009 TNI Standard and the 2003 NELAC Standard (if applicable).

4.2.4 Technical Manager or Designee

The Technical Manager's 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. At the Irvine Laboratory, the Technical Manager for the Chemistry Group is also the Operations Manager and reports to the Laboratory Director; the Technical Manager for the Microbiology Group is also the Department Manager for the Microbiology Department and reports to the Operations Manager.

The Technical Manager shall:

- Exercise day-to-day supervision of laboratory operations for the appropriate field of accreditation and reporting of results.
- Monitor the validity of the analyses performed and data generated in the laboratory to assure reliable data. This activity begins with the review and support of all new business contracts, ensuring data quality, analyzing internal and external nonconformances to identify root cause issues, implementing the resulting corrective and preventive actions, and facilitating the data review process (training, development, and accountability at the bench).
- Review and approve, with input from the QA Manager, proposals from marketing, in accordance with an established procedure for the review of requests and contracts.
- Manage laboratory operations: work scheduling, sample tracking, and prompt reporting of results.
- Supervise and train employees, set goals and objectives for the employees, and achieve the quality objectives of the laboratory.
- Determine qualifications required for technical positions and evaluate job candidates against those requirements.
- Certify technical laboratory employees based on education and background to ensure that employees have demonstrated capability in the activities for which they are responsible.
- Enhance efficiency and improve quality through technical advances and improved LIMS utilization.
- Forecast capital needs based on instrument life cycle and manage asset inventory.
- Coordinate audit responses with the Operations Group.

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- Comply with the 2009 TNI Standard and the 2003 NELAC Standard (if applicable).

4.2.5 Operations Manager

The Operations Manager manages and directs the analytical production sections of the laboratory and assists the Technical Manager in determining efficient means to maximize instrument utilization. The Operations Manager reports directly to the Laboratory Director. In the absence of the Operations Manager, the Laboratory Director will fulfill this role.

The Operations Manager shall:

- Evaluate the level of internal/external non-conformances for all departments.
- Continuously evaluate production capacity and improve capacity utilization.
- Continuously evaluate turnaround time and address any problems that may hinder meeting the required and committed turnaround time from the various departments.
- Develop and improve the training of all analysts in cooperation with the Technical Manager and the QA Manager and in compliance with regulatory requirements.
- Ensure efficient utilization of supplies.
- Constantly monitor and modify, if needed, the procedures for processing samples through the departments.
- Coordinate audit responses with Department Managers or supervisors.
- Comply with the 2009 TNI Standard and the 2003 NELAC Standard (if applicable).

4.2.6 Department Manager

Department Managers are accountable for all analyses and analysts under their experienced supervision. The scope of responsibility ranges from the new-hire process and existing technology through the ongoing training and development programs for existing analysts and new instrumentation. Department Managers report directly to the Operations Manager.

The Department Manager shall:

- Manage the department's laboratory operations including work scheduling, sample tracking, analysis, data review, and prompt reporting of results.
- Ensure that all tasks performed by the department are conducted according to the requirements of the QAM, laboratory SOPs, policies, and QAPPs (if applicable).

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- Perform frequent SOP reviews to ensure that current practices are consistent with the published SOP. Changes in procedures or deviations from the SOP must be immediately reported to the Operations Manager and the QA Manager for approval and update to the applicable SOP.
- Provide guidance to laboratory analysts in resolving problems encountered during daily sample preparation/analysis.
- Perform second-level review of raw data for accuracy and completeness, check calibrations and calculations, reconcile any nonconforming data, and accept or reject data based on conformance with established QA/QC criteria.
- Report nonconformance situations to the Operations Manager and the QA Manager.
- Provide written responses to external and internal audit issues.
- Identify, initiate, and implement corrective actions through root-cause analysis and investigations.
- Develop, implement, and schedule a system for preventive maintenance, troubleshooting, and repair of analytical instruments and equipment, to ensure they meet performance criteria and calibration requirements.
- Maintain adequate and valid inventory of reagents, standards, spare parts, and other relevant resources required to perform daily analysis.
- Ensure all logbooks are reviewed, maintained current, and are properly labeled or archived.
- Achieve optimum TAT on analyses and conform with holding times.
- Supervise, train, and set goals and objectives for the analysts to achieve the quality objectives of the laboratory.

4.2.7 Laboratory Analyst

The laboratory analyst is responsible for the generation, interpretation, review, and reporting of data. Laboratory analysts report directly to their respective Department Managers.

The laboratory analyst shall:

- Perform analyses based on understanding of and conformance to the requirements of the QAM, laboratory SOPs, policies, and QAPPs (if applicable).
- Ensure sample analysis is completed within specified holding time, and immediately notifies the Department Manager if holding time will not be met.
- Ensure that all steps related to sample analysis are timely and completely documented, with integrity and accuracy.

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- Document standard and sample preparation, instrument calibration and maintenance, and data calculations and review in logbooks, laboratory notebooks, bench sheets, and in the LIMS, as appropriate.
- Document all nonconformance situations, instrument problems, matrix effects, and QC failures, which might affect the quality and reliability of the data, in logbooks, laboratory notebooks, bench sheets, and in an NCM using the NCM program in the LIMS, as appropriate.
- Report changes or deviations from the SOPs to the Department Manager, who will then report the changes or deviations to the Operations Manager and the QA Manager.
- Perform 100% initial technical review of sample preparation, calculations, qualitative identification, and raw data, with the authority to stop, accept, or reject data based on conformance with well-defined QA/QC criteria. This review must be completed prior to submitting data for second-level review.
- Perform second-level review of data, as appropriate.
- Report analytical results within the specified TAT.
- Suggest method improvements to the Department Manager.
- Identify, initiate, and implement corrective actions through root-cause analysis and investigations.
- Monitor, calibrate, and maintain support laboratory equipment such as refrigerators, freezers, water systems, process meters, and gas supply systems, as necessary.

4.2.8 Client Services Manager

The CSM reports directly to the Client Service Director (Western Region) and indirectly to the Laboratory Director. The CSM serves as the interface between the laboratory's Project Management team, technical departments, and clients.

The CSM shall:

- Oversee training and growth of the Project Management team.
- Act as technical liaison for the Project Management team.
- Provide human resource management support to the Project Management team.
- Assist PMs with responses to client inquiries or with resolutions to problems or complaints.
- Ensure that client specifications, when known, are met by communicating project and QA requirements to the laboratory.
- Notify Department Managers or supervisors of incoming projects and sample delivery schedules.

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- Discuss with client any project-related problems, resolve service issues, and coordinate technical details with the laboratory staff.
- Monitor the status of projects in-house to ensure timely and accurate delivery of reports.
- Prepare price quotes or project bids.

4.2.9 Project Manager

The PM serves as the liaison between the laboratory and its clients and is instrumental in assisting both the laboratory and the client during the course of a project. PMs report directly to the CSM.

The PM shall:

- Understand contractual requirements and effectively communicate client needs to laboratory staff.
- Coordinate client requests for sample containers and other services.
- Coordinate/arrange sample pick-up from client offices or project sites.
- Notify laboratory staff of incoming projects and sample delivery schedules.
- Investigate problems with samples and containers received from the field.
- Review sample login sheets.
- Monitor analytical work progress, provide clients with project status, and ensure timely delivery of reports.
- Notify clients of project-related nonconformances, changes, or difficulties encountered during analysis.
- Assist clients with technical questions and coordinate communication with the laboratory staff regarding technical issues.
- Conduct completeness review of all reports generated for the project.
- Approve final reports, as designated by the Laboratory Director.
- Coordinate subcontract work.
- Resolve service issues and maintain client satisfaction.
- Prepare price quotes or project bids.

4.2.10 Sample Control Department Manager

The Sample Control Department Manager is responsible for the daily activities within the Sample Control department. The Sample Control Department Manager reports directly to the Operations Manager.

The Sample Control Department Manager shall:

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- Supervise the department's laboratory operations including, but not limited to, courier scheduling, initiation of container lot testing, sample container order preparation, sample receiving and tracking, shipping, and login.
- Ensure that all tasks performed by the department are conducted according to the requirements of the QAM, laboratory SOPs, policies, and QAPPs (if applicable).
- Perform frequent SOP reviews to ensure that current practices are consistent with the published SOP. Changes in procedures or deviations from the SOP must be immediately reported to the Operations Manager and the QA Manager for approval and update to the applicable SOP.
- Assist PMs and analysts in resolving inconsistencies and problems with samples received.
- Assist in routing workshare and subcontract analyses.
- Report nonconforming situations to the Operations Manager and the QA Manager.
- Provide written responses to external and internal audit issues.
- Identify, initiate, and implement corrective actions through root-cause analysis and investigations.
- Ensure all logbooks are reviewed, maintained current, and are properly labeled or archived.

4.2.11 Sample Control Technician

The Sample Control Technician is responsible for sample container order preparation, sample receiving and tracking, shipping, and login. The Sample Control Technician reports directly to the Sample Control Department Manager.

The Sample Control Technician shall:

- Conform to proper sample acceptance policies, sample receipt procedures, sample preservation, sample container order preparation, and shipment, as defined in the QAM, laboratory SOPs, policies, and QAPPs (if applicable).
- Ensure that all procedures related to sample control are timely and completely documented, with integrity and accuracy.
- Report changes or deviations from the SOPs to the Sample Control Department Manager, who will then report the changes or deviations to the Operations Manager and the QA Manager.
- Login client and QC (e.g., MDL study, PT, and storage blank) samples.
- Communicate with PMs and initiate NCMs for any anomalies or deficiencies identified during sample receipt.

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- Identify, initiate, and implement corrective actions through root-cause analysis and investigation.
- Suggest process improvements to the Sample Control Department Manager.
- Monitor, calibrate, and maintain support laboratory equipment such as refrigerators, freezers, and water systems, as necessary.
- Secure sample storage and preservation, and review storage monitoring records.
- Route workshare and subcontract analyses.
- Assist with sample disposal.

4.2.12 Environmental Health and Safety Coordinator

The EH&S Coordinator ensures that systems are maintained for the safe operation of the laboratory. The EH&S Coordinator reports directly to the Laboratory Director and to Corporate EH&S, for advice and resources.

The EH&S Coordinator shall:

- Conduct ongoing and necessary safety training for current and new employees.
- Assist in developing and maintaining the Chemical Hygiene/Safety Manual.
- Oversee the inspection and maintenance of general safety equipment (e.g., fire extinguishers, safety showers, eyewash fountains, etc.) and ensure prompt repairs when needed.
- Supervise and schedule fire drills and emergency evacuation drills.
- Ensure that general protective equipment are available when needed.
- Assist in the internal and external coordination of the medical consultation/monitoring program conducted by TestAmerica's medical consultants.
- Oversee hazardous waste accumulation and disposal, and maintain all hazardous waste-related documentation such as manifests, biennial reports, and waste profiles.

4.3 DEPUTIES

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

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Table 4-1. Key Personnel and Deputies

Key Personnel	Deputy[1]
Laboratory Director[2]	Operations Manager
QA Manager	Senior QA Specialist
Operations Manager	Laboratory Director
Department Manager	Department Group Leader
Client Services Manager	Department Group Leader
EH&S Coordinator	Laboratory Director

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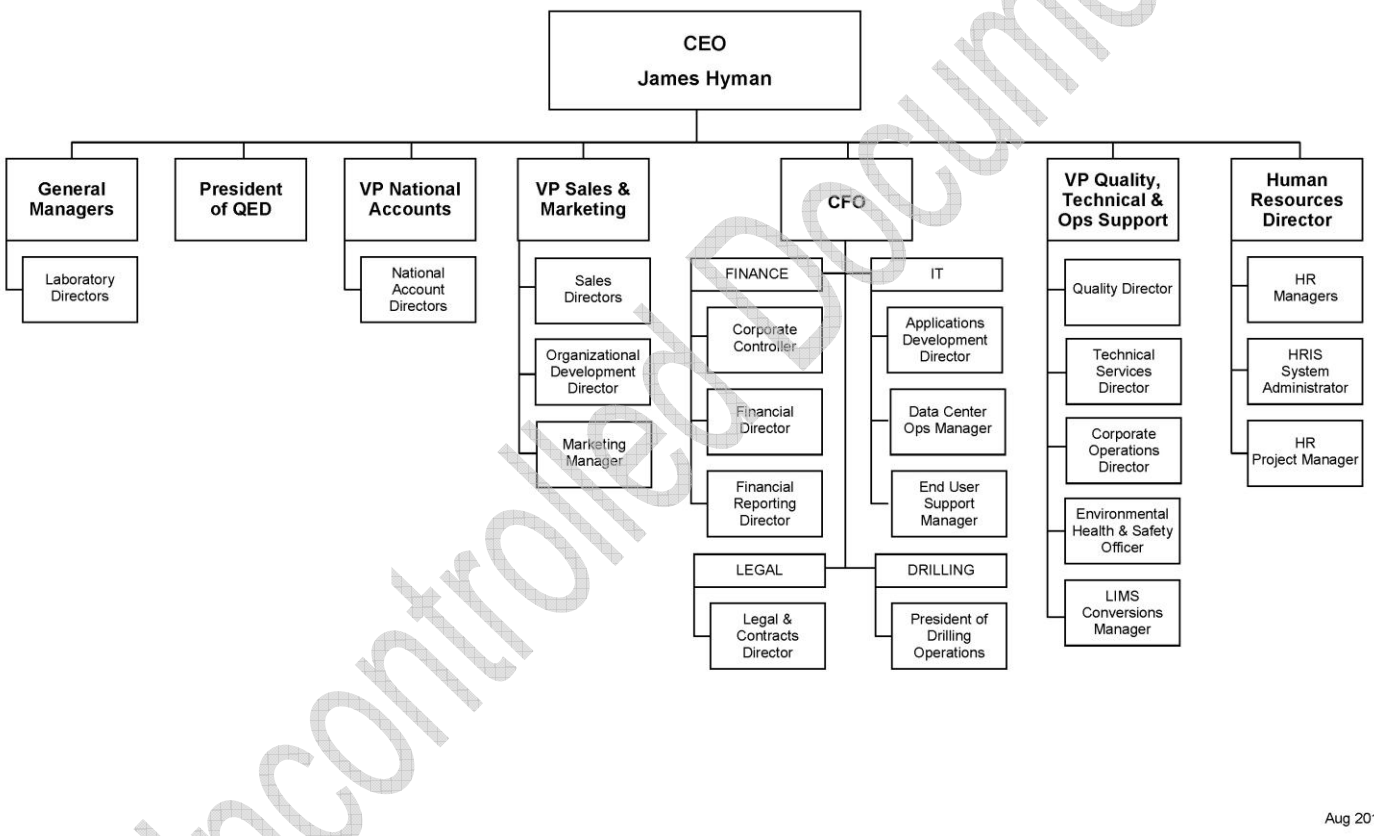
[1] The assigned deputy for each key person is another full-time staff member, at the laboratory, who meets the qualifications of the key person whose functions they would perform in their absence.
[2] If the Laboratory Director will be absent for more than 65 consecutive calendar days, the regulatory agencies shall be notified in writing.

Figure 4-1. Corporate and Laboratory Organization Charts

Corporate



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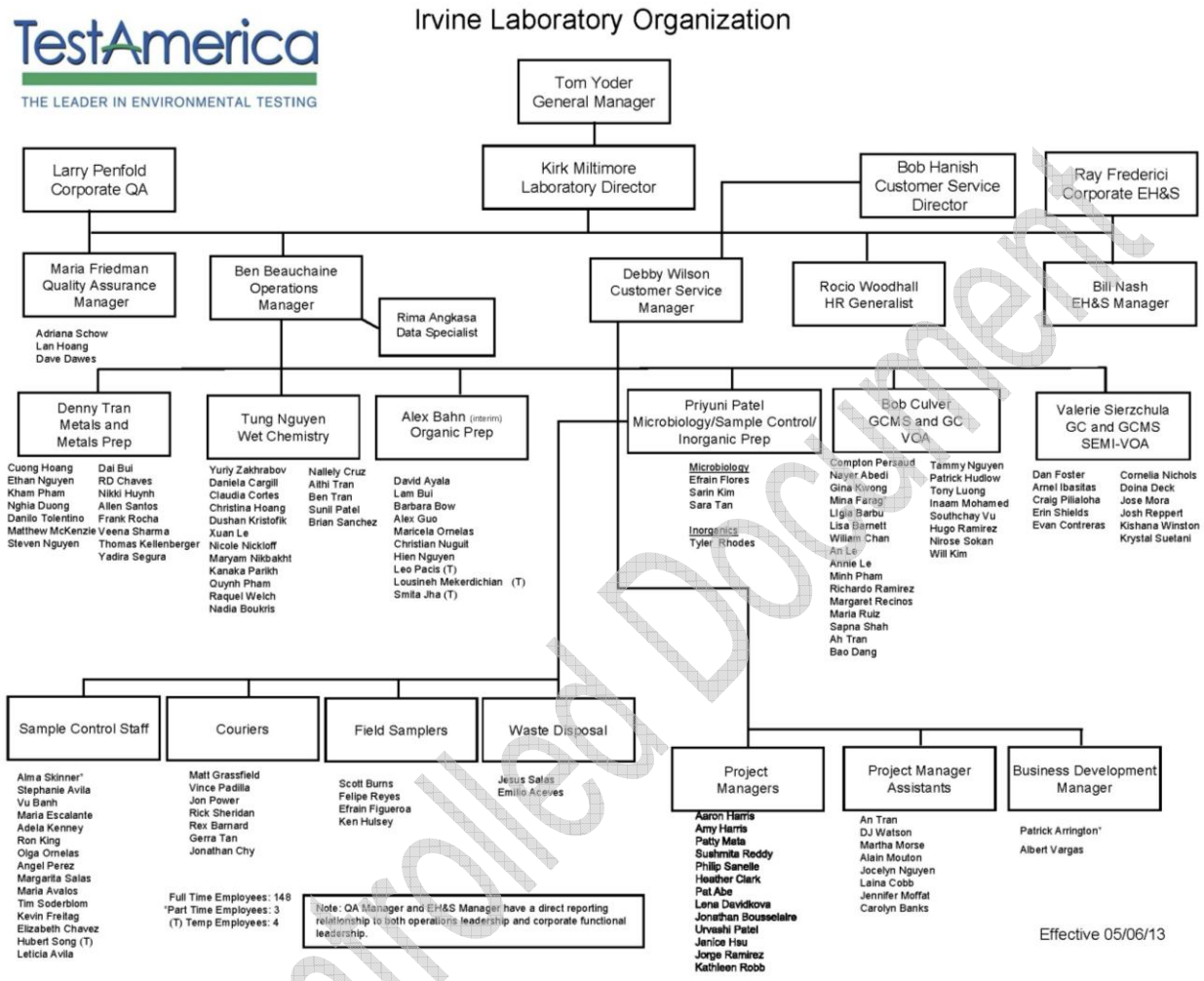

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SECTION 5

QUALITY SYSTEM

5.1 QUALITY POLICY STATEMENT

It is TestAmerica's Policy to:

- Provide data of known quality to its clients by adhering to approved methodologies, regulatory requirements, and the QA/QC protocols.
- Effectively manage all aspects of the laboratory and business operations by the highest ethical standards.
- Continually improve systems and provide support to quality improvement efforts in laboratory, administrative, and managerial activities. TestAmerica recognizes that the implementation of a QA program requires management's commitment and support as well as the involvement of the entire staff.
- Provide clients with the highest level of professionalism and the best service practices in the industry.
- Comply with ISO/IEC 17025:2005(E), the 2003 NELAC Standard, and the 2009 TNI Standard (if applicable).
- Continually improve the effectiveness of the management system.

Every staff member at the laboratory plays an integral part in QA and is held responsible and accountable for the quality of their work. It is, therefore, required that all laboratory staff 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 elements of TestAmerica's Ethics and Data Integrity Program include:

- An Ethics Policy (Corporate Legal Document No. CW-L-P-004) and Employee Ethics Statements
- ECOs
- 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 (Corporate Legal SOP No. CW-L-S-002)
- Procedures and guidance for recalling data, if necessary (Corporate Legal SOP No. CW-L-S-002)
- Effective external and internal monitoring system that includes procedures for internal audits (Section 15)

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- Production of results that are accurate and include QA/QC information that meets client's pre-defined DQOs
- Presentation of services in a confidential, honest, and forthright manner
- A means to provide employees with guidelines and an understanding of the Ethical and Quality Standards of our industry
- Operation of facilities in a manner that protects the environment and the health and safety of employees and the public
- Obedience or compliance with all pertinent federal, state, and local laws and regulations, and encouragement to other members of our industry to do the same
- Education of clients as to the extent and kinds of services available
- Assertion of competency only for work for which adequate personnel and equipment are available and for which adequate preparation has been made
- Promotion of the status of environmental laboratories, their employees, and the value of services rendered by them

5.3 QUALITY SYSTEM DOCUMENTATION

The laboratory's Quality System is communicated through a variety of documents:

- QAM – Each laboratory has a laboratory-specific QAM.
- 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, pre-formatted bench sheets, forms).
- Laboratory SOPs – General and Technical
- Laboratory QA/QC Policy Memorandums

5.3.1 Order of Precedence

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

- CQMP
- Corporate SOPs and Policies
- Laboratory QA/QC Policy Memorandum
- Laboratory QAM
- Laboratory SOPs and Policies
- Other (Work Instructions, memos, flow charts, etc.)

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Note: The laboratory has the responsibility and authority to operate in compliance with regulatory requirements of the jurisdiction in which the work is performed. Where the CQMP conflicts with those regulatory requirements, the regulatory requirements of the jurisdiction shall hold primacy. The laboratory QAM shall take precedence over the CQMP in those cases.

5.4 QA/QC OBJECTIVES FOR THE MEASUREMENT OF DATA

QA and QC are activities undertaken to achieve the goal of producing data that accurately characterize the sites or materials that have been sampled.

QA is generally understood to be more comprehensive than QC. QA can be defined as the integrated system of activities that ensures that a product or service meets defined standards.

QC 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 RLs.

RFPs and QAPPs provide a mechanism for the client and the laboratory to discuss the DQOs 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 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 DQOs 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, MSD, or LCSD samples.

5.4.2 Accuracy

The laboratory objective for accuracy is to meet the performance for accuracy demonstrated for the methods on similar samples and to meet DQOs 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

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use of LCS and/or MS. A statement of accuracy is expressed as an interval of acceptance recovery about the mean recovery.

5.4.3 Representativeness

The laboratory objective for representativeness is to provide data which is representative of the sampled medium. Representativeness is defined as the degree to which data represent a characteristic of a population or set of samples and is a measurement of both analytical and field sampling precision. The representativeness of the analytical data is a function of the procedures used in procuring and processing the samples. Representativeness can be documented by the RPD 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 RL 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 RLs, with those of other laboratories.

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 analytes and

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subsequently identified/detected through one or more of the following, depending on the analytical method: specific retention times (separation and identification), confirmations with different columns or detectors (separation and identification), specific mass spectra (identification), etc.

5.4.7 Sensitivity

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

5.5 CRITERIA FOR QUALITY INDICATORS

The laboratory maintains the precision and accuracy acceptability limits for performed analyses using the Analysis/Matrix table in the LIMS. This table includes an effective date, is updated each time new limits are generated, and is managed by the laboratory's QA department. Unless otherwise noted, limits within these tables are laboratory-generated. Some acceptability limits are derived from EPA methods when they are required. Where EPA method limits are not required, the laboratory has developed limits from evaluation of data from similar matrices. Criteria for development of control limits are contained in laboratory SOP No. IR-QA-CNTRLIM.

5.6 STATISTICAL QUALITY CONTROL

Statistically-derived precision and accuracy limits are required by selected methods and programs. The laboratory routinely utilizes statistically-derived limits to evaluate method performance and determine when corrective action is appropriate. The analysts are instructed to use the current limits in the LIMS (dated and approved by the QA Manager). All historical limits can be queries from the LIMS using the "Historical" feature. If a method defines the QC limits, the method limits are used.

If a method requires the generation of historical limits, the laboratory develops such limits from recent data in the QC database of the LIMS, following the guidelines described in laboratory SOP No. IR-QA-CNTRLIM. All calculations and limits are documented and dated when approved and effective. On occasion, clients request contract-specified limits for a specific project.

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 re-analyzed or if an NCM must be generated to explain the reason for the QC outlier and the corrective action performed.

5.6.1 QC Charts

When QC limits are calculated, QC charts are generated showing warning and control limits for the purpose of evaluating trends. The QA Manager evaluates these trends to determine if adjustments need to be made to the current QC limits or if a need for corrective action is indicated. All findings are documented and kept on file. Refer to laboratory SOP No. IR-QA-

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CNTRLIM for more details regarding generation of control limits and development of control charts.

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 16). These metrics are used to drive continuous improvement in the laboratory's Quality System.

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SECTION 6

DOCUMENT CONTROL

6.1 OVERVIEW

The QA department is responsible for the control of documents used in the laboratory to ensure that approved and 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:

- Laboratory QAM
- Laboratory SOPs
- Laboratory Policies
- Work Instructions and Forms
- Corporate Policies and Procedures distributed outside the Intranet

Corporate Quality posts Corporate Manuals, SOPs, Policies, Work Instructions, White Papers, and Training Materials on the company Intranet site. These Corporate documents are only considered controlled when they are read on the 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 Corporate documents is found in Corporate SOP No. CW-Q-S-001.

The laboratory posts SOPs and Policies on the local QA server. These documents are only considered controlled when they are read on the local QA server. Access to these documents via the local QA server is restricted to viewing only; documents cannot be printed. When a copy of these documents is requested, the QA Manager, or designee, provides an uncontrolled copy (watermarked or labeled as “Uncontrolled”).

The 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 (hardcopies 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, training files, MDL studies, PT studies, certifications and related correspondence, and NCMs. Raw analytical data consists of bound logbooks, instrument printouts, any other notes, magnetic media, electronic data, and final reports.

6.2 DOCUMENT APPROVAL AND ISSUE

The pertinent elements of a document control system for each document include a unique document title and number, pagination, the total number of pages of the item or

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an 'end of document' page, the effective date, the revision number, and the laboratory's name. The QA department is responsible for the maintenance of this system.

Controlled documents are authorized by the QA department. In order to develop a new document, a Department Manager or Supervisor submits a draft (hardcopy or electronic) to the QA department for suggestions and approval before use. Upon approval, the QA department adds the identifying version information to the document and retains that document as the official document on file. That document is then provided to all applicable operational units (may include electronic access). Controlled documents are identified as such and records of their distribution are kept by the QA department. Document control may be achieved by either electronic or hardcopy distribution.

The QA department maintains a list of the official versions of controlled documents.

Quality system policies and procedures will be reviewed at a minimum of every two years and revised as appropriate. Quality system policies and procedures that affect Drinking Water projects will be reviewed annually and revised as appropriate. Changes to documents occur when a procedural change warrants.

6.3 PROCEDURES FOR DOCUMENT CONTROL POLICY

For changes to the QAM, refer to the procedures discussed in Section 3.4.1. For changes to SOPs, refer to laboratory SOP No. IR-QA-DOC.

Forms, worksheets, Work Instructions, and information are organized by department in the local QA server.

Uncontrolled copies must not be used within the laboratory.

Subsequent employee training in these documents is discussed in laboratory SOP No. IR-QA-TRAIN.

6.4 OBSOLETE DOCUMENTS

All invalid or obsolete documents are removed, or otherwise prevented from unintended use, using specific procedures as described above. In general, obsolete documents are collected from employees according to distribution lists (if applicable) and are marked obsolete on the cover or destroyed. At least one copy of the obsolete document is archived for the retention period described in Section 14.

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SECTION 7

SERVICE TO THE CLIENT

7.1 OVERVIEW

The laboratory 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 the laboratory'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 laboratory's capability to perform them must be established. Projects, proposals, and contracts are reviewed for adequately defined requirements and the laboratory's capability to meet those requirements. Alternate test methods that are capable of meeting the client's requirements may be proposed by the laboratory. A review of the laboratory'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 (percent recovery), and precision requirements (RPD). The reviewer ensures that the laboratory's test methods are suitable to achieve these 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 TAT will be checked for feasibility.

Electronic or hardcopy deliverable requirements are evaluated against the laboratory'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 laboratory to complete the work satisfactorily. Any discrepancy between the client's requirements and the laboratory's capability to meet those requirements is resolved in writing before

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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, SAPs, contract amendments, and documented communications become part of the project record.

The same contract review process used for the initial review 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 PM is considered adequate. The PM confirms that the laboratory has any required certifications, that it can meet the client's data quality and reporting requirements and that the laboratory has the capacity to meet the client's TAT 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 Manager, who will decide which laboratory 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 Corporate Legal Document No. CA-L-P-002.

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

- Legal & Contracts Director
- General Manager
- Laboratory Operations Manager
- Laboratory CSM
- Laboratory PM
- Laboratory and/or Corporate Technical Manager
- Laboratory and/or Corporate IT
- AEs
- Laboratory and/or Corporate Quality
- Laboratory and/or Corporate EH&S
- Laboratory Director - reviews the formal laboratory quote and makes final acceptance for their facility

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The National Account Manager, 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 backup will fulfill the review requirements.

The Legal & Contracts Director maintains copies of all signed contracts. A copy is also kept with the assigned laboratory PM.

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. These records are kept on file with the assigned laboratory PM.

The contract will be distributed to and maintained by the appropriate sales/marketing personnel and the AE. A copy of the contract and formal quote will be filed with the laboratory PM and the Laboratory Director.

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 or e-mail documentation of conversations with the client. These records are stored with the project or client folder, as appropriate, and become part of the project records.

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, the laboratory assigns a PM to each client. It is the PM's and the Technical Manager'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.

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

The laboratory has established procedures in order to ensure that communication is inclusive and effective. These include, but are not limited to, use of project memos and QC summaries; discussion/notification during daily production meetings; conducting meetings with the project teams; and/or conducting start-up meetings between the laboratory personnel and the client.

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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, as stated above. Project notes are updated. After the modification is implemented into the laboratory process, documentation of the modification is made in the case narrative of the data report(s).

The laboratory 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.

7.4 SPECIAL SERVICES

The laboratory 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. The laboratory has procedures to ensure confidentiality to clients (Sections 15 and 25).

The laboratory's standard procedures for reporting data are described in Section 25. Special services are also available and provided upon request. These services include:

- Reasonable access for our clients or their representatives to the relevant areas of the laboratory for the witnessing of tests performed for the client.
- Assist client-specified third party data validators, as specified in the client's contract.
- Supplemental information pertaining to the analysis of their samples.

Note: An additional charge may apply for additional data/information that was not requested prior to the time of sample analysis or previously agreed upon.

7.5 CLIENT COMMUNICATION

PMs are the primary communication link to the clients. They shall inform their clients of any delays in project completion as well as any nonconformances in either sample receipt or sample analysis. Project Management will maintain ongoing client communication throughout the entire client project.

The Laboratory Director, QA Manager, and Technical Manager are available to discuss any technical questions or concerns that the client may have.

7.6 REPORTING

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The laboratory works with our clients to produce any special communication reports required by the contract.

7.7 CLIENT SURVEYS

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

TestAmerica's Sales and Marketing teams periodically develop laboratory- and client-specific surveys to assess client satisfaction.

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SECTION 8

SUBCONTRACTING OF TESTS

8.1 OVERVIEW

For the purpose of this QAM, the phrase "subcontract laboratory" refers to a laboratory external to the TestAmerica laboratories. The phrase "worksharing" refers to internal transfers of samples between the TestAmerica 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 the need arises to outsource testing for our clients because of project scope, changes in laboratory capabilities, capacity, or unforeseen circumstances, we must be assured that the subcontractors or worksharing laboratories understand the requirements and will meet the same commitments we have made to the client. Refer to Corporate Legal Document No. CA-L-S-002 regarding subcontracting and to Customer Service Document No. CA-C-S-001 regarding worksharing.

When outsourcing analytical services, the laboratory will assure, to the extent necessary, that the subcontract or workshare laboratory maintains a program consistent with the requirements of this document, the requirements specified in NELAC/TNI/ISO 17025 and/or the client's 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/non-TNI accredited work where required.

PMs, CSMs, and AEs 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 worksharing arrangement in writing and, when possible, approval from the client shall be retained in the client folder or project folder.

Note: In addition to the client, some regulatory agencies (e.g., USDA) or contracts, may require notification prior to placing such work.

8.2 QUALIFYING AND MONITORING SUBCONTRACTORS

Whenever a PM (or CSM or AE) becomes aware of a client requirement or laboratory need where samples must be outsourced to another laboratory, the other laboratory shall be selected based on the following:

- The first priority is to attempt to place the work in a qualified TestAmerica 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 client folder or

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project folder.

- Firms listed as pre-qualified and currently under a subcontract with TestAmerica. A listing of all approved subcontract laboratories is available on the TestAmerica Intranet site. Supporting documentation is maintained by Corporate offices and by the TestAmerica laboratory originally requesting approval of the subcontract laboratory. Verify necessary accreditation, where applicable (e.g., NELAC, TNI, A2LA, or State certification).
- Firms identified in accordance with the company's Small Business Subcontracting program as small, women-owned, veteran-owned, and/or minority-owned businesses.
- NELAC/TNI or A2LA accredited laboratories.
- Firms selected must hold the appropriate certification to perform the work required.

All TestAmerica laboratories are pre-qualified for worksharing 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 acknowledgment that the samples can be sent to that laboratory (an e-mail is sufficient documentation or if acknowledgment is verbal, the date, time, and name of person providing acknowledgment must be documented). The originating laboratory is responsible for communicating all technical, quality, and deliverable requirements as well as other contract needs. Refer to Customer Service Document No. CA-C-S-001 regarding worksharing.

When the potential subcontract laboratory has not been previously approved, AEs or PMs may nominate a laboratory as a subcontractor based on need. The decision to nominate a laboratory must be approved by the Laboratory Director. The Laboratory Director requests that the QA Manager begin the process of approving the subcontract laboratory, as outlined in Corporate Legal Document No. CA-L-S-002 on subcontracting. The client must provide acknowledgment that the samples can be sent to that laboratory (an e-mail is sufficient documentation or if acknowledgment is verbal, the date, time, and name of person providing acknowledgment must be documented).

8.2.1 Once the appropriate accreditation and legal information is received by the laboratory, it is evaluated for acceptability (where applicable) and forwarded to Corporate Contracts for formal contracting with the laboratory. They will add the laboratory to the approved list on the Intranet site and notify the Finance Group for JD Edwards assignment.

8.2.2 The client will assume responsibility for the quality of the data generated from the use of a subcontractor they have requested the laboratory to use. The qualified subcontractors on the Intranet site are known to meet minimal standards. TestAmerica does not certify laboratories. The subcontractor is on our approved list and can only be recommended to the extent that we would use them.

8.2.3 The status and performance of qualified subcontractors will be monitored periodically by the Corporate Contracts and/or Quality departments. Any

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problems identified will be brought to the attention of TestAmerica's Corporate Finance or Corporate Quality personnel.

- 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.
- Information must be updated on the Intranet when new information is received from the subcontract laboratories.
- Subcontractors in good standing will be retained on the Intranet listing. The QA Manager will notify all TestAmerica laboratories, Corporate Quality, 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 Laboratory Directors, QA Managers, and Sales personnel.

8.3 OVERSIGHT AND REPORTING

The PM must request that the selected subcontractor be presented with a subcontract, if one is not already executed between the laboratory and the subcontractor. The subcontract must include terms which flow down the requirements of our clients, either in the subcontract itself or through the mechanism of jobs relating to individual projects. A standard subcontract and the Laboratory 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 AE 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 subcontract laboratory, the PM confirms their certification status to determine if it is current and scope-inclusive. The information is documented in a Subcontracted Sample Form (Figure 8-1) and the form is retained in the client folder or project folder. For TestAmerica laboratories, certifications can be viewed on the company's TotalAccess Database.

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

All subcontracted samples must be accompanied by a TestAmerica COC form. A copy of the original COC sent by the client must also be included with all samples workshared within TestAmerica. Client COCs are only forwarded to external subcontractors when samples are shipped directly from the project site to the subcontract laboratory. Under routine circumstances, client COCs are not provided to external subcontractors.

Through communication with the subcontract laboratory, the PM monitors the status of the subcontracted analyses, facilitates successful execution of the work, and ensures the timeliness and completeness of the analytical report.

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

Reports submitted from subcontract 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 subcontract laboratory. If subcontract laboratory data is incorporated into the originating laboratory's EDD (i.e., imported), the report must explicitly indicate which laboratory produced the data for which methods and samples. A copy of the subcontract laboratory's report must be included in the originating laboratory's final report, regardless of whether the subcontract laboratory's results are incorporated into the originating laboratory's report.

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

8.4 CONTINGENCY PLANNING

The Laboratory Director may waive the full qualification of a subcontractor process temporarily to meet emergency needs; however, this decision and justification must be documented in the client files or project files and the Purchase Order Terms and Conditions For Subcontracted Laboratory Services must be sent with the samples and COC. In the event this provision is utilized, the laboratory (e.g., PM) will be required to verify and document the applicable accreditations of the subcontractor. All other quality and accreditation requirements will still be applicable, but the subcontractor need not have signed a subcontract with TestAmerica at this time. The comprehensive approval process must then be initiated within 30 calendar days of subcontracting.

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Figure 8-1.

Example - Subcontracted Sample Form

Date/Time: _____

Subcontracted Laboratory Information:

- Subcontractor's Name:
- Subcontractor Point of Contact: _____
- Subcontractor's Address: _____
- Subcontractor's Phone: _____
- Analyte/Method: _____
- Certified for State of Origin: _____
- NELAC/TNI Certified: Yes_____No_____
- **USDA Permit (__Domestic __ Foreign)** **Yes**_____**No**_____
- A2LA (or ISO 17025) Certified: Yes_____No_____
- CLP-like Required: Yes_____No_____
  (Full doc required)
- Requested Sample Due Date: _____
  (Must be put on COC)
- Client POC Approval on file to Subcontract Samples to Sub Laboratory Yes_____No_____

Project Manager: _____

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

Laboratory Project Number (Billing Control #): _____

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

PM Signature_____**Date**_____

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SECTION 9

PURCHASING SERVICES AND SUPPLIES

9.1 OVERVIEW

Evaluation and selection of suppliers and vendors is performed, in part, on the basis of the quality of their products, their ability to meet the demand for their products on a continuous and short-term basis, the overall quality of their services, their past history, and competitive pricing. This is achieved through evaluation of objective evidence of quality furnished by the supplier, which can include certificates of analysis, recommendations, and proof of historical compliance with similar programs for other clients. To ensure that quality critical consumables and equipment conform to specified requirements, which may affect quality, all purchases from specific vendors are approved by a member of the supervisory or management staff. Capital expenditures are made in accordance with Corporate Finance Document No. CW-F-S-007.

Contracts will be signed in accordance with Corporate Finance Document No. CW-F-P-002. RFPs will be issued where more information is required from the potential vendors than just price. Process details regarding procurement are available in Corporate Finance Policy No. CW-F-P-004. RFPs allow TestAmerica to determine if a vendor is capable of meeting requirements such as supplying to all of the TestAmerica laboratories, 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.

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, AND SUPPLIES

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 Quality Document No. CA-Q-S-001.

9.3.1 Purchasing

Chemical reagents, solvents, glassware, and general supplies are ordered as needed to maintain sufficient quantities on hand. Materials used in the analytical process must be 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 laboratory SOPs.

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The analyst completes a requisition in JD Edwards when requesting reagents, standards, or supplies or, for select items, may check the item out of the on-site consignment system that contains items approved for laboratory use. The Operations Manager approves orders placed in JD Edwards, as necessary.

9.3.2 Receiving

It is the responsibility of the Sample Control department to receive the shipment. It is the responsibility of the analyst who ordered the materials to document the date the materials were received. Once the ordered reagents or materials are received, the analyst compares the information on the label or packaging to the original order to ensure that the purchase meets the quality level specified. MSDS are available 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

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, analytical reagent grade will 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 date noted in the laboratory SOPs. If expiration 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 and solvents, unless noted otherwise by the manufacturer or by the reference source method. Chemicals/solvents should not be used past the manufacturer's or SOP's expiration date.

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. To prevent a tank from going to dryness, or introducing potential impurities, the pressure should be closely watched as it decreases to approximately 15% of the original reading, at which point it should be replaced. For example, a standard sized laboratory gas cylinder containing 3,000 psig of gas should be replaced when it drops to approximately 500 psig. 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 specific conductivity of less than 1- µmho/cm (or specific resistivity greater than 1.0

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megaohm-cm) at 25°C. The specific conductivity (or specific resistivity) is checked and recorded daily. If the water's specific conductivity is greater than the specified limits, the Department Manager, Technical Manager, and QA Manager must be notified immediately in order to decide on cessation (based on intended use) of activities, and make arrangements for correction. More stringent method or client requirements, when applicable, must be met.

The laboratory may purchase reagent grade (or other similar quality) water 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 must be documented and submitted to the QA department.

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 bottleware used for sampling must be certified clean and the certificates must be maintained. If uncertified sampling bottleware is purchased, all lots must be verified clean prior to use. This verification must be documented and submitted to the QA department.

Records of manufacturer's certification and traceability statements are maintained in files or binders in each laboratory section or uploaded in the LIMS. These records include, at a minimum, the date of receipt, the lot number (when applicable), and the expiration date (when applicable). Incorporation of the item into the record indicates that the analyst has compared the new certificate with the previous one for the same purpose and that no difference is noted, unless approved and so documented by the Technical Manager or QA Manager.

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. Storage conditions must meet the Corporate EH&S Document No. CW-E-M-001 and laboratory SOPs or manufacturer instructions.

9.4 PURCHASE OF EQUIPMENT / INSTRUMENTS / SOFTWARE

When a new piece of equipment/instrument/software is needed, either for additional capacity or for replacing inoperable ones, the analyst or the Department Manager makes a request to the Technical Manager and/or the Laboratory Director. If they agree, the procedures outlined in Corporate Technical Services Document No. CA-T-P-001, regarding qualified products list, are followed. A decision is made as to which piece of equipment/instrument/software can best satisfy the requirements. The appropriate written requests are completed and the Corporate Purchasing Group places the order.

Upon receipt of a new or used piece of equipment/instrument, a New Instrumentation Checklist is initiated (see figure 9-1). The checklist must be submitted to the QA department so that the equipment/instrument may be assigned an identification name

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and added to the equipment/instrument list. QA will also notify the IT department so that the instrument may be synchronized for backups. The capability of the equipment/instrument is assessed to determine if it is adequate for the specific application. A calibration curve is generated, followed by MDL studies, DOCs, and other relevant criteria (refer to Section 19). The manufacturer's operation manual is retained at the laboratory bench.

Upon receipt of new software, the IT department is notified so that the new software may be added to the software list. The capability of the software is assessed to determine if it is adequate for the specific application. Its operation must be deemed reliable and evidence of verification must be retained by either the IT department or the QA department, depending on software use. Software certificates supplied by the vendors, if any, are filed with the IT department. Records of software purchases are also maintained by the IT department.

9.5 SERVICES

Service to analytical instruments (except analytical balances) is performed on an as-needed basis. Routine preventative maintenance is discussed in Section 20. The need for service is determined by analysts, Department Managers, or the Technical Manager. The service providers that perform the services are approved by the Technical Manager and the Laboratory Director.

9.6 SUPPLIERS

TestAmerica selects vendors through a competitive proposal/bid process, strategic business alliances, or negotiated vendor partnerships (contracts). This process is defined in Corporate Finance Policy No. CW-F-P-004. The level of control used in the selection process is dependent on the anticipated spending amount 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.

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.

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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 JD Edwards Vendor Add Request Form.

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 is consulted with vendor and product selection that have an impact on quality.

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Figure 9-1.

New Instrumentation Checklist

Instrumentation/Equipment Checklist

To be completed by the department:

Department:			
ID Number:			
Date Installed:			
Method(s) Performed:			

Type*:			
Manufacturer:			
Model Number:			
Serial Number:			

*IC, GC, Autosampler, Balance, ASE etc.

To be completed by QA:

Item	Applicable	Date/ Initials	Comments
Maintenance/monitoring logbook created	Yes☐ No☐		
IT informed (so data backup process can be updated)	Yes☐ No☐		
Instrument tagged with ID number	Yes☐ No☐		
Instrument ID number entered into Element	Yes☐ No☐		
Calibrated thermometer placed in unit	Yes☐ No☐		
Instrument has been added to MDL database	Yes☐ No☐		
Laboratory equipment list updated	Yes☐ No☐		

G:\EQUIPMENT\New Instrumentation Checklist_r2.doc
Version 07/09/2009

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SECTION 10

COMPLAINTS

10.1 OVERVIEW

The laboratory considers an effective client complaint handling processes to be of significant business and strategic value. Listening to and documenting client concerns captures 'client knowledge' that enables our operations to continually improve processes and 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 (e.g., communication, 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 addressing both external and internal complaints with the goal of providing satisfactory resolution to complaints in a timely and professional manner.

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 12. The laboratory utilizes the NCM program in the LIMS or the laboratory's iCAT program, as appropriate, to document complaints and the corrective actions performed.

10.2 EXTERNAL COMPLAINTS

An employee that receives a complaint initiates the complaint resolution process by first documenting the complaint in an NCM or in the iCAT, as appropriate.

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 likelihood of future occurrence and mitigation of client impact.

The general steps in the complaint handling process are:

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- Receiving and Documenting 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.

10.3 INTERNAL COMPLAINTS

Internal complaints include, but are not limited to, errors and nonconformances, 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 12. In addition, Corporate Management, Sales and Marketing, and IT may initiate a complaint by contacting the laboratory or through the corrective action system described in Section 12.

10.4 MANAGEMENT REVIEW

The number and nature of client complaints is reported by the QA Manager to the Laboratory Director, the General Manager, and the Corporate Quality 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 Systems Review (Section 16).

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SECTION 11

CONTROL OF NONCONFORMING WORK

11.1 OVERVIEW

When data discrepancies are discovered or deviations and departures from laboratory SOPs, 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 12).

Due to the frequently unique nature of environmental samples, sometimes, departures from documented policies and procedures are needed. When an analyst encounters such a situation, the problem is presented to the Department Manager. The Department Manager discusses the reason for the departure and proposes a resolution to the Technical Manager and the QA Manager. Depending on the nature of the departure, the PM or the Laboratory Director may be involved to contact the client to decide on a logical course of action. The analyst documents the departure using the NCM program in the LIMS. The NCM is then attached to the final report to the client.

Project Management may encounter situations whereby a client may request that a special procedure that is not standard laboratory practice be applied to a sample. The laboratory 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 laboratory does not normally report. The laboratory would not have validated the method for this compound following the procedures in Section 19 and would have to do so if it chooses to accept the request. Another example might be a request to report a compound based only on a one-point calibration. Such a request would need to be approved by the Technical Manager and the QA Manager, documented, and included in the client folder or project folder.

Any compound reported that is not in compliance with NELAC or TNI Standard or the analytical method requirements must be reported in an NCM. In addition, regardless of whether the data is being reported to a NELAC/TNI or non-NELAC/non-TNI state, deviations must be reported in an NCM. Deviations must be noted and explained in the final reports to the client.

11.2 RESPONSIBILITIES AND AUTHORITIES

Corporate Legal SOP No. CW-L-S-002 outlines the general procedures for the reporting and investigation of data discrepancies and alleged incidents of misconduct or violations of TestAmerica's data integrity policies as well as the policies and procedures related to the determination of the potential need to recall data.

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Under certain circumstances, the Laboratory Director, the Technical Manager, or the QA Manager may 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 re-analyze, 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. This information may also be documented in logbooks and/or data review checklists, as appropriate. 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 Management (Laboratory Director, QA Manager, and Operations Manager) within 24 hours of discovery. The reporting of issues involving alleged violations of the company's Data Integrity or Manual Integration procedures must be conveyed to an ECO, to the Director of Quality & Client Advocacy, and to the laboratory's Corporate Quality Director within 24 hours of discovery.

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, the QA Manager, the ECOs, Corporate Quality, General Managers, and the Quality Directors 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.

11.3 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.

Corporate Legal SOP No. CW-L-S-002 distinguishes between situations when it would be appropriate for laboratory management 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 ECOs and Corporate Management. Laboratory level decisions are documented and approved using the laboratory's standard nonconformance/corrective action reporting in lieu of the data recall determination form contained in Corporate Legal SOP No. CW-L-S-002.

11.4 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. On a monthly basis, the QA department evaluates nonconformances to determine if any nonconforming work

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has been repeated multiple times. If so, the laboratory's corrective action process may be followed.

11.5 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 personnel noted in Section 11.2, Paragraph 5.

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

The Laboratory Director shall arrange for the appropriate personnel to meet with the QA Manager, as needed. This meeting shall be held to confirm that there is a problem, that suspension/restriction of the method is required and will be concluded with a discussion of the steps necessary to bring the method/target analyte 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 analyte, or test fully back on line.

The QA Manager will also initiate a corrective action report, as described in Section 12, 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 Quality. This fax/e-mail acts as notification of the incident.

After suspension/restriction, the laboratory will hold all reports to clients pending review. No faxing, mailing, or distributing through electronic means may occur. The report must not be posted for viewing on the Internet. It is the responsibility of the Laboratory Director to hold all reporting and to notify all relevant laboratory personnel regarding the suspension/restriction (i.e., Project Management, Sample Control, etc.). Clients will NOT generally be notified at this time. Analysis may proceed in some instances, depending on the nonconformance issue.

Within 72 hours, the QA Manager will determine if conformance is now met and reports can be released, OR determine the plan of action to bring work into conformance, and release work. A team, with all principals involved (Laboratory Director, QA Manager, and Operations Manager) can devise a start-up plan to cover all steps from client notification through conformance and release of reports. Project Management and the Directors of Client Services and Sales and Marketing must 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.

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SECTION 12

CORRECTIVE ACTION

12.1 OVERVIEW

A major component of TestAmerica's 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 recurrence. Corrective actions are documented using the NCM program in the LIMS or the iCAT, as appropriate. Refer to Figure 12-1 and 12-2, respectively.

12.2 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, PT performance, client complaints, staff observation, etc.

The purpose of a corrective action system is to:

- Identify nonconformance events and assign responsibility for investigating.
- Resolve nonconformance events and assign responsibility for any required corrective action.
- Identify systematic problems before they become serious.
- Identify and track client complaints and provide resolution.

12.2.1 **NCM** – The NCM program in the LIMS is used to document nonconformances (e.g., anomalies and deficiencies). The types of nonconformances to be reported include, but are not limited to, the following:

- Deviations from an established procedure or SOP
- QC outside of limits
- Isolated reporting/calculation errors
- Client complaints requiring report revisions
- Discrepancies in materials / goods received vs. manufacturer packing slips

12.2.2 **iCAT** – The iCAT program is used to document incidents and complaints that are not considered isolated incidents, as well as those that require greater flexibility in the assignment and tracking of corrective actions and associated communications than is afforded by the NCM program. The types of incidents and complaints to be reported in the iCAT include, but are not limited to, the following:

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- Client complaints
- Internal and external audit findings
- Systematic reporting/calculation errors
- Identified poor process and method performance or questionable trends that are found in the review of NCMs
- Issues found while reviewing NCMs that warrant further investigation
- Data recall investigations
- Failed or unacceptable PT results
- Excessive revised reports

This will provide background documentation to enable root cause analysis and preventive action.

12.3 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.

12.3.1 Cause Analysis

- Upon discovery of a nonconformance event, the event must be defined and documented. An NCM or an iCAT record must be initiated, someone is assigned to investigate the issue, and the event is investigated for cause. Table 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 Operations Manager, the Laboratory Director, or the QA Manager are consulted.

12.3.2 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 the iCAT is used for this documentation.

12.3.3 Root Cause Analysis

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Root Cause Analysis is a class of problem solving (investigative) methods aimed at identifying the basic or causal factor(s) that underlie variation in performance or the occurrence of a significant failure. The Root Cause may be buried under seemingly innocuous events, many steps preceding the perceived failure. At first glance, the immediate response is typically directed at a symptom and not the cause. Typically, Root Cause Analysis would be best with three or more incidents to triangulate a weakness.

Systematically analyze and document the Root Causes of the more significant problems that are reported. Identify, track, and implement the corrective actions required to reduce the likelihood of recurrence of significant incidents. Trend the Root Cause data from these incidents to identify Root Causes that, when corrected, can lead to dramatic improvements in performance by eliminating entire classes of problems.

Identify the one event associated with problem and ask why this event occurred. Brainstorm the root causes of failures, for example, by asking why events occurred or conditions existed; and then why the cause occurred five consecutive times until you get to the Root Cause. For each of these sub events or causes, ask why it occurred. Repeat the process for the other events associated with the incident.

Root Cause Analysis does not mean the investigation is over. Look at technique, or other systems outside the normal indicators. Often, creative thinking will find Root Causes that ordinarily would be missed, and continue to plague the laboratory or operation.

12.3.4 Monitoring of the Corrective Actions

- The Laboratory Director, Technical Manager, and the QA Manager are responsible to ensure that the corrective action taken was effective.
- Ineffective actions are documented and re-evaluated until acceptable resolution is achieved. The Technical Manager is accountable to the Laboratory Director to ensure final acceptable resolution is achieved and documented appropriately.
- Each NCM is entered into the LIMS for tracking purposes and a monthly summary of all corrective actions is available for review to aid in ensuring that the corrective actions have taken effect.
- The QA Manager reviews monthly NCMs and iCAT issues for trends. Highlights are included in the QA monthly report (refer to Section 16). 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.

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12.3.5 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 conformance with its own policies and procedures, or on its conformance with state or federal requirements.
- 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.

(Also refer to Section 15.1.4, Special Audits.)

12.3.6 Timeline for corrective action responses

When anomalies, deficiencies, audit findings (internal and external), and client complaints affect the laboratory operations, corrective actions must be immediately initiated and put in place. To that effect, timely responses are expected from each laboratory employee. Table 12-2 defines the timeline for submitting corrective action responses.

12.4 TECHNICAL CORRECTIVE ACTIONS

In addition to providing acceptance criteria and specific protocols for technical corrective actions in the laboratory SOPs, the laboratory has general procedures to be followed to determine when departures from the documented policies, procedures, and QC have occurred (refer to Section 11). The documentation of these procedures is done using the NCM program in the LIMS or the laboratory's iCAT program, as appropriate.

Table 1 includes examples of general technical corrective actions. For specific criteria and corrective actions, refer to the analytical methods or specific laboratory SOPs.

Table 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 laboratory SOPs and in Sections 19 and 20. All corrective actions are reviewed monthly, at a minimum, by the QA Manager and highlights are included in the QA monthly report.

To the extent possible, samples shall be reported only if all QC 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 PM is notified via the NCM and appropriate corrective action (e.g., re-analysis) is taken and documented.

12.5 BASIC CORRECTIONS

When mistakes occur in records, each mistake shall be crossed-out [not obliterated (e.g. no white-out)], and the correct value entered alongside. All such corrections shall be

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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 information to a record. All additions made later to the initial record 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 12-1.

Example – NCM Program in LIMS

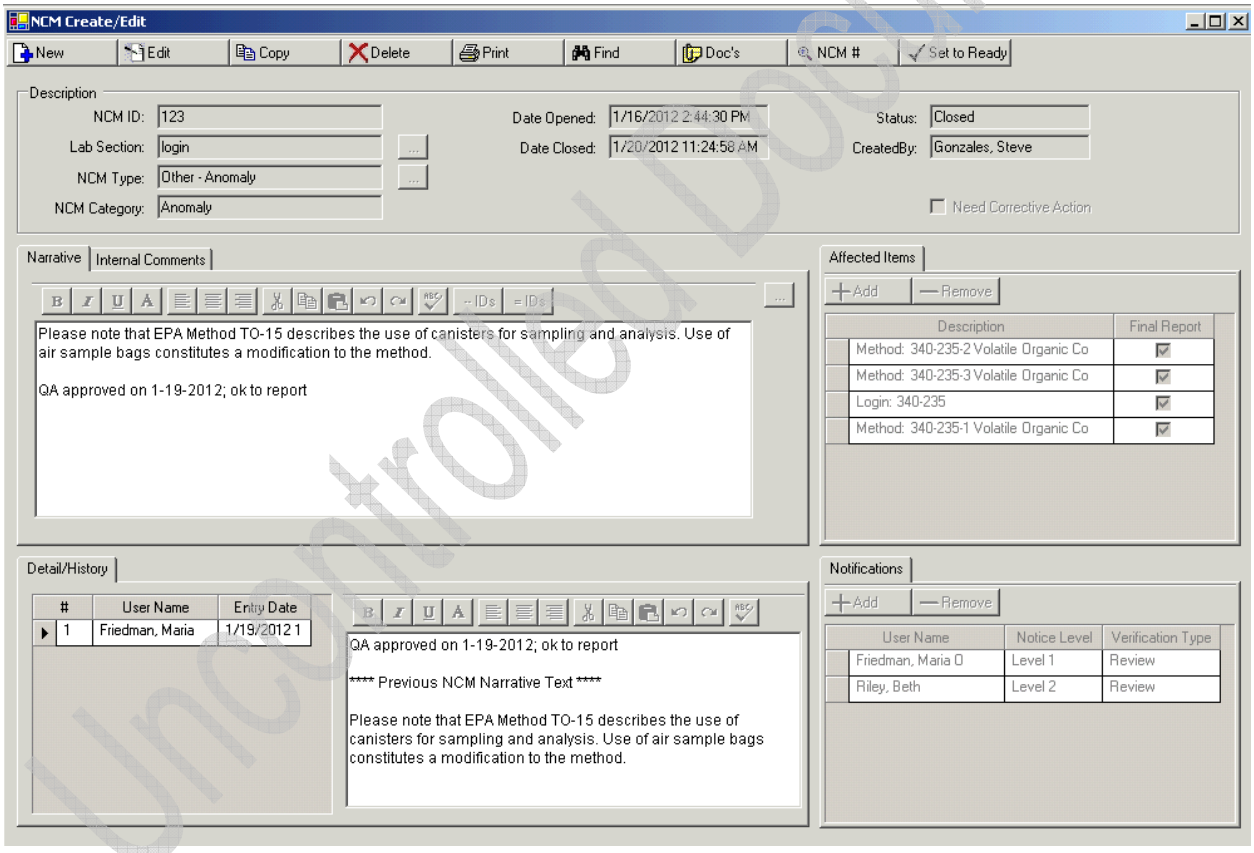

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Figure 12-2.

Example – iCAT Program

Incident/Complaint Activity Tracker (iCAT)

Home | Help | ADD NEW

User Logged In: DaystromW Status: Open Filter: For Any

	#	Opened By	Opened On	Type	Subject	Client	Status	Due Date	Action Item Total	Open Action Items	Pending QA Review	Action Due From
Select	8	WilsonD	2/21/2013	Data Report Issue - Incomplete Data	MRL Reporting		Open	4/30/2013	3	1	2	SchowA
Select	11	WilsonD	2/22/2013	Service Issue - Other	Disposal Requirements		Open	4/30/2013	1	1	0	DaystromW
Select	22	WilsonD	3/15/2013	Data Report Issue - Other	Procedure Changes	Chevron Refinery	Open	4/2/2013	1	1	0	DawesD
Select	23	WilsonD	3/15/2013	Technical Issue - QC Data	Special EDD	Ecology Auto Parts	Open	4/19/2013	1	1	0	DaystromW
Select	24	WilsonD	3/15/2013	Data Report Issue - Errors	Notice of Violation	CH2/Honeywell	Open	4/30/2013	5	1	4	DawesD
Select	25	WilsonD	3/19/2013	Data Report Issue - Other	Arizona Reporting		Open	4/30/2013	1	0	1	
Select	31	FriedmanM	3/28/2013	Audit Finding: external	Tesoro Audit 2013	Tesoro	Open	4/30/2013	3	0	3	
Select	35	FriedmanM	3/28/2013	Audit Finding: external	AZ Audit 2013	AZDHS	Open	3/28/2013	23	5	11	BanhA, HoangL, SchowA
Select	39	WilsonD	4/1/2013	Service Issue - Other	Vials leaking	American Inc for Eaton	Open	4/30/2013	3	1	0	PatelP
Select	40	WilsonD	4/2/2013	PT and Double Blind Failures	Failed NDMA PT sample for Aerojet	CRA for Aerojet Project	Open	4/12/2013	3	0	3	
Select	41	FriedmanM	4/2/2013	Audit finding: internal	Logbooks		Open	4/8/2013	7	5	2	BanhA, NguyenT, PatelP, SchowA, TranD
Select	44	WilsonD	4/4/2013	Technical Issue - Other	URS PAH Project	URS	Open	5/1/2013	4	3	1	BanhA, ReddyS, SierzchulaV
Select	46	WilsonD	4/7/2013	Data Report Issue - Incomplete Data	Did not log in 524	City of San Juan Capistrano	Open	4/15/2013	5	2	2	HarrisAW, WilsonD
Select	47	WilsonD	4/7/2013	Technical Issue - Other	525 contamination issue	TestAmerica Phoenix	Open	4/30/2013	1	0	1	
Select	48	WilsonD	4/7/2013	Audit Finding: external	608 analytes being inactivated	various	Open	4/30/2013	1	1	0	beauchaineb
Select	49	WilsonD	4/7/2013	Other	Cyanide default RL		Open	4/30/2013	1	1	0	SchowA
Select	50	WilsonD	4/7/2013	Other	Policy for MDL and RL's on Summary Analytes		Open	5/15/2013	2	1	1	FriedmanM
Select	51	HoangL	4/9/2013	Audit finding: internal	Checklist		Open	5/15/2013	1	1	0	HoangL
Select	54	HoangL	4/9/2013	Audit finding: internal	EPA 3546		Open	5/10/2013	1	1	0	BanhA

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Figure 12-3.

Example – Corrective Action Report

TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING

Corrective Action Report

LABORATORY:
Source of Issue:
Date Initiated:
Initiated By::
Responsible for Investigation:

Description of Problem:

Investigation Summary:

Root Cause Analysis

The immediate cause(s) include:

The underlying cause(s) include:

Corrective Action Plan

To correct the immediate problem, the following actions will (were) taken:

To prevent recurrence of this problem, the following actions will (were) taken:

Corrective Action Plan Approved By:

QA Manager _____ Date _____

Laboratory Director _____ Date _____

Monitoring of Corrective Action Status

[enter schedule for on-going assessments of corrective action status. When follow-up performed, enter name and date of person who performed the independent assessment and a statement of completion]

Corrective Action Closed By:

QA Manager _____ Date _____

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Table 12-1.

Example – General Corrective Action Procedures

QC Activity *(Individual Responsible for Initiation/Assessment)*	Acceptance Criteria	Recommended Corrective Action
Initial Instrument Blank *(Analyst)*	- Instrument response < MDL	- Prepare another blank. - If still unacceptable, determine cause of contamination: reagents, environment, equipment failure, etc.
ICAL standards *(Analyst, Department Manager)*	- See details in laboratory SOP.	- Re-analyze standards. - If still unacceptable, re-prepare standards and recalibrate instrument.
ICV standard (second-source) *(Analyst, Department Manager)*	- See details in laboratory SOP.	- Re-prepare and re-analyze ICV standard. - If still unacceptable, then re-prepare ICAL standards or use new primary standards and recalibrate instrument.
CCV standard *(Analyst, Data Reviewer)*	- See details in laboratory SOP.	- Re-analyze CCV standard. - If still unacceptable, then recalibrate and re-analyze affected samples.
LCS and LCSD *(Analyst, Data Reviewer)*	- % Recovery and RPD within limits specified in the LIMS	- Batch must be re-prepared and re-analyzed. This includes any allowable marginal exceedence. When not using marginal exceedences, the following exceptions apply: 1) when the acceptance criteria for the positive control are exceeded high (i.e., high bias) and there are associated samples that are non-detects, then those non-detects may be reported with data qualifying codes; 2) when the acceptance criteria for the positive control are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit/decision level, if known, with data qualifying codes. **Note:** If there is insufficient sample or the holding time cannot be met, contact client and report with flags.

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QC Activity *(Individual Responsible for Initiation/Assessment)*	Acceptance Criteria	Recommended Corrective Action
MS and MSD *(Analyst, Data Reviewer)*	- % Recovery and RPD within limits specified in the 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. - If the LCS is within acceptable limits the batch is acceptable. - The results of the duplicates, matrix spikes and the LCS are reported with the data set. - For matrix spike or duplicate results outside criteria, the data for that sample shall be reported with qualifiers.
Surrogates *(Analyst, Data Reviewer)*	- % Recovery within limits of method or within three standard deviations of the historical mean. See LIMS.	- Individual sample must be re-analyzed (to verify matrix interference, if any). Place comment in LIMS report. - Surrogate results outside criteria shall be reported with qualifiers.
Method Blank *(Analyst, Data Reviewer)*	< RL[1, 2]	- Re-analyze Method Blank. - If still positive, determine source of contamination. If necessary, reprocess (i.e., digest or extract) entire sample batch. Report method blank results. - Qualify the result(s) if the concentration of a targeted analyte in the Method Blank is at or above the reporting limit AND is > 1/10 of the amount measured in the sample.
PT Samples *(QA Manager, Technical Manager, Department Manager)*	- Criteria supplied by PT provider/supplier.	- Any failures or warnings must be investigated for cause. Failures may result in the need to repeat a PT study to show the problem is corrected. Certifying agencies must be informed of the results of the investigation of failures and the planned or performed corrective actions.

[1] Program- or project-specific requirements may dictate that method blank must not contain target analytes greater than ½ the RL.

[2] Except as noted below for certain compounds, or if specified otherwise by the client, the method blank should be below the MDL. Concentrations up to 5X RL will be allowed for the ubiquitous laboratory and reagent contaminants: Methylene chloride, Toluene, Acetone, 2-Butanone, and Phthalates **provided** they appear in similar levels in the reagent blank and client samples. This allowance presumes that the MDL 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 MDL, the method blank must be below MDL.

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QC Activity *(Individual Responsible for Initiation/Assessment)*	Acceptance Criteria	Recommended Corrective Action
Internal / External Audits *(QA Manager, Department Manager, Laboratory Director)*	- Defined in Quality System documentation such as SOPs, QAM, etc.	- Nonconformances must be investigated, must be reported through the NCM program in the LIMS and in the laboratory's iCAT program, as appropriate, and necessary corrective actions must be performed.
Reporting / Calculation Errors *(Depends on issue – possible individuals include Analysts, Data Reviewers, PMs, Department Manager, QA Manager, Corporate Quality, Corporate Management)*	- Corporate Legal SOP No. CW-L-S-002	- Corrective action is determined by type of error. Follow the procedures in Corporate Legal SOP No. CW-L-S-002.
Client Complaints *(PMs, Laboratory Director, Sales and Marketing)*		- Corrective action is determined by the type of complaint. For example, a complaint regarding an incorrect address on a report will result in the report being corrected and then follow-up must be performed on the reasons the address was incorrect (e.g., database needs to be updated).
QA Monthly Report (refer to Section 16 for an example) *(QA Manager, Laboratory Director)*	- QAM, SOPs	- Corrective action is determined by the type of issue. For example, NCMs for the month are reviewed and possible trends are investigated.

Table 12-2.

Timeline for Corrective Action Responses

Type of Corrective Action Response	Response Time
Acknowledgment of QA Policies (either electronic or hardcopy)	1 to 14 calendar days, as designated by the QA Manager based on urgency of corrective action
Acknowledgment of SOPs and SOP Revisions	14 to 30 calendar days, as designated by the QA Manager based on urgency of corrective action
Acknowledgment of QA Manual and QA Manual Revisions	30 calendar days, or as designated by the QA Manager
Acknowledgment of Published Methods	30 calendar days

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Type of Corrective Action Response	Response Time
Internal audit findings	7 to 30 calendar days, as designated by the QA Manager based on urgency of corrective action
External audit findings	7 to 30 calendar days, as designated by external auditor based on client requirements
Data Recall Investigations	3 to 7 days, as designated by QA Manager or Corporate QA Director
Client complaints	1 to 14 calendar days, as designated by the QA Manager based on urgency of corrective action
All Others	1 to 30 calendar days, as designated by the QA Manager based on urgency of corrective action

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SECTION 13

PREVENTIVE ACTION / IMPROVEMENT

13.1 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 and continuous process of improvement activities 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 the laboratory's commitment to its Quality Program. It is beneficial to identify and address negative trends before they develop into complaints, problems, and corrective actions. Additionally, customer service and client satisfaction can be improved through continuous improvements to laboratory systems.

Opportunities for improvement may be discovered during management reviews, the QA Metrics Report, evaluation of internal or external audits, results and evaluation of PT performance, data analysis and review processing operations, client complaints, staff observation, etc.

The monthly Management Systems Metrics Report shows performance indicators in all areas of the laboratory and 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 in evaluating the management and quality system performance on an ongoing basis and provide a tool for identifying areas for improvement.

The laboratory's corrective action process 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 nonconformance event. Historical review of corrective action provides a valuable mechanism for identifying preventive action opportunities.

13.1.1 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.

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- 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, and management review.

13.1.2 Any preventive actions undertaken or attempted shall be taken into account during the annual Management Systems Review (Section 16). A highly detailed report is not required; however, a summary of successes and failures within the preventive action program is sufficient to provide management with a measurement for evaluation.

13.2 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. Some of the types of changes covered under this system include facility changes, major accreditation changes, addition or deletion to capabilities or instrumentation, key personnel changes, and LIMS changes. TestAmerica Irvine has not implemented the Management of Change process at the time of the effective date of this QAM but is in the planning stage of implementation.

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SECTION 14

CONTROL OF RECORDS

14.1 OVERVIEW

The laboratory maintains a records management system appropriate to its needs and that conforms 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.

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 14-1. Records are of two types, either electronic or hardcopy paper formats, depending on whether the record is computer- or hand-generated (some records may be in both formats). Quality records are maintained by the QA department in the laboratory's local server, which is backed up as part of the regular laboratory backup. Technical records are maintained by the laboratory department responsible for generating the specific technical record. When archived, they are maintained by the individual Department Managers.

Table 14-1. Record Index[1]

	Record Types[1]:	Retention Time:
Technical Records	- Raw data - Logbooks[2] - Certificates of Analysis for standard materials - Analytical records	5 years from the date the laboratory report was mailed to the client[3]
Official Documents	- QAM - Work Instructions - Policies - SOPs - Policy memoranda - Manuals	5 years from document retirement date[3]

[1] Record types encompass hardcopy and electronic records.
[2] Examples of logbook types: Maintenance, Instrument Run/Analysis/Injection, Preparation (standard and samples), Standard and Reagent Receipt, Archiving, Temperature Monitoring (hardcopy or electronic records).
[3] See exceptions under Section 14.1.2.

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	Record Types[1]:	**Retention Time:**
QA Records	- Data investigation[4] - Internal and External audits / responses - Laboratory certifications / permits - Corrective / Preventive actions - Management reviews - Method and software validation/ verification data - MDLs, IDLs, RLs, QC limits - DOCs - Storage blank reports - PT reports	5 years from archival[3]
Project Records	- Sample receipt and COC documentation - Contracts and Amendments - Correspondence - QAPPs - SAPs - Telephone logbooks - Laboratory reports	5 years from the date the laboratory report was mailed to the client[3]
Administrative Records	- Finance and Accounting	10 years
	- Employee Handbook	Indefinitely
	- Personnel files, employee signature and initials, training records (administrative and technical)	Refer to HR Manual
	- Administrative Policies	7 years
	- EH&S Manual	7 years
	- Disposal records and permits	Indefinitely

14.1.1 All records are stored and retained in such a way that they are secure and readily retrievable at the laboratory facility or from an off-site location that provides a suitable environment to prevent damage, deterioration, and loss. 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.

14.1.2 **Retrieval of Archived Records**

Retrieval of records archived, whether from on-site or off-site storage, must be documented.

14.1.2.1 For records stored in file boxes or file cabinets on-site, a sign-out sheet, available from the laboratory's designated Record Organizers (either PMAs or the EH&S Coordinator), is completed to document who pulled out the record, what record was pulled out, when the record was pulled out, who returned the record, and

[4] Retention time is 5 years or the life of the affected raw data storage, whichever is greater (beyond 5 years, if ongoing project or pending investigation).

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when the record was returned. The sign-out sheet replaces the same spot where the original record was filed inside the file box or cabinet. The sign-out sheet is pulled out and completed when the record is returned. This procedure ensures that the chronological order the record was originally filed is not disturbed, remains consistent, and facilitates tracking.

14.1.2.2 For records stored off-site, the manifest of the records transferred off-site is consulted to determine which file boxes (that contain the record in question) have to be requested for retrieval:

14.1.2.2.1 Report Organizers are notified of the request to retrieve a particular record.

14.1.2.2.2 Report Organizers consult the manifest to determine the barcode assigned to the file box that contained the requested record.

14.1.2.2.3 Report Organizers transmit the request information to the off-site storage facility and the file box is delivered to the laboratory.

14.1.2.2.4 Report Organizers maintain records of all transfer of records (in and out) from the off-site storage facility.

14.1.2.3 Tracking of stored records both on-site and off-site is accomplished using the laboratory's Archived Records database. Details on the use of this database are addressed in laboratory SOP No. IR-QA-DOC.

14.1.3 Record Retention Requirements

Retention of records are maintained on-site at the laboratory for at least six months after their generation and moved off-site for the remainder of the required storage time. Records stored off-site should be accessible within two business days of a request for such records. Records are maintained for a minimum of five years unless otherwise specified by a client or regulatory requirement.

14.1.4 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.

14.1.5 Refer to Table 14-1 for the standard retention times of different types of records.

14.1.6 Programs with Longer Retention Requirements

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Some regulatory programs have longer record retention requirements than the standard record retention time. 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. Records that must be archived longer than the normal five-year retention span are marked with an identifier that is used during archiving to segregate such records from the general population. These records are then archived with the special retention time requirement clearly labeled.

14.1.7 The laboratory has procedures to protect and backup records stored electronically and to prevent unauthorized access to or amendment of these records. All analytical data are maintained as hardcopy or in a secure readable electronic format. For analytical reports that are maintained as copies in PDF format, refer to Section 14.1.8 for more information.

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

- The records include the identity of personnel involved in sampling, sample receipt, preparation, and testing. All analytical work contains the initials (at least) of the personnel involved. The laboratory's copy of the COC is stored in the LIMS server. During sample login, the COC is scanned and this copy is stored in the PDF/COC folder in the LIMS server. If a correction was made to a COC at any time before final report is issued, the corrected COC is scanned and is stored with the first scanned copy in the same folder location in the LIMS server. The COC would indicate the name of the sampler.
- 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). PDF copies of final reports are automatically designated by the LIMS as "Final" and include the job number (e.g., "440-12345 Final Report.pdf"). The final report package would include the following information in the following order:
    - Cover page
    - Table of Contents
    - Definitions/Glossary
    - Case Narrative (with NCMs, if applicable)

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  - Detection Summary
  - Client Sample Results
  - QC Sample Results
  - QC Association Summary
  - Lab Chronicle
  - Certification Summary
  - Method Summary
  - Sample Summary
  - COC
  - Receipt Checklists
  - Sampling equipment field data sheets and certification, if applicable
  - Subcontract report, if applicable
  - Raw data, if requested
- Instrument data are stored and identified sequentially by instrument. A given day's analyses are maintained in the order of the analysis. Injection logbooks are maintained for each instrument or method; a copy of each day's injection log or instrument sequence is stored with the data to aid in reconstructing 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 and/or entered into the LIMS for each method.
- Changes to hardcopy records shall follow the procedures outlined in Sections 12 and 19. 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 "Received by," "Prepared by," "Reviewed by," "Analyzed by," or Approved by."
- All generated data, except those that are generated by automated data collection systems, are recorded directly, promptly, and legibly in permanent dark ink.
- Hardcopy data may be scanned into PDF 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 hardcopy that was scanned.
- Also refer to Section 19.14.1.

14.1.9 Refer to Table 14-2 for the standard retention times of different types of records.

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Table 14-2. Example: Special Record Retention Requirements

Program	[1]Retention Requirement
Drinking Water – All States	10 years (all records)
Drinking Water Lead and Copper Rule	12 years (all records)
FIFRA – 40 CFR Part 160	Retain for life of research or marketing permit for pesticides regulated by EPA
TSCA - 40 CFR Part 792	10 years after publication of final test rule or negotiated test agreement

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

14.2 TECHNICAL AND ANALYTICAL RECORDS

14.2.1 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. 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 the sampling, performance of each analysis, and reviewing of results.

14.2.2 Observations, data, and calculations are recorded real-time and are identifiable to the specific task.

14.2.3 Changes to hardcopy records shall follow the procedures outlined in Section 12 and 19. 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 injection logs, include:

- Laboratory sample ID code
- Date of analysis; time of analysis is also required if the holding time is 72 hours or less, or when time critical steps are included in the analysis (e.g., drying, incubation, etc.); instrumental analyses have the date and time of analysis recorded as part of their general operations. Where a time critical step exists in an analysis, location for such a time is included as part of the documentation in a specific logbook or on a bench sheet.
- Instrumentation identification and instrument operating conditions/parameters. Operating conditions/parameters are typically recorded in the instrument maintenance logbook.
- Analysis type
- All manual calculations and manual integrations
- Analyst's or operator's initials/signature

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- Sample preparation including, but not limited to, 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
- QC protocols and assessment
- Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries
- Method performance criteria including expected QC requirements. These are indicated both in the LIMS and in specific analytical report formats.

14.3 LABORATORY SUPPORT ACTIVITIES

In addition to documenting all of 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 hardcopy or electronic, for calibrations, samples, and QC measures, including analysts' worksheets and data output records (chromatograms, strip charts, and other instrument response readout records)
- A written description or reference to the specific 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
- PT results and raw data
- Results of data review, verification, and cross-checking procedures

14.3.1 Sample Handling Records

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

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- Sample storage and tracking, including shipping receipts, sample transmittal/COC forms
- Procedures for the receipt and retention of samples, including all provisions necessary to protect the integrity of samples

14.4 ADMINISTRATIVE RECORDS

The laboratory also maintains the administrative records in either electronic or hardcopy form. Refer to Table 14-1.

14.5 RECORDS MANAGEMENT, STORAGE, AND DISPOSAL

14.5.1 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 upon request.

14.5.2 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.

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

14.5.4 The laboratory has a record management system (a.k.a., document control) for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage, and reporting. Laboratory notebooks or logbooks issued by the QA department are numbered sequentially. No more than one notebook or logbook is active at a time for a given analysis, instrument, or task, so all data are recorded sequentially within a series of sequential notebooks or logbooks. Records are considered archived when noted as such in the records management system.

14.5.5 Transfer of ownership

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

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14.5.6 Records Disposal

Records are removed from the archive and destroyed 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. Refer to Tables 14-1 and 14-2.

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

If a third-party records management company is hired to dispose of records, a “Certificate of Destruction” is required.

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SECTION 15

AUDITS

15.1 INTERNAL AUDITS

Internal audits are performed to verify that laboratory operations comply with the requirements of the laboratory's quality system and with the external quality programs under which the laboratory operates. Audits are planned and organized by the QA Manager. Personnel conducting the audits should be independent of the area being evaluated. Auditors will have sufficient authority, access to work areas, and organizational freedom necessary to observe all activities affecting quality and to report the assessments to laboratory management and, when requested, to Corporate management.

Audits are conducted and documented, as described in Corporate Quality SOP No. CA-Q-S-004. The types and frequency of routine internal audits are described in Table 15-1. Special or ad hoc assessments may be conducted, as needed, under the direction of the QA Manager.

Table 15-1. Types of Internal Audits and Frequency

Description	Performed by	Frequency
Quality Systems Audits	QA Department, QA-approved designee, or Corporate Quality	All areas of the laboratory, annually
Method Audits	Joint responsibility: a) QA Manager or designee b) Technical Manager or designee	All methods within a two-year period, with at least 15% of methods every quarter
Special Audits	QA Department or QA-approved designee	Surveillance or spot checks performed as needed (e.g., to confirm corrective actions from other audits)
PT	Analysts, with QA oversight	Two successful per year for each NELAC/TNI field of testing, or as dictated by regulatory requirements

15.1.1 Annual Quality Systems Audit

An annual quality systems audit is required to ensure compliance to analytical methods and SOPs, TestAmerica's Data Integrity and Ethics Policies, NELAC/TNI quality systems, client and State requirements, and the effectiveness of the internal controls of the analytical process including, but not limited to, data review, QCs, preventive action, and corrective action. The completeness of earlier corrective actions is assessed for effectiveness and sustainability. The audit is divided into sections for each operating or support

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area of the laboratory, and each section is comprehensive for a given area. The area audits may be performed on a rotating schedule throughout the year to ensure adequate coverage of all areas. This schedule may change as situations in the laboratory warrant.

15.1.2 QA Technical Audits

QA technical audits are based on client projects, associated sample delivery groups, and the methods performed. Reported results are compared to raw data to verify the authenticity of results. The validity of calibrations and QC results are compared to data qualifiers, footnotes, and case narratives. Documentation is assessed by examining injection logs and records of manual integrations. Manual calculations are checked. Where possible, electronic audit miner programs (e.g., Chrom AuditMiner) are used to identify unusual manipulations of the data deserving closer scrutiny. QA technical audits will include all methods within a two-year period.

15.1.3 SOP Method Compliance

Compliance of all SOPs with the source methods and compliance of the operational groups with the SOPs will be assessed by the Technical Manager or qualified designee, at least every two years. The work of each newly hired analyst is assessed within three months of working independently (e.g., completion of method IDOC). In addition, as analysts add methods to their capabilities, (new IDOC) reviews of the analyst work products will be performed within three months of completing the documented training**.**

15.1.4 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.

15.1.5 Performance Testing

The laboratory participates in performance audits conducted through the analysis of PT samples provided by a third party. PT samples are analyzed either annually or semi-annually based on the laboratory's accreditation requirements (e.g., NELAP/TNI and Nevada DEP require semi-annual PT samples while Arizona DHS and California ELAP require annual PT samples). The laboratory generally participates in the following types of PT studies: Drinking Water (WS), Non-potable Water (WP), Underground Storage Tank (UST), and Soil (HW).

It is TestAmerica's policy that PT samples be treated as typical samples in the production process. Furthermore, where PT samples present special or

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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 must be in agreement with any decisions made to treat a PT sample differently due to some special circumstance.

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.

15.2 EXTERNAL AUDITS

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. 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. When requested, a copy of the audit report and the laboratory's corrective action plan will be forwarded to Corporate Quality.

The laboratory 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.

15.2.1 Confidential Business Information 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 the 2003 NELAC Standard and 2009 TNI Standard.

15.3 AUDIT FINDINGS

Audit findings are documented using the iCAT. The laboratory's corrective action responses for both types of audits (internal or external) may include action plans that

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could not be completed within a pre-defined timeframe. In these instances, a completion date must be set and agreed to by Operations Management and the QA Manager.

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. . When requested, a copy of the audit report and the laboratory's corrective action plan will be forwarded to Corporate Quality.

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.

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.

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SECTION 16

MANAGEMENT REVIEWS

16.1 QUALITY ASSURANCE REPORT

A comprehensive QA report shall be prepared each month by the laboratory's QA department and forwarded to the Laboratory Director, Operations Manager, their Corporate Quality Director as well as their General Manager. All aspects of the QA system are reviewed to evaluate the suitability of policies and procedures. During the course of the year, the Laboratory Director, General Manager, or Corporate Quality may request that additional information be added to the report.

On a monthly basis, Corporate Quality compiles information from all the monthly laboratory reports. The Corporate Quality Directors prepare 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 Senior Management Team and General Managers.

16.2 ANNUAL MANAGEMENT SYSTEMS REVIEW

The senior laboratory management team (Laboratory Director, Operations Manager, QA Manager, and Client Services Manager) conducts an annual review of its quality systems and the LIMS to ensure its continuing suitability and effectiveness in meeting client and regulatory requirements and to introduce any necessary changes or improvements. It will also provide a platform for defining goals, objectives, and action items that feed into the laboratory planning system. Corporate Operations and Corporate Quality may be included in this meeting at the discretion of the Laboratory Director. The LIMS review consists of examining any audits, complaints, or concerns that have been raised through the year that are related to the LIMS. The laboratory will summarize any critical findings that cannot be solved by the laboratory and report them to Corporate IT.

This management systems review (Corporate Quality SOP No. CA-Q-S-008 and Work Instruction No. CA-Q-WI-020) uses information generated during the preceding year to assess the "big picture" by ensuring that routine actions taken and reviewed on a monthly basis are not components of larger systematic concerns. The monthly review 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 re-issue requests
- Review of client feedback and complaints

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- Issues arising from any prior management or staff meetings
- Minutes from prior senior laboratory 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)
- Compliance to the Ethics Policy and Data Integrity Plan. Include any evidence/incidents of inappropriate actions or vulnerabilities related to data integrity.

A report is generated by the QA Manager and management. The report is distributed to the appropriate General Manager and the Corporate 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)]. Due dates for corrective actions must be set to be no later than six months following the date of the report.

The report will be summarized and communicated to all laboratory personnel during one of the monthly all staff meeting. Changes to the quality systems requiring update to the QAM shall be included in the next revision of the QAM.

16.3 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. Corporate Legal SOP No. CW-L-S-002 shall be followed. All investigations that result in finding of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notification of clients.

TestAmerica's CEO, Vice-President of Quality, Technical and Operations Support, General Managers, and Corporate Quality Directors receive a monthly report from the Corporate Quality Director summarizing any current data integrity or data recall investigations. The General Managers are also made aware of progress on these issues for their specific laboratories.

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SECTION 17

PERSONNEL

17.1 OVERVIEW

The laboratory'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 charts in Figure 4-1.

All personnel must demonstrate competence in the areas where they have responsibility. Any staff who 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 laboratory operations, test methods, QA/QC procedures, and records management.

Laboratory management is responsible for formulating goals for laboratory 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 laboratory 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.

17.2 EDUCATION AND EXPERIENCE REQUIREMENTS FOR TECHNICAL PERSONNEL

The laboratory makes every effort to hire analytical staff that possesses a college degree (AA, BA, and BS) in an applied science with some chemistry in the curriculum. 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. Where specific education and experience requirements are dictated by regulatory programs or States, these requirements must be met.

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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 in the TestAmerica Intranet's Human Resources webpage. See also 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, see guidelines in the table below.

Table 17-1. Education and Experience Guidelines

Specialty	Education	Experience
Extractions, Digestions, some electrode methods (pH, Dissolved Oxygen, Redox, etc.), or Titrimetric and Gravimetric Analyses	H.S. Diploma	On the job training
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, etc.), HPLC, GCMS	A college degree in an applied science or 2 years of college chemistry, or	5 years of prior analytical experience is required
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
Technical Managers/Department Managers	Bachelor degree in an applied science or engineering with 24 semester hours in chemistry (or 16 semester hours in general microbiology and biology for Microbiology), and	2 years experience in environmental analysis of representative analytes for which they will oversee An advanced (MS, PhD) degree may substitute for one year of 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.

17.3 TRAINING

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The laboratory 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 required employee training:

Table 17-2. Required Employee Training

Required Training	Time Frame	Employee Type
EH&S	Prior to laboratory work	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
QAM	30 days of hire	All
Ethics – Refresher	Quarterly	All
IDOC	Prior to unsupervised method performance or analysis of client samples	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 Section 19.4.2.

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

- Documentation in each employee training file that they have read, understood, and agreed to follow the most recent version of the QAM and SOPs in their area of responsibility. This documentation is updated as the QAM and the SOPs are updated.
- Documentation from any training courses or workshops on specific equipment, analytical techniques, or other relevant topics that maintained in their training file.
- Documentation of proficiency (refer to Section 19).
- An Ethics Agreement signed by each staff member (renewed each year) and evidence of quarterly ethics training.
- A Confidentiality Agreement signed by each staff member signed at the time of employment and annually.
- Documentation and attestation forms, maintained by Human Resources, on employment status and records, benefit programs, timekeeping/payroll, and employee conduct (e.g., ethics violations). This information is maintained in the employee's secured personnel file.

Evidence of successful training could include such items as:

- Adequate documentation of training within operational areas, including one-on-one

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technical training for individual technologies, and particularly for people cross-trained.

- Analysts knowledge to refer to QAM and QA SOPs for quality issues.
- Analysts following SOPs, i.e., practice matches SOPs.
- Analysts regularly communicate to supervisors and QA if SOPs need revision, rather than waiting for auditors to find problems.

Further details regarding the laboratory's training program are described in laboratory SOP No. IR-QA-TRAIN.

17.4 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 one week of hire followed by technical data integrity training within 30 days, comprehensive training within 90 days, and quarterly refresher for all employees. The Laboratory Director or the QA Manager at each facility typically 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 (Corporate Legal Document No. CW-L-P-004) and an Ethics Statement. All initial and quarterly training is documented by signature on the signed Ethics Statement 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
- 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, accepting/offering kickbacks, illegal accounting practices, unfair competition/collusion)

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- 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 PM 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 (800-736-9407) is maintained by TestAmerica and administered by the Corporate Quality department.

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SECTION 18

ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS

18.1 OVERVIEW

The laboratory is a 45,000 ft^2 secure laboratory facility with controlled access and designed to accommodate an efficient work flow 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 work place. The laboratory provides and requires the use of protective equipment including safety glasses, protective clothing, gloves, etc. The 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, microbiological sample analysis, and administrative functions.

18.2 ENVIRONMENT

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

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

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

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

18.3 WORK AREAS

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

- Microbiological culture handling and sample incubation areas
- Volatile organic chemical handling areas (e.g., sample preparation and waste disposal) and volatile organic chemical analysis 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 environment. Work areas include:

- Access and entry ways to the laboratory
- Sample receipt
- Sample storage
- Chemical and waste storage
- Data handling and storage
- Sample processing
- Sample analysis

Refer to the following documents and procedures for specific requirements for microbiological laboratory facility:

- Standard Methods, 20th Ed., 9020B, Section 2
- TNI V1M5, 1.7.3.7.a

18.4 FLOOR PLAN

A floor plan can be found in Appendix 1.

18.5 BUILDING SECURITY

Building keys 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 that laboratory. In addition to

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signing into the laboratory, the EH&S Manual (Corporate EH&S Document No. CW-E-M-001) 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. Signs are posted in the laboratory designating employee-only areas: "Authorized employees beyond this point."

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SECTION 19

TEST METHODS AND METHOD VALIDATION

19.1 OVERVIEW

The laboratory uses methods that are appropriate to meet our clients' requirements and that are within the scope of the laboratory's capabilities. These include sample handling and transport, sample storage and preparation, 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, SOPs, reference methods, and manuals relevant to the work 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.

19.2 STANDARD OPERATING PROCEDURES

The laboratory 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 laboratory 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:

- All SOPs contain a revision number, effective date, and appropriate approval signatures. Controlled copies are available to all staff.
- Procedures for writing an SOP are incorporated by reference to Corporate Quality Document No. CW-Q-S-002.
- SOPs are reviewed at a minimum of every 2 years (annually for Drinking Water projects), and where necessary, revised to ensure continuing suitability and compliance with applicable requirements.

19.3 LABORATORY METHODS MANUAL

For each test method, the laboratory shall have available the published referenced method as well as the laboratory developed SOP.

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 laboratory SOP.

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The laboratory maintains an SOP Index for both technical and non-technical SOPs. Technical SOPs are maintained to describe a specific test method. Non-technical SOPs are maintained to describe functions and processes not related to a specific test method. The QA Department maintains a list of all laboratory SOPs.

19.4 SELECTION OF METHODS

Since numerous methods and analytical techniques are available, continued communication between the client and the 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 PM. These mechanisms ensure that the proper analytical methods are applied when the samples arrive for login. 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.

19.4.1 Sources of Methods

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

When clients do not specify the method to be used or when 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.

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

- *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*

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- *Standard Methods for the Examination of Water and Wastewater, 20th and on-line editions; 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; Final Update IV, January 2008.*
- *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.

19.4.2 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, DOC may be performed on QC samples.

19.4.2.1 A DOC is performed whenever there is a change in instrument type (e.g., new instrumentation), method, or personnel (e.g., analyst has not performed the method within the last 12 months).

19.4.2.2 An IDOC for an analyst must be thoroughly documented and approved by the QA Manager prior to independently analyzing client samples or reviewing data (first- or second-level review). All associated documentation must be retained in accordance with the laboratory's archiving procedures.

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19.4.2.3 Ongoing DOCs for analysts must be performed and approved by the QA Manager annually or a new IDOC is performed, in order to continue or resume analyzing client samples or reviewing data (first- or second-level reviews). All associated documentation must be retained in accordance with the laboratory's archiving procedures.

19.4.2.4 The laboratory must have an approved SOP, demonstrate satisfactory performance, and conduct an MDL study. There may be other requirements, as stated within the published method or regulations (e.g., RT 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 QAM (SOP, MDL, and DOC). 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 or criteria are per project DQOs).
- The laboratory's nominal or default RL is equal to the QL, must be at or above the lowest non-zero standard in the calibration curve, and must be reliably determined. Project RLs are client-specified reporting levels, which may be higher than the QL. Results reported below the QL must be qualified as estimated values. Also see Section 19.6.1.3.
- The client request is documented and the laboratory informs the client of its procedure for working with unusual compounds. The final report must be footnoted or qualified, as applicable: *Reporting Limit based on the low standard of the calibration curve.*

19.4.3 IDOC and Ongoing DOC Procedures

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

19.4.3.2 The analyte(s) shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at one to four times the RL (for IDOCs) or at the concentration specified by a method or the laboratory SOP (for Ongoing DOCs).

19.4.3.3 Four aliquots shall be prepared and analyzed according to the test method. The four aliquots shall be analyzed consecutively on the same day or consecutively over a period of consecutive days,

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meaning one replicate per day for four days or two consecutive aliquots per day for two days, or three consecutive aliquots in one day and one replicate the next day, however preferred, as long as the aliquots are analyzed in consecutive order in consecutive days.

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

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

19.4.3.6 Compare the information obtained above to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or to the laboratory-generated acceptance criteria (or interim criteria) for the LCS, if there is no mandatory criteria established. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.

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

- Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with Section 19.4.3.3 above.
- Beginning with Section 19.4.3.3 above, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, will confirm a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with Section 19.4.3.1 above.

Note: All analytes that the laboratory can possibly report (i.e., those analytes with approved ICAL and MDL studies) must be included in the analyst IDOC. Routine LCS or LCSD analytes may be used for ongoing DOCs.

A certification statement (see Figure 19-1) shall be used to document the completion of each IDOC for an analyst. A similar form may be used to document an ongoing DOC. A copy of the certification is archived in the QA files. Approved DOCs for all analysts are summarized in the QA files.

19.5 LABORATORY-DEVELOPED METHODS AND NON-STANDARD METHODS

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Any new method developed by the laboratory must be fully defined in an SOP 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.

19.6 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.

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.

19.6.1 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.

19.6.1.1 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.

19.6.1.2 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.

19.6.1.3 Relationship of Limit of Detection to the Quantitation Limit

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 concentration of analyte that can be

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quantitatively determined with acceptable precision and bias. 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.

19.6.1.4 Determination of Interferences

A determination that the method is free from interferences in a blank matrix is performed.

19.6.1.5 Determination of Range

Where appropriate to the method, the quantitation range is determined by comparison of the response of an analyte in a curve to established or targeted criteria. Generally, the upper QL is defined by the highest acceptable calibration concentration. The lower QL cannot be lower than the lowest non-zero calibration level, and can be constrained by required levels of bias and precision.

19.6.1.6 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.

19.6.1.7 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.

19.6.1.8 Continued Demonstration of Method Performance

Continued demonstration of method performance is addressed in the SOP. Continued demonstration of method performance is generally accomplished by batch-specific QC samples such as

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LCS, method blank, or PT samples.

19.7 METHOD DETECTION LIMITS / LIMITS OF DETECTION

MDLs are initially determined in accordance with 40 CFR Part 136, Appendix B or, alternatively, by other technically acceptable practices that have been accepted by regulators. MDL is also sometimes referred to as 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. Generally, the analyst prepares at least 7 replicates of standard spiked at one to five times the estimated MDL (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 analyzed in the same manner as the samples. Where possible, the 7 replicates should be analyzed over two to four days to provide a more realistic MDL.

Refer to Corporate Quality SOP No. CA-Q-S-006 or laboratory SOP No. IR-QA-MDL for details on the MDL study process.

19.8 INSTRUMENT DETECTION LIMITS

19.8.1 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 mostly used in metals analyses but may be useful in demonstration of instrument performance in other areas.

19.8.2 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 three times the absolute value of the standard deviation.

19.8.3 If IDL is greater than the MDL, it may be used as the reported MDL.

19.9 VERIFICATION OF DETECTION AND REPORTING LIMITS

19.9.1 Once the MDL is determined, it must be verified on each instrument used for the given method, by analyzing a QC sample (prepared in the same manner as client samples) at no more than three times the calculated MDL for single analyte analyses (e.g., most Wet Chemistry methods, Atomic Absorption, etc.) or no more than four times the calculated MDL for multiple analyte analyses (e.g., GC, GC/MS, ICP methods, etc.). MDLV standards, like MDL standards, are analyzed through the entire analytical process under acceptable calibration and batch QC. The analytes must be qualitatively identified. This verification does not apply to methods that are not readily spiked (e.g., pH, Turbidity, etc.) or where the laboratory does not report to the MDL. If the MDL cannot be successfully verified, then the laboratory will not

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report to the MDL, or redevelop their MDL, or perform and pass two consecutive MDLVs at a higher concentration and set the MDL (or LOD) at the higher concentration.

19.9.2 When the laboratory establishes a QL, it must be initially verified by the analysis of a low-level standard or QC sample at one to two times the RL and annually, thereafter. The annual requirement is waived for methods that have an annually verified MDL. The laboratory will comply with any regulatory requirement.

19.10 RETENTION TIME WINDOWS

Most organic analyses and some inorganic analyses use chromatography techniques for qualitative and quantitative determinations. For every chromatography analysis, or as specified in the reference method, each analyte will have a specific time of elution from the column to the detector. This is known as the analyte's RT. The variance in the expected time of elution is defined as the RT window. As the key to analyte identification in chromatography, RT windows must be established on every column for every analyte used for that method. These records are kept with the files associated with an instrument for later quantitation of the analytes. Procedures to be followed are defined in the laboratory SOPs.

19.11 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 RT windows, sample blanks, spectrochemical, atomic absorption, or fluorescence profiles, co-precipitation evaluations, and specific electrode response factors.

19.12 ESTIMATION OF UNCERTAINTY OF MEASUREMENT

19.12.1 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 measurand" (as defined by the International Vocabulary of Basic and General Terms in Metrology, ISO Geneva, 1993, ISBN 9610171). 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, standards, analytical procedure, and random variation. Some national accreditation organizations require the use of an "expanded uncertainty": the range within which the value of the measurand is believed to lie within at least a 95% confidence level with the coverage factor k=2.

19.12.2 Uncertainty is not error. Error is a single value, the difference between the true result and the measured result. In 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

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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.

19.12.3 The minimum uncertainty associated with results generated by the laboratory can be determined by using the 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 and the variability due to matrix effects). 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.

19.12.4 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 uncertainties at approximately the 99% confidence level with a coverage factor of k = 3. As an example, for a reported result of 1.0 mg/L with an LCS recovery range of 50 to 150%, the estimated uncertainty in the result would be 1.0 ± 0.5 mg/L.

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

19.13 SAMPLE RE-ANALYSIS GUIDELINES

Because there is a certain level of uncertainty with any analytical measurement, a sample re-preparation (where appropriate) and subsequent analysis (hereafter referred to as 're-analysis") may result in either a higher or lower value from an initial sample analysis. There are also variables that may be present that may affect the results of a re-analysis. Based on the above comments, the laboratory will re-analyze samples at a client's request with the following caveats. Client-specific Contractual Terms & Conditions for re-analysis protocols may supersede the following items:

- Homogenous samples: If a re-analysis agrees with the original result to within the RPD limits for MS/MSD or duplicate sample analyses, or within ± 1 RL for samples ≤ 5x the RL, 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 re-analysis does not agree (as defined above) with the original result, then the laboratory will investigate the discrepancy and re-analyze the sample a third time for confirmation, if sufficient sample is available.
- Any potential charges related to re-analysis are discussed in the contract terms and conditions or discussed at the time of the request. The client will typically be charged for re-analysis unless it is determined that the laboratory was in error.

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- 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 if unsure.

19.14 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.

19.14.1 Computer- and Electronic Data-Related Requirements

The three basic objectives of our computer security procedures and policies are shown below. Details are outlined in laboratory SOP No. IR-IT-COMPSEC. The laboratory is currently using TALS, which is a proprietary LIMS that has been designed to meet the needs of the laboratory. It is referred to as LIMS for the remainder of this section. The LIMS utilizes Microsoft SQL Server, which is an industry standard relational database platform. It is referred to as Database for the remainder of this section.

19.14.1.1 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. QA approval must be received prior to use. Cells containing calculations must be lock-protected and controlled.
- Instrument hardware and software adjustments are safeguarded through maintenance logs, audit trails, and controlled access.

19.14.1.2 Ensure Information Availability: Protection against loss of information or service is ensured through scheduled backups, stable file server network architecture, secure storage of media, line filter, Uninterruptible Power Supply, and maintaining older versions of software as revisions are implemented.

19.14.1.3 Maintain Confidentiality: Ensure data confidentiality through physical access controls, such as password protection or website access approval, when electronically transmitting data.

19.14.2 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

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readings, and concentrations). The analyst calculates the final results from the raw data or uses appropriate computer programs to assist in the calculation of final reportable values.

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

Manual integration of peaks will be documented and reviewed and the raw data will be flagged in accordance with Corporate Quality Document No. CA-Q-S-002.

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

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

19.14.2.2 Reporting units are defined in the laboratory SOPs.

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

19.14.2.4 For those methods that do not have an instrument printout or an instrumental output compatible with the LIMS, 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.

19.14.2.5 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 instrument output compatible with the LIMS, the raw results

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and dilution factors are transferred into LIMS electronically after reviewing the quantitation report, and removing not needed/not requested or poor spectrally-matched compounds. The analyst prints a copy, if applicable, of what has been entered to check for errors. Otherwise, the instrument's record of calibrations, concentrations, RTs, chromatograms, and mass spectra, if applicable, are retained with the data file. The data file is stored in a folder in the instrument computer. Periodically, this file is transferred to the server and, eventually, to a tape file.

19.14.3 Logbook Use Guidelines

Logbooks 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, temperature when applicable, calculations being traceable, etc.).

- Corrections are made following the procedures outlined in Section 12.
- Logbooks are controlled by the QA department. A record is maintained of all logbooks in the laboratory.
- Unused portions of pages must be Z'd out, initialed/signed, and dated.
- Logbooks are created with the approval of the QA Manager at the facility. The QA Department controls all logbooks following the procedures in Section 6.
- Logbooks are reviewed monthly by the Department Manager of the department where the logbook resides. The name of the reviewer and date of review is documented on each page of the logbook. Once reviewed, the Department Manager updates the laboratory's Logbook Tracking Database to mark the latest review performed on a particular logbook. QA uses the same database to track missing or overdue logbook reviews.

19.14.4 Review / Verification Procedures

Review procedures are outlined in the laboratory SOPs to ensure that reported data are free from calculation and transcription errors and that QC parameters have been reviewed and evaluated before data are reported. The laboratory follows Corporate Quality Document No. CA-Q-S-002 regarding manual integrations to ensure the authenticity of the data. The general review concepts are discussed below; more specific information can be found in the laboratory SOPs.

All data, regardless of regulatory program or level of reporting, are subject to a thorough review process. All levels of the review are documented.

19.14.4.1 The data review process at the laboratory starts at the Sample Control level. Sample Control personnel review COC forms and input the sample information and required analyses into the LIMS.

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The PMAs review the transaction of the COC forms and the information entered into the LIMS. The PMs perform final review of the same.

19.14.4.2 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. To ensure data compliance, the Department Manager or a different analyst performs a second level of review.

Primary Technical Review

The primary technical review of analytical data is often referred to as a "bench-level" review. In most cases, the analyst who generates the data (prepares and/or analyzes the sample/reduces the data) is the primary technical reviewer. In some cases, an analyst may be reducing data for samples ran by an autosampler that was set up by a different analyst. In this case, the identities of both analysts must be identified in the raw data. At a minimum, this information must be identified in the injection or run log.

One of the most important aspects of primary technical review is to make sure that the test instructions are clear, and that all project-specific requirements have been understood and followed. If directions to the analyst are unclear, the analyst must go to the Department Manager or to the PM, who must clarify the instructions.

Once an analysis is complete, the primary technical reviewer ensures the following requirements are met:

- Sample preparation information is complete, accurate, and documented
- Initial and/or continuing calibrations are valid
- Calculations have been performed correctly
- Quantitation has been performed accurately
- Qualitative identifications are accurate
- Manual integrations are appropriate and the reason for performing them is documented with dated initials or signature
- Data flags to indicate manual integrations are recorded
- Manual integrations are authorized by a date and signature or initials of primary analyst
- Client-specific requirements have been followed

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- Method and process SOPs have been followed
- Method QC criteria have been met
- QC samples are within established limits
- QC data are properly linked to the client samples
- Dilution factors are correctly recorded and applied
- Deficiencies and/or anomalies have been properly documented and communicated into the NCM program in the LIMS
- COC instructions have been followed
- All components of a full raw data package, if applicable, have been submitted

Anomalous results and/or nonconformances noted during the primary technical review are communicated to the Department Manager and to the PM, for immediate resolution. Unacceptable analytical results may require re-analysis of the samples. Any problems that cannot be immediately resolved are brought to the attention of the Technical Manager and the QA Manager for further investigation and corrective action. As stated above, anomalies, nonconformances, and/or deficiencies are documented using the NCM program in the LIMS or in iCAT, as appropriate.

Revisions are never erased, deleted, or overwritten. They are corrected by the person who edited the data by drawing a single line through the error, documenting the correction, and adding their dated initials or signature. See Section 12.5.

Primary technical review is documented by the dated initials or signature of the primary technical reviewer, on pre-printed checklists (or electronic checklists, where applicable).

Secondary Technical Review

The secondary technical review is a complete technical review of a data set. The following items are reviewed:

- Qualitative Identification
- Quantitative Accuracy
- Calibration (initial and continuing)
- QC Samples
- Method QC Criteria
- Adherence to method and process SOPs.
- Manual integrations, with dated initials or signature of the

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primary reviewer

- Special Requirements/Instructions
- Completed full raw data package, if applicable

Secondary technical review is documented by the dated initials or signature of the secondary technical reviewer, on the same pre-printed checklist (or electronic checklist, where applicable) used during the primary technical review.

If problems are found during the secondary technical review, the reviewer must work with the appropriate personnel to resolve them. If changes are made to the data, such as alternate qualitative identification, identification of additional target analytes, re-quantitation, or re-integration, the reviewer must contact the laboratory analyst and/or primary technical reviewer of the data so that they are aware of the changes made.

19.14.4.3 As a final review prior to the release of the report, the PM reviews the results for appropriateness and completeness. This review and approval ensures that client requirements have been met and that the final report has been properly completed.

The appropriateness and completeness review includes the generation of a case narrative and/or cover letter with the final report to the client, which outlines anomalous data and nonconformances, using project notes and NCMs generated during the primary and secondary technical reviews. This review also focuses on the accuracy of final client reporting forms, the use of appropriate data flags (if applicable), and addresses the following questions:

- Is the project report complete?
- Do the data meet the client's expectations?
- Were the DQOs of the project met?
- Are QC failures approved and appropriately explained in the NCM and/or case narrative?

The PM or PMA generates the invoice, and the PM signs the final report package for submission to the client.

19.14.4.4 A visual summary of the flow of samples and information through the laboratory, as well as data review and validation, is presented in Figure 19-2.

19.14.5 Manual Integrations

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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 QC 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 Corporate Quality Document No. CA-Q-S-002 as guideline.

19.14.5.1 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 integration is required. Analysts are encouraged to ask for assistance from a senior analyst or Department Manager when in doubt.

19.14.5.2 Analysts shall not increase or decrease peak areas 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 principles and policy and is ground for immediate termination.

19.14.5.3 Client samples, performance evaluation samples, and QC samples are all treated equally when determining whether or not a peak area or baseline should be manually adjusted.

19.14.5.4 All manual integrations require 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, LCS, 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.

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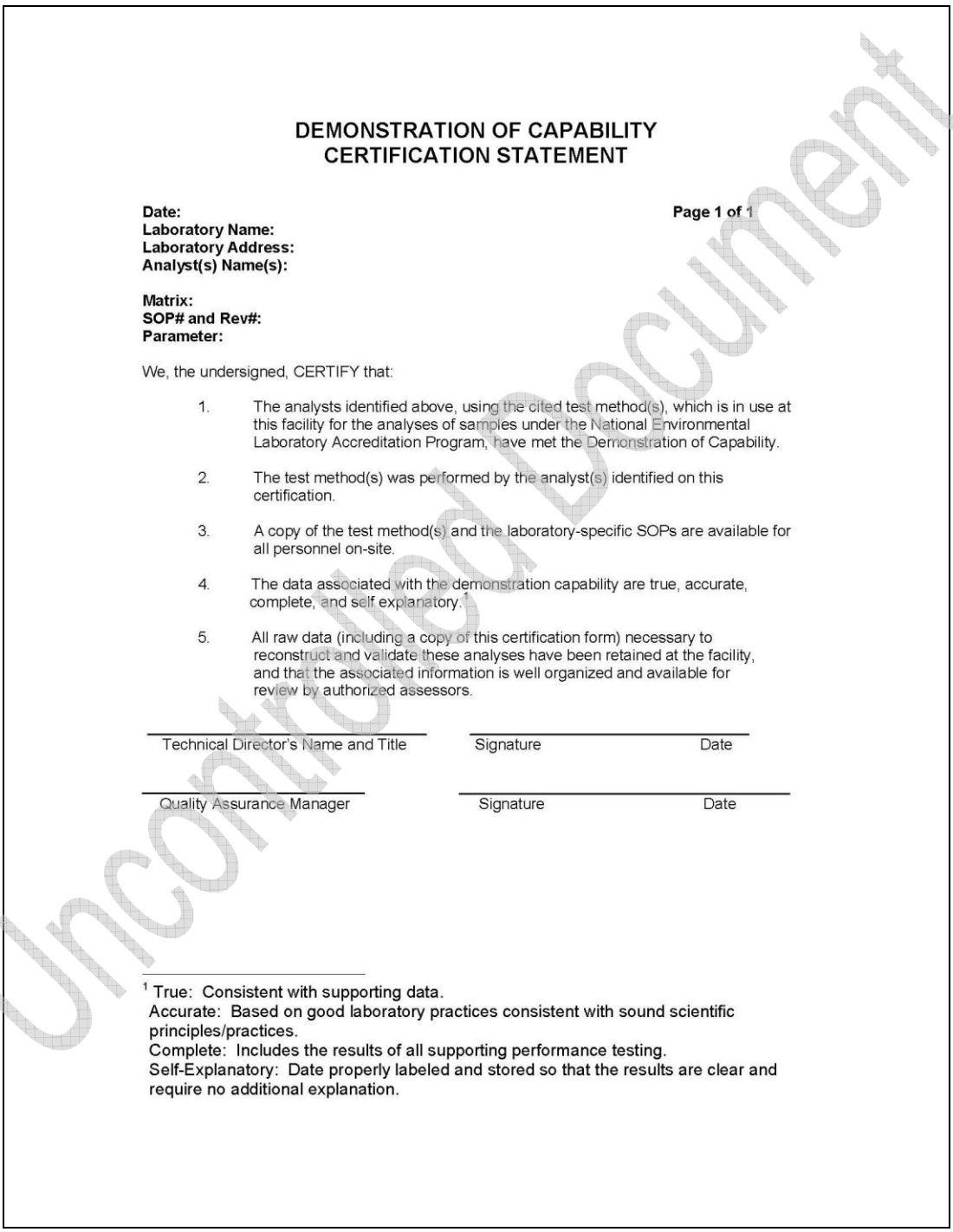
Figure 19-1.

Example - Demonstration of Capability Documentation



DEMONSTRATION OF CAPABILITY
CERTIFICATION STATEMENT

Date: **Page 1 of 1**
Laboratory Name:
Laboratory Address:
Analyst(s) Name(s):

Matrix:
SOP# and Rev#:
Parameter:

We, the undersigned, CERTIFY that:

1. The analysts identified above, using the cited test method(s), which is in use at this facility for the analyses of samples under the National Environmental Laboratory Accreditation Program, have met the Demonstration of Capability.
2. The test method(s) was performed by the analyst(s) identified on this certification.
3. A copy of the test method(s) and the laboratory-specific SOPs are available for all personnel on-site.
4. The data associated with the demonstration capability are true, accurate, complete, and self explanatory.[1]
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 assessors.

Technical Director's Name and Title | Signature | Date

Quality Assurance Manager | Signature | Date

[1] 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: Date properly labeled and stored so that the results are clear and require no additional explanation.

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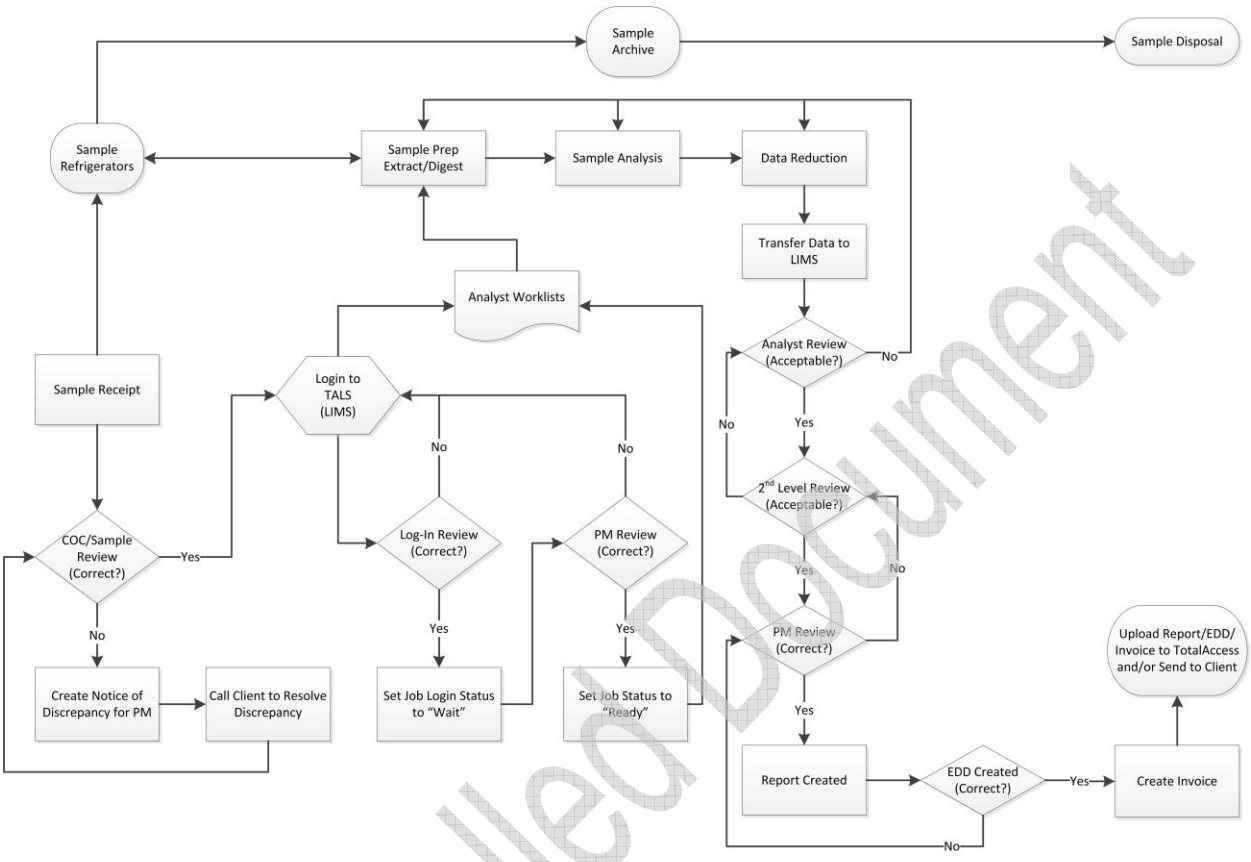
Figure 19-2. TestAmerica Irvine Workflow



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SECTION 20

EQUIPMENT AND CALIBRATIONS

20.1 OVERVIEW

The laboratory purchases the most technically advanced analytical instrumentation for sample analyses. Instrumentation is purchased on the basis of accuracy, dependability, efficiency, and sensitivity. Each laboratory is furnished with all items of sampling, preparation, analytical testing, and measurement equipment necessary to correctly perform the tests for which the laboratory has capabilities. Each piece of equipment is capable of achieving the required accuracy and complies with specifications relevant to the method being performed. Before being placed into use, the equipment (including sampling equipment) is calibrated and checked to establish that it meets its intended specification. The calibration routines for analytical instruments establish the range of quantitation. Calibration procedures are specified in laboratory SOPs. A list of laboratory equipment and instrumentation is presented in Table 20-1.

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

20.2 PREVENTIVE MAINTENANCE

20.2.1 The laboratory follows a well-defined maintenance 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.

20.2.2 Routine preventive maintenance procedures and frequency, such as 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 QC criteria.

20.2.3 Table 20-2 lists examples of scheduled routine maintenance. It is the responsibility of each Department Manager to ensure that instrument maintenance logbooks are kept for all equipment in their respective departments. Preventative maintenance procedures may be or are outlined in laboratory SOPs or instrument manuals.

20.2.4 Instrument maintenance logbooks are controlled and are used to document instrument problems, instrument repair, and maintenance activities. Maintenance logbooks shall be kept for all major pieces of equipment.

20.2.4.1 Documentation must include all major maintenance activities such as contracted preventive maintenance and service, and in-house

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activities such as the replacement of electrical components, lamps, tubing, valves, columns, detectors, cleaning, and adjustments.

20.2.4.2 Each entry in the instrument maintenance logbook 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.) must also be documented in the instrument maintenance records.

20.2.4.3 When maintenance or repair is performed by an outside agency, service receipts detailing the service performed shall be affixed into the logbooks adjacent to pages describing the maintenance performed. The service receipt that is taped or stapled into the logbook must be initialed and dated on the edge, with initials and date overlapping the attached receipt and the page where attached.

20.2.5 <u>Tag-Out Procedures</u>

If instruments or support equipment require repair or maintenance, they shall be taken out of operation or otherwise isolated, and tagged as out-of-service until such a time as the repairs or maintenance have been made and the instrument or support equipment can be demonstrated as operational by calibration and/or verification or other tests to demonstrate acceptable performance. The laboratory shall examine the effect of this defect on previous analyses or usage of the support equipment.

20.2.5.1 When an instrument or support equipment must be tagged as out-of-service, the laboratory personnel performing the repair or maintenance, or monitoring the repair or maintenance by an outside agency (see Section 20.2.4.3 above), shall notify the QA Department. The QA Department shall then tag the instrument or support equipment as out-of-service.

Note: If the repair or maintenance can be started and completed, and 'return to control' demonstrated and documented, within the same work shift, it is not necessary to tag-out the instrument or support equipment.

20.2.5.2 When repair or maintenance has been completed and 'return to control' has been demonstrated and documented, the QA Department shall be notified so that the out-of-service tag may be removed. Only QA may remove any out-of-service tag attached to an instrument or support equipment.

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20.2.5.3 The repair or maintenance must be documented in the designated maintenance logbooks.

20.2.6 In the event of equipment malfunction that cannot be resolved, service shall be obtained from the instrument vendor manufacturer, or qualified service technician, if such a service can be tendered. If on-site service is unavailable, arrangements shall be made to have the instrument shipped back to the manufacturer for repair. Backup instruments that have been approved for the analysis shall perform the analysis normally carried out by the malfunctioning instrument. If the backup is not available and the analysis cannot be carried out within the needed timeframe, the samples shall be workshared or subcontracted.

20.2.7 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 laboratory operations.

20.3 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 sample dilution into a specified volume. All raw data records associated with the support equipment are retained to document instrument performance.

20.3.1 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 initial serviceable 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 every 5 years by an outside calibration laboratory. Any weights (including ASTM Type 1) used for daily balance checks or other purposes are recalibrated/recertified annually to NIST standards (this may be done internally if laboratory maintains “calibration only” ASTM Type 1 weights). 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 logbooks, and the recalibration or

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recertification certificates kept in the QA files.

20.3.2 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 µmhos/cm.

Turbidity meters are also calibrated before each use.

All of this information is documented in logbooks. See also the laboratory SOPs on pH and Conductivity, and Turbidity for further information.

20.3.3 Thermometers

All thermometers are calibrated on an annual basis with a NIST-traceable thermometer at temperatures bracketing the range of use. IR thermometers, digital probes, and thermocouples are calibrated quarterly. IR thermometers should be calibrated over the full range of use, including ambient, iced (4°C), and frozen (0 to -5°C), per the Drinking Water Manual.

The mercury NIST thermometer is recalibrated every three 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 thermometers have increments of no more than 1°C (or 0.5°C or less increments for drinking water microbiological laboratories) and have ranges applicable to method and certification requirements. The NIST-traceable thermometer is used for no other purpose than to calibrate other thermometers.

All of this information is recorded in logbooks, and the recalibration or recertification certificates kept in the QA files.

20.3.4 Refrigerators/Freezer Units, Waterbaths, Ovens, and Incubators

The temperature of all refrigerator units and freezers used for sample and standard storage are monitored each working day (twice for microbiology).

Ovens, waterbaths, and incubators are monitored once each working day (twice for microbiology).

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

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Samples and standards storage refrigerator temperatures are kept between >0°C and ≤ 6°C. Freezers are kept at -15 ± 5°C.

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

All of this information is documented in daily temperature logbooks and method-specific logbooks.

20.3.5 Autopipettors, Dilutors, and Syringes

Mechanical volumetric dispensing devices including burettes (except Class A Glassware) are given unique identification numbers and the delivery volumes are verified gravimetrically, at a minimum, on a monthly basis.

For those dispensers that are not used for analytical measurements, a label must be applied to the device stating that it is not calibrated. Any device not regularly verified must not be used for any quantitative measurement.

Glass micro-syringes with volumes of ≥ 20 µL are checked for accuracy every six months. Glass micro-syringes with volumes < 20µL are certified by the manufacturer (e.g., Hamilton Company); certificate of accuracy and precision must be obtained and kept in the QA files.

20.3.6 Autoclaves

The performance of each autoclave shall be initially evaluated by establishing its functional properties and performance, for example heat distribution characteristics with respect to typical uses. Autoclaves shall meet specified temperature tolerances. Pressure cookers shall not be used for sterilization of growth media.

Demonstration of sterilization temperature shall be provided by use of a continuous temperature recording device or by use of a maximum registering thermometer with every cycle. At least once during each month that the autoclave is used, appropriate biological indicators shall be used to determine effective sterilization. The selected biological indicator shall be effective at the sterilization temperature and time needed to sterilize lactose-based media. Temperature sensitive tape shall be used with the contents of each autoclave run to indicate that the autoclave contents have been processed.

Records of autoclave operations shall be maintained for every cycle. Records shall include: date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time (may be recorded as time in and time out) and analyst's initials.

Autoclave maintenance, either internally or by service contract, shall be performed annually, and shall include a pressure check and verification of temperature device. Records of the maintenance shall be maintained in

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equipment logs.

NOTE: When it has been determined that the autoclave has no leaks, pressure checks can be documented using the formula PV = nRT.

The autoclave mechanical timing device shall be checked quarterly against a stopwatch and the actual time elapsed documented.

20.3.7 Field Sampling Devices (Isco Auto Samplers)

Each Auto Sampler (ISCO) is assigned a unique identification number and is recorded on the sampling documentation.

The Auto Sampler is calibrated each day of use based on the sample volume required for the specific sampling event. The results are recorded on the field sampling request form. The technician will adjust the delivery volume prior final set-up to ensure the correct aliquot is collected.

20.4 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 MDLs, 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 ICAL. Records contain, but are not limited to, the following: calibration date, method, instrument, analyst(s) initials or signatures, analysis date, analytes, concentration, response, and type of calibration (average RF, curve, or other calculations that may be used to reduce instrument responses to concentration).

Sample results must be quantitated from the ICAL and may not be quantitated from any CCV, unless otherwise required by regulation, method, or program.

If the ICAL results are outside acceptance criteria, corrective action must be performed and any affected samples re-analyzed, if sufficient sample remains. If the re-analysis is not possible, any data associated with an unacceptable ICAL will be reported with appropriate data qualifiers (refer to Section 12).

Note: Instruments must be calibrated initially and as needed thereafter and at least annually. Project-specific requirements may dictate more frequent calibrations (e.g., quarterly), as agreed upon with the client.

20.4.1 Calibration Standards

Calibration standards are prepared using the procedures indicated in the Reagents and Standards section of the determinative laboratory SOP. If a reference method does not specify the number of calibration points, a

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minimum of three calibration points (exception being ICP and ICP/MS methods) will be used.

Standards for instrument calibration are obtained from a variety of sources. All standards are traceable to national or international standards of measurement, or to national or international standard reference materials.

The lowest concentration calibration standard that is analyzed during an ICAL must be at or below the stated RL for the method, based on the final volume of extract or sample.

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 the ICAL standards (within calibration range to at least the same number of significant figures used to report the data) must be reported as having less certainty (e.g., use defined qualifiers or flags and report in an NCM using the NCM program in the LIMS). The exception to these rules is ICP methods or other methods where the referenced method does not specify two or more standards.

All ICALs 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). Any claim of unavailability of second-source standards must be accompanied by supporting documentation (e.g., e-mails from several prospective vendors where they state that the standard being sought is unavailable). The ICAL verification must occur immediately after the calibration curve has been analyzed, and before the analysis of any samples.

20.4.2 Calibration Verification

The calibration relationship established during the ICAL must be verified at least daily, as specified in the laboratory SOPs in accordance with the referenced analytical methods and in the 2003 NELAC Standard and 2009 TNI Standard. 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. The ICAL is verified with a standard source secondary (second source standard) to the ICAL standards, but CCVs may use the same source standards as the calibration curve.

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 CF or RF calculated during calibration is used to update the CF or RF used for sample quantitation. This approach, while employed in other EPA programs, amounts to a daily single-point calibration.

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All target analytes and surrogates, including those reported as non-detects, must be included in periodic calibration verifications for purposes of RT confirmation and to demonstrate that calibration verification criteria are being met, i.e., RPD, per NELAC (2003) Standard, Section 5.5.5.10 or per 2009 TNI Standard, EL-V1M4 Section 1.7.2.

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

Note: If an internal standard calibration is being used (basically in GC/MS), then bracketing standards are not required; only daily verifications are needed. The results from these verification standards must meet the CCV and the RT criteria (if applicable).

Generally, ICALs 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 CCV (or the GC/MS tuning standard in GC/MS methods). The shift ends after the completion of the analysis of the last sample, QC, or standard that can be injected within 12 hours of the beginning of the shift.

A 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 may have more frequent CCV requirements. Most inorganic methods require the CCV to be analyzed after every 10 samples or injections, including matrix or batch QC samples.

If the results of a CCV are outside the established acceptance criteria and analysis of a second consecutive (and immediate) CCV fails to produce results within acceptance criteria, corrective action shall be performed. Once corrective actions have been completed and documented, the laboratory shall demonstrate acceptable instrument / method performance by analyzing two consecutive CCVs, or a new initial instrument calibration shall be performed.

Sample analyses and reporting of data may not occur or continue until the analytical system is calibrated or calibration verified. However, data associated with unacceptable calibration verification may be fully useable under the following special conditions:

- when the acceptance criteria for the CCV are exceeded high (i.e., high bias) and the associated samples within the batch are non-detects, then those non-detects may be reported with a footnote or case narrative explaining the high bias. Otherwise the samples affected by the unacceptable CCV shall be re-analyzed after a new calibration curve has been established, evaluated and accepted; or

- when the acceptance criteria for the CCV are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum

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regulatory limit/decision level, if known. Otherwise the samples affected by the unacceptable CCV shall be re-analyzed after a new calibration curve has been established, evaluated and accepted.

Samples reported under the two conditions identified above will be appropriately flagged.

20.4.2.1 Verification of Linear and Non-Linear Calibrations

Calibration verification for calibrations involves the calculation of the percent drift or the percent difference of the instrument response between the ICAL and each subsequent analysis of the verification standard. (These calculations are available in the laboratory SOPs.) Verification standards are evaluated based on the percent difference from the average CF or RF of the ICAL or based on percent drift or percent recovery if a linear or quadratic curve is used.

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 ICAL that meets the specifications listed in the laboratory SOPs is performed.

When the acceptance criteria for the calibration verification are exceeded high (i.e., high bias) and the associated samples within the batch are NDs, then those NDs may be reported with a qualifier or case narrative explaining the high bias. Otherwise, the samples affected by the unacceptable calibration verification shall be re-analyzed after a new ICAL has been established, evaluated, and accepted.

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, if known. Otherwise, the samples affected by the unacceptable calibration verification shall be re-analyzed after a new ICAL has been established, evaluated, and accepted.

20.5 TENTATIVELY IDENTIFIED COMPOUNDS – 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. See the method-specific SOPs for guidelines on analyzing and reporting TICs.

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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 should not be reported as a TIC. If the compound is reported on the same form as true TICs, it should 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.

20.6 GC/MS TUNING

Prior to any GC/MS 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 spectrometer, the parameters may be adjusted within the specifications set by the manufacturer or the analytical method. These generally do not 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 instrument maintenance logbook.

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Table 20-1. Example: Instrumentation List

Department	Instrument Type	Manufacturer	Model Number	Serial Number	Year Put into Service	Instrument ID
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3133A37156	1992	GC 14
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3203A40477	1993	GC 15
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3203A41169	1993	GC 18
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890A	S/N2750A15898	1997	GC 19
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3336A60066	1997	GC 21
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3033A33301	1998	GC 24
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3121A35567	1993	GC 29
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3223A2733	1993	GC 33
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3336A60064	1993	GC 41
BTEX	Gas Chromatograph (FID/PID/ELCD)	Hewlett Packard	5890 Series II	S/N3203A40699	1993	GC 17
BTEX	Gas Chromatograph (FID/TCD)	Varian	CP-3800	11827	2013	GC 95
BTEX	Gas Chromatograph (FID/TCD)	Varian	CP-3800	05262	2013	GC 96
Extractions	Accelerated Solvent Extractor	Dionex	ASE 200	00120362	2001	ASE 01
Extractions	Accelerated Solvent Extractor	Dionex	ASE 200	97240463	2001	ASE 03
Extractions	Accelerated Solvent Extractor	Dionex	ASE 200	96090216	2001	ASE 04
Extractions	Accelerated Solvent Extractor	Dionex	ASE 200	07090745	2007	ASE 05
Extractions	Accelerated Solvent Extractor	Dionex	ASE 200E	07090746	2007	ASE 06
Extractions	Accelerated Solvent Extractor	Dionex	ASE 200	99120782	2002	ASE 07
Extractions	Flashpoint Tester	Koehler	K-162	10A/Y-2	1992	
Extractions	Microwave	CEM	MARS5	MD3165	2010	MARS 01
Extractions	Microwave	CEM	MARS XPRESS	MD8441	2010	MARS 02
Extractions	Rotator/ Shaker	Thermolyne *Big Bill"	M49235		Not Available	ROT 02
Extractions	SPE-Controller	Horizon Technology	SPE-DEX	020357	2003	01
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890Ser.II/5971	3140A39653	1993	GCMS 04

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Department	Instrument Type	Manufacturer	Model Number	Serial Number	Year Put into Service	Instrument ID
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890Ser.II/5972	3235A46723	1995	GCMS 05
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	6890/5973/G2589A	US10130035/US10480674	2003	GCMS 37
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973/G2578A	US10341048/US33210028	2005	GCMS 49
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890Ser.II/5971	3033A30488/3133A37717	1993	GCMS 50
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5975B/G3171A	CN10636107/US62724086	2006	GCMS 61
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890IIB/5971A	2921A24077/3188A02848	1992	GCMS 62
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	6890/5973/G2579A	CN10427051/US41720775	2007	GCMS 65
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973 Inert	CN10349032/US33220240	2008	GCMS 71
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	6890Plus (G1530A)/5973 (G1098A)	US00032006/US93122851	2008	GCMS 72
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	6890/5973	US10226108/US21843299	2010	GCMS 84
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	7890/5975	CN10752039/US80148288	2010	GCMS 88
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	7890/5975	CN10824037/US83140433	2010	GCMS 89
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890/5970	3336A60053/3307A00396	2011	GCMS 90
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890/5972	3310A48102/2950A00539	2011	GCMS 91
GCMS-SV Drinking Water	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973N	US10232062/US21863660	2009	GCMS 75
GCMS-SV Drinking Water	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890/5971A	3133A37717/2950A00539	2009	GCMS 76
GCMS-SV Drinking Water	Gas Chromatograph/Mass Spectrometer	Agilent	6890/G1530N	US10226108	2010	GCMS 82
GCMS-SV Drinking Water	Gas Chromatograph/Mass Spectrometer	Agilent	6890/G1530N	US10243060	2010	GCMS 83
GCMS-Vol Drinking Water	Gas Chromatograph/Mass Spectrometer	Agilent	6890N / 5973	CN10521030 / US40620627	2009	GCMS 74
GCMS-Vol Drinking Water	Gas Chromatograph/Mass Spectrometer	Agilent	6890N / 5973	CN10503040 / US10461983	2009	GCMS 77
GCMS-Vol Drinking Water	Gas Chromatograph/Mass Spectrometer	Agilent	6890N / 5973	US00002015 / US10440578	2009	GCMS 78

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Department	Instrument Type	Manufacturer	Model Number	Serial Number	Year Put into Service	Instrument ID
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	6890/5973A	US00020097/US72810389	1999	GCMS 01
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890II/5972	3336A60514/3524A02884	1997	GCMS 07
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	6890/5973A	US00007750/US70810354	2000	GCMS 09
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	6890/5973A	US00022931/US82311546	2000	GCMS 13
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6850/5973N	US00001207/US01140222	2001	GCMS 31
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6850/5973	US00001206/US01140215	2001	GCMS 32
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6850/5973N	US0001947/US10340261	2002	GCMS 33
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6850/5973N	US00002140/US10440793	2002	GCMS 34
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6850/5973N	US00002860/US21843317	2003	GCMS 36
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890/5973	US00034262/US01112246	2004	GCMS 43
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973	CN10318006/US30945515	2004	GCMS 44
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973	CN10318007/US30945517	2004	GCMS 45
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890II/5971A	3235A46434/3040A01409	2000	GCMS 53
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973	CN0523048/US43146864	2006	GCMS 55
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973	CN01521014/US44647184	2005	GCMS 56
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973	US00001682/US92522712	2001	GCMS 58
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973N	US10222064/US10462085	2006	GCMS 59
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973	US10206070/US10462145	2006	GCMS 60
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973 inert	CN10339005/US35120285	2007	GCMS 66
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N / 5973 Inert	CN10345035 / US33220184	2009	GCMS 73
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Hewlett Packard/O.I.	6890/5973	US00029799	2011	GCMS 92

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Department	Instrument Type	Manufacturer	Model Number	Serial Number	Year Put into Service	Instrument ID
GCMS-Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890A/5973	4500041055/45104 41650	2013	GCMS 94
GC-Semi	Gas Chromatograph	Agilent	6890N/1530N	CN10551059	2007	GC 64
GC-Semi	Gas Chromatograph (Dual ECD)	Hewlett Packard	5890 Series II	3223A43015	Not Available	GC 02
GC-Semi	Gas Chromatograph (Dual ECD)	Hewlett Packard	5890 Series II	336A51142	Not Available	GC 22
GC-Semi	Gas Chromatograph (Dual ECD)	Agilent	6890N	US10215019	2002	GC 35
GC-Semi	Gas Chromatograph (Dual ECD)	Agilent	6890N/G1530N	US10250081	Not Available	GC 43
GC-Semi	Gas Chromatograph (Dual ECD)	Agilent	6890N/G1540N	US10423015	Not Available	GC 52
GC-Semi	Gas Chromatograph (Dual ECD)	Agilent	6890N/G1540N	US10423014	Not Available	GC 54
GC-Semi	Gas Chromatograph (Dual ECD)	Agilent	6890N/G1540N	CN10551052	2007	GC 63
GC-Semi	Gas Chromatograph (Dual ECD)	Agilent	6890N/G1530N	US10322076	2007	GC 67
GC-Semi	Gas Chromatograph (Dual ECD)	Agilent	7890A/G3440A	CN10741034	2007	GC 68
GC-Semi	Gas Chromatograph (Dual ECD)	Hewlett Packard	5890 Series II	3336A56851	2010	GC 85
GC-Semi	Gas Chromatograph (Dual FID)	Hewlett Packard	5890 Series II	3126A36534	Not Available	GC 12
GC-Semi	Gas Chromatograph (Dual FID)	Agilent	6890N/G1540N	US10546009	2007	GC 69
GC-Semi	Gas Chromatograph (Dual FID)	Agilent	6890N/G1540N	US10546010	2007	GC 70
GC-Semi	Gas Chromatograph (FID)	Agilent	6890N	CN10505005	2013	GC 93
GC-Semi	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	2921A23920	2011	GC 46
GC-Semi	Gas Chromatograph (FID/PID)	Agilent	5890 Series II	S/N3133A37568	2008	GC 74
GC-SV Drinking Water	Gas Chromatograph (Dual ECD)	Agilent	6890N	US10212094	2009	GC 79
GC-SV Drinking Water	Gas Chromatograph (Dual ECD)	Agilent	6890N	US10244152	2009	GC 80
GC-SV Drinking Water	Gas Chromatograph (Dual ECD)	Agilent	6890N	US10402034	2009	GC 81
GC-SV Drinking Water	Gas Chromatograph (Dual ECD)	Agilent	6890N	US10244151	2010	GC 82
GC-SV Drinking Water	Gas Chromatograph (Dual ECD)	Agilent	6890N	CN10631072	2010	GC 86
HPLC	HPLC (DAD)	Agilent	1100	DE14914766	2009	HPLC 03

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Department	Instrument Type	Manufacturer	Model Number	Serial Number	Year Put into Service	Instrument ID
HPLC	HPLC (DAD)	Hewlett Packard	G1316A	US54000547	2009	HPLC 05
HPLC	HPLC (FLD)	Agilent	1100	DE14903835	2009	HPLC 02
HPLC	HPLC (FLD)	Agilent	1100	DE14903629	2009	HPLC 04
HPLC	HPLC (MWD)	Hewlett Packard	Series 1050	2807G00138	2008	HPLC 01
Inorganic Prep	pH Meter	Mettler Toledo	SevenEasy	1227116127	Not Available	pH 01
Inorganics	Water Bath	Precision	185	N/A	2010	04
Inorganics	Water Bath	Fisher	IsoTemp 228	1608090911951	2009	05
Metals	GFAA	Perkin Elmer	SIMAA 6000	5016	1993	GFAA
Metals	Hg FIAS Mercury Analyzer	Perkin Elmer	FIMS 400	4167	1995	CV-Hg 02
Metals	Hg FIAS Mercury Analyzer	Perkin Elmer	FIMS 400	401510021001	2010	CV-Hg 03
Metals	Inductively Coupled Plasma Spectrophotometer	Perkin Elmer	Optima 4300 DV	077N1100901	2002	ICP 04
Metals	Inductively Coupled Plasma Spectrophotometer	Perkin Elmer	Optima 5300DV	077N5112802	2006	ICP 05
Metals	Inductively Coupled Plasma Spectrophotometer	Perkin Elmer	Optima 8300	078N1051001	2011	ICP 07
Metals	Inductively Coupled Plasma Spectrophotometer/MS	Perkin Elmer	ELAN 6100E	1650004	2001	ELAN 01
Metals	Inductively Coupled Plasma Spectrophotometer/MS	Perkin Elmer	ELAN 6100E	G1970008	2004	ELAN 02
Metals	Inductively Coupled Plasma Spectrophotometer/MS	Agilent	7700 series G3281A	JP09480189	2010	ICP-MS 04
Metals	Inductively Coupled Plasma Spectrophotometer/MS	Agilent	7700 series G3281A	JP12091608	2012	ICP-MS 05
Metals	Mercury Analyzer	Leeman	Hydra AF Gold+	AFG+ 3010	2010	CV-Hg 04
Metals prep	pH Meter	Orion	EA940	TZ22A	2011	pH 07
Microbiology	Compound Microscope (10x100)	VWR	BB-P/TB-P	V167531	2009	
Microbiology	Incubator for Micro				2009	I 06
Microbiology	Incubator for Micro (35C)	VWR	1915	800902	2009	01
Microbiology	Incubator for Micro (35C)	VWR	1915	1102003	2009	02
Microbiology	Incubator for Micro (55C)	Fisher Scientific	516D	502N0034	2009	I 07

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Department	Instrument Type	Manufacturer	Model Number	Serial Number	Year Put into Service	Instrument ID
Microbiology	pH Meter	Fisher Scientific	Accumet AB15 Plus	AB92334024	2010	pH
Microbiology	Quanti Tray Sealer	Idexx	89-10894-04	6345	2009	
Microbiology	Stereo Microscope with Fluorescence source	VWR	HF-745	V167693	2009	
Microbiology	UV Lamp (big)	UVP	C-65	95025701	2009	
Microbiology	UV Lamp (small)	UVP	CC-10	95007201	2009	
Microbiology	Water Bath, circulating (44.5C)	Precision	2862	200035	2009	02
Microbiology	Water Bath, circulating (44.5C)	Precision	2866	205648-295	2010	03
Sample Control	CSB Battery	CSB	EVX 12120 F2		Not Available	01
Sample Control	CSB Battery	CSB	EVX 12120 F2		Not Available	02
Sample Control	CSB Battery	CSB	EVX 12120 F2		Not Available	03
Sample Control	CSB Battery	CSB	EVX 12120 F2		Not Available	04
Sample Control	CSB Battery	CSB	EVX 12120 F2		Not Available	05
Sample Control	CSB Battery	CSB	EVX 12120 F2		Not Available	06
Sample Control	High Capacity Battery (120V)		913		Not Available	01
Sample Control	High Capacity Battery (120V)		913		Not Available	02
Sample Control	High Capacity Battery (120V)		913		Not Available	03
Sample Control	ISCO Battery Ni-Cd (12VDC, 4.0 Ampere Hour)	Teledyne	601684040 934		Not Available	01
Sample Control	ISCO Battery Ni-Cd (12VDC, 4.0 Ampere Hour)	Teledyne	601684040 934		Not Available	02
Sample Control	ISCO Battery Ni-Cd (12VDC, 4.0 Ampere Hour)	Teledyne	601684040 934		Not Available	03
Sample Control	ISCO Battery Ni-Cd (12VDC, 4.0 Ampere Hour)	Teledyne	601684040 934		Not Available	04
Sample Control	ISCO Battery Ni-Cd (12VDC, 4.0 Ampere Hour)	Teledyne	601684040 934		Not Available	05
Sample Control	ISCO Battery Ni-Cd (12VDC, 4.0 Ampere Hour)	Teledyne	601684040 934		Not Available	06
Sample Control	ISCO Battery Ni-Cd (12VDC, 4.0 Ampere Hour)	Teledyne	601684040 934		Not Available	07
Sample Control	ISCO Samplers	GLS Teledyne	60-2954-00		Not Available	01

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Department	Instrument Type	Manufacturer	Model Number	Serial Number	Year Put into Service	Instrument ID
Sample Control	ISCO Samplers	GLS Teledyne	60-2954-00		Not Available	02
Sample Control	ISCO Samplers	GLS Teledyne	60-2954-00		Not Available	03
Sample Control	ISCO Samplers	GLS Teledyne	60-2954-00		Not Available	04
Sample Control	ISCO Samplers	GLS Teledyne	60-2954-00		Not Available	05
Sample Control	ISCO Samplers	GLS Teledyne	60-2954-00		Not Available	06
Sample Control	ISCO Samplers	603714001	3710		Not Available	09
Sample Control	ISCO Samplers	603714001	3710		Not Available	10
Sample Control	pH Meter	Thermo Scientific			Not Available	01
Sample Control	pH Meter	Thermo Scientific			Not Available	02
Wetchem	Ammonia Probe	Orion	96-12		Not Available	
Wetchem	Balance, Analytical	American Scientific	EA-180A	2904054	Not Available	BAL 7
Wetchem	Balance, Analytical	Sartorius	A200S	36100415	Not Available	BAL 28
Wetchem	Balance, Analytical	Denver	P-214	27150172	Not Available	BAL 64
Wetchem	Balance, Analytical	Denver	P-214	27150174	Not Available	BAL 65
Wetchem	Balance, Analytical	Denver	P-214	27150173	Not Available	BAL 67
Wetchem	Balance, Top Loader	Sartorius	12000S	40040045	Not Available	BAL 45
Wetchem	Balance, Top Loader	Denver	P-602	27150182	Not Available	BAL 57
Wetchem	Balance, Top Loader	Denver	P-602	27150183	Not Available	BAL 58
Wetchem	Balance, Top Loader	Denver	P-602	27150184	Not Available	BAL 59
Wetchem	Balance, Top Loader	Denver	P-602	27150186	Not Available	BAL 60
Wetchem	Balance, Top Loader	Denver	P-602	27150187	Not Available	BAL 61
Wetchem	Balance, Top Loader	Denver	P-602	27150188	Not Available	BAL 62
Wetchem	Balance, Top Loader	Denver	P-602	27050794	Not Available	BAL 63
Wetchem	Balance, Top Loader	Ohaus	C11P9	0605016JHP	Not Available	BAL 68
Wetchem	BOD auto-analyzer	Mantech	Tetra Rinse	MS-004-189	Not Available	BOD- 01
Wetchem	BOD probe	Jenco			Not Available	

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Department	Instrument Type	Manufacturer	Model Number	Serial Number	Year Put into Service	Instrument ID
Wetchem	Conductivity Meter	VWR	21800-012	Q022545	2009	COND 03
Wetchem	Conductivity/Dissolved Oxygen Probe	Corning	M90	001253	Not Available	
Wetchem	Digestion Unit	Gerhardt	Kjeldatherm KB	4062216	2007	TKN 02
Wetchem	Drying Oven	Lab Line			Not Available	Oven 01
Wetchem	Drying Oven	Scientific Products	DX-61	194002	Not Available	Oven 02
Wetchem	Drying Oven	Fisher	630G	801N0001	Not Available	Oven 03
Wetchem	Drying Oven	Fisher	Isotemp Standard OB602G	2032100355237	2010	Oven 06
Wetchem	Drying Oven	Fisher	Isotemp Standard OB702F	2153100457536	2010	Oven 07
Wetchem	Drying Oven	Fisher	Isotemp Standard	613226-529	2013	Oven 08
Wetchem	Fluoride Probe	Orion	96-09	9609BN	Not Available	
Wetchem	Incubator for BOD	VWR	2020	6003205	2002	I 02
Wetchem	Incubator for BOD	Fisher	307C	00037-090-00	2002	I 04
Wetchem	Ion Chromatograph	Dionex	CD 20	98060923	1996	IC 03
Wetchem	Ion Chromatograph	Dionex	DX-100	94120366	1997	IC 05
Wetchem	Ion Chromatograph	Dionex	CD 25	01090576	2002	IC 06
Wetchem	Ion Chromatograph	Dionex	LC 25	02050420	2005	IC 07
Wetchem	Ion Chromatograph	Dionex	ICS-1000	03110585	2002	IC 08
Wetchem	Ion Chromatograph	Dionex	LC 30	97040546	2002	IC 09
Wetchem	Ion Chromatograph	Dionex	LC20	94010215	2007	IC 11
Wetchem	Ion Chromatograph	Dionex	AD 25	01070608	2007	IC 12
Wetchem	Ion Chromatograph	Dionex	CD25A/AS 40	03070269/96060542	2007	IC 13
Wetchem	Ion Chromatograph	Dionex	CD25/IP25	04060626/04060363	2008	IC 14
Wetchem	Ion Chromatograph	Metrohm	861/838	1861004003159/1838001009124	2010	IC 15
Wetchem	Ion Chromatograph	Metrohm	881	1881000007119	2010	IC 16
Wetchem	Ion Chromatograph	Metrohm	761	NA	2010	IC 17
Wetchem	Ion Chromatograph	Metrohm	881	1881000123101	2013	IC 20

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Department	Instrument Type	Manufacturer	Model Number	Serial Number	Year Put into Service	Instrument ID
Wetchem	Ion Chromatograph (with UV/VIS detector)	Metrohm	881/887	15105/03140	2011	IC 18
Wetchem	Ion Chromatograph (with UV/VIS)	Dionex	AD 20	98020642	2000	IC 04
Wetchem	Ion Chromatograph/Mass Spectrometer	Metrohm (IC) / Agilent (MS)	LC30-1/LC110/IC800	1820023004102/US34800214	2005	ICMS 01
Wetchem	Ion Chromatograph/Mass Spectrometer	Metrohm (IC) / Agilent (MS)	761-SL / G1956B	1830002008183 / US42500764	2012	ICMS 02
Wetchem	pH Meter	Beckman	Phi - 40		Not Available	pH 03
Wetchem	pH Meter	Beckman	Phi - 40		Not Available	pH 04
Wetchem	pH Meter	Beckman	Phi - 32		Not Available	pH 05
Wetchem	pH Meter for Ammonia	Pinnacles Series	M530P	05470998	Not Available	pH 01
Wetchem	pH Meter for Fluoride	Fisher Scientific Acc Research	AR15	AR81208052	Not Available	pH 02
Wetchem	pH Probe	Orion	91-56	9156000	Not Available	pH 01
Wetchem	pH Probe	Orion	91-56		Not Available	pH 02
Wetchem	pH/mV Meter for Alkalinity	Denver Instrument	UB-10 (Basic)	300728.1	2008	pH 03
Wetchem	pH/mV Meter for BOD	Denver Instrument	Basic	13036	Not Available	pH 06
Wetchem	TOC Analyzer	O.I. Analytical	Solids	C905776109	2009	TOC 01
Wetchem	TOC Analyzer	Shimadzu	5000A	33N01036A	1998	TOC 02
Wetchem	TOC Analyzer	Tekmar-Dohrmann	Phoenix 8000	US02106006	2002	TOC 03
Wetchem	TOC Analyzer	Shimadzu	VCSH	HS1104535257CS	2011	TOC 04
Wetchem	UV/VS Spectrometer	Thermo Spectronic	Genesys20	3SGG06B0117	2002	SPEC 01
Wetchem	UV/VS Spectrometer	Thermo Spectronic	Genesys20	3SGQ068003	2012	SPEC 02

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Table 20-2. Example: Schedule of Routine Maintenance

Instrument	Procedure	Frequency
Graphite Furnace (GFAA)	Inspect graphite tube Inspect contact rings Clean windows Align lamp	Daily Daily Daily Daily
Mercury Analyzer	Check tubing for wear Fill rinse tank with 10% HCl Fill reductant bottle with 10% Stannous Chloride	Daily Daily Daily
ICP	Check/replace pump tubing Check liquid argon supply Check fluid level in waste container Check/clean/replace filters Check torch Clean torch and nebulizer	Daily/as needed Daily Daily Daily/as needed Daily As needed
ICP/ MS	Check/replace pump tubing Inspect torch and injector cones Clean/replace ion lens Replace torch o-rings Check/replace gas filters Change rough pump oil Check chiller water level	Daily/as needed Daily As needed As needed As needed As needed Weekly
UV-Vis Spectrophotometer	Clean sample holder Precision check/alignment of flow cell Wavelength verification check	As required As required Semi-annually
Gas Chromatograph/Mass Spectrometer (GCMS)	Bake trap (VOC only) Clean source Check/change vacuum pump oil Clean injectors; replace liners (SVOC only) Replace column Clean cooling fan grills	Daily As needed Annually, as needed Daily As needed Semiannually
Gas Chromatograph (GC)	Change septum Check gases Replace or clip column Clean injectors; replace liners Clean cooling fan grills	As needed Daily As needed As needed Semiannually
Electron Capture Detector (ECD)	Detector wipe test (Ni-63) Detector cleaning	Semi-annually Sent out, as needed
Flame Ionization Detector (FID)	Detector cleaning	As required
Flame Photoionization Detector (FPD)	Clean and/or Replace Lamp	As required
Photoionization Detector (PID)	Change O-rings Clean lamp window	As required As required

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Instrument	Procedure	Frequency
Ion Chromatograph (IC)	Replace column disks Change guard columns Check pump seals Replace tubing Replace suppressor Check fluid level in waste container Clean cooling fan grills	As required As required As required As required As required Daily Semiannually
Balances	Class “S” traceable weight check Clean pan and check if level Outside calibration service	Daily, when used Daily At least Annually
Conductivity Meter	0.01M KCl calibration Conductivity cell cleaning	Daily As required
Turbidimeter	Check light bulb Clean sample holder	Daily, when used Daily, when used
Deionized/Distilled Water	Daily conductivity check Check deionizer light Monitor for VOA’s System cleaning Replace cartridge & large mixed bed resins	Daily Daily As required As required As required
Drying Ovens	Temperature monitoring Temperature adjustments	When used As required
Refrigerators/ Freezers	Temperature monitoring Temperature adjustment Defrosting/cleaning	Daily As required As required
pH/Specific Ion Meter	Calibration/check slope Clean electrode	Daily As required
BOD Incubator	Temperature monitoring Incubator cleaning	Daily As required
Centrifuge	Check brushes and bearings	As needed
Water baths	Temperature monitoring Water replaced	Daily Monthly or as needed
Automated Solvent Extraction units (ASE)	Check solvent reservoirs Check tubing	Daily Daily
TurboVaps	Check gas lines Check water level Calibrate temperature	Daily Daily Annually
Total Organic Carbon Analyzer	Check gas flow Check reagent reservoir levels Replace o-rings Check autosampler needle Replace scrubbers Replace catalyst	Daily Daily As needed Daily Annually As needed
Automated Analyzer	Clean sampler Check all tubing Clean detector Clean optics and cells	Daily Daily Daily Daily

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Instrument	Procedure	Frequency
Infrared Spectrophotometer (IR)	Clean lens/optimize	As needed
Flashpoint Apparatus	Check gas line for leaks Check stirrer speed	Daily Annually
Rotators	Verify rotation speed	Annually

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SECTION 21

MEASUREMENT TRACEABILITY

21.1 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, and Deionized and Reverse Osmosis water systems, automatic pipettes and other volumetric measuring devices. (Refer to Section 20.3.) With the exception of Class A Glassware and Glass microliter syringes, monthly accuracy checks are performed for all mechanical volumetric devices. Microsyringes are verified at least semi-annually or disposed after 6 months of use. Wherever possible, subsidiary or peripheral equipment is checked against standard equipment or standards that are traceable to national or international standards. Class A Glassware and Glass microliter syringes should be routinely inspected for chips, acid etching, or deformity (e.g., bent needle). If the Class A glassware or syringe is suspect, the accuracy of the glassware will be assessed prior to use.

21.2 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, or another accreditation organization that is a signatory to an MRA of one or more of the following cooperations: ILAC or APLAC. A calibration certificate and scope of accreditation is kept on file at the laboratory. Refer to Section 20 for calibration of weights and thermometers.

21.3 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, or other approved accreditation bodies 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. 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.

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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. The appropriate QC criteria for specific standards are defined in laboratory SOPs. In most cases, the analysis of an 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, LCS).

All standards and reference materials must be stored and handled according to manufacturer's recommendations in order to prevent contamination or deterioration. If the manufacturer did not provide a recommendation, the requirements in the specific analytical methods or laboratory SOPs must be followed. Refer to Corporate EH&S Document No. CW-E-M-001 for additional information. For safety requirements, refer to the same documents.

Standards and reference materials shall not be used after their expiration dates.

21.4 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 Corporate Quality Document No. CA-Q-S-001.

All manufacturer- or vendor-supplied Certificate of Analysis or Purity must be retained, stored appropriately, and readily available for use and inspection. These records are maintained in binders or other organized files stored within each department. 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 laboratory SOP No. IR-QA-STDCNTRL.

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.

21.4.1 Standards are logged into the LIMS and are assigned a unique identification number. The following information is typically recorded in the electronic database within the LIMS:

- Standard ID
- Description of standard

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- 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
- Comments (e.g., recommended storage conditions)

Records are maintained electronically and/or in QA-controlled logbooks 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 laboratory SOPs.

21.4.2 All standards, reagents, and reference materials must be labeled in an unambiguous manner, at a minimum, with the following information:

- Expiration date (include prep date for reagents)
- Standard ID (specified from LIMS or as recorded in logbook)
- Date of receipt and initials of analyst who received commercially purchased items or date of preparation and initials of analyst who prepared the laboratory-prepared items
- Date opened (for multi-use containers, if applicable) and initials of analyst who opened the container
- Description of standard (if prepared at the laboratory)
- Concentration (if applicable)
- Special health/safety warnings, if applicable

Special health/safety warnings on original standard or reagent containers must be transferred to the containers of any laboratory-prepared standards or reagents.

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All containers of prepared reagents must include an expiration date and an ID number to trace back to preparation.

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 as specified in the laboratory SOP.

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SECTION 22

SAMPLING

22.1 OVERVIEW

The laboratory provides sampling services. Sampling procedures are described in laboratory SOP No. IR-SC-FIELD. The laboratory also supplies samplers with the necessary coolers, sample containers, sample labels, custody seals, COC forms, and packing materials required to properly pack and ship samples to the laboratory.

22.2 SAMPLING CONTAINERS

The laboratory offers clean sampling containers for use by clients. These containers are either 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.

22.2.1 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

22.3 DEFINITION OF HOLDING TIME

The date and time of sampling documented on the COC form establishes the start (day and time zero) of the sample holding time. 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 time expressed in “hours” (e.g., 6 hours, 24 hours, etc.) is 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 re-analysis.

22.4 SAMPLING CONTAINERS, PRESERVATION REQUIREMENTS, HOLDING TIMES

The preservation and holding time criteria specified in the laboratory SOPs are derived from the source documents for the methods. If method-required holding time or preservation requirements (as defined in the laboratory SOP) are not met, the results will be qualified and explained in an NCM. As soon as possible or “ASAP” is an EPA

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designation for tests for which rapid analysis is advised, but for which neither EPA nor the laboratory have a basis for a holding time.

22.5 SAMPLE ALIQUOTS / SUB-SAMPLING

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 and the quantity of sample fitted within the container need consideration when sub-sampling for sample preparation. It is the laboratory's responsibility to take a representative sub-sample or aliquot of the sample provided for analysis.

Analysts should handle each sample as if it is potentially dangerous. Personal protective equipment, at a minimum, must be worn when preparing aliquots for analysis.

Guidelines on taking sample aliquots and sub-sampling are defined in laboratory SOP No. IR-QA-SUBSAMP.

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SECTION 23

HANDLING OF SAMPLES

23.1 CHAIN OF CUSTODY

Sample management procedures at the laboratory ensure that sample integrity and custody are maintained and documented from sampling/receipt through disposal. The COC form is the written documented history of any sample and is initiated when sampling containers 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 23-1.

23.1.1 Field Documentation

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

- Sample identification
- Date and time of sampling
- Preservative

During the sampling process, the COC form is completed and must be legible. This form includes information such as:

- Client name, address, phone number, and fax number (if available)
- Project name and/or number
- Sample identification
- Date, time, and location of sampling
- Sample collector name
- Matrix description
- Container description
- Total number of each type of container
- Preservatives used
- Analysis requested
- Requested TAT
- Any special instructions
- Purchase Order number or billing information (e.g., quote number), if

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available

- Date and time that each person received or relinquished the sample(s), including their signed name.

When the sampling personnel delivers the samples directly to TestAmerica personnel, the samples are stored in a cooler with ice, as applicable, and remain solely in the possession of the client's field technician (or sampler) until the samples are delivered to the laboratory personnel. 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.

When the sampling personnel delivers the samples through a common carrier (e.g., FedEx and UPS), the COC relinquished date/time is completed by the sampling personnel and samples are released to the carrier. Samples are only considered to be received by the laboratory when personnel at the fixed laboratory facility have physical contact with the samples.

Note: Independent couriers like FedEX and UPS are not required to sign the COC form. The COC is usually kept in the sealed sample cooler. Receipt information from these couriers is recorded in the Project Receipt Checklist (see Figure 23-3); tracking numbers are recorded for all receipts each date.

23.1.2 Legal / Evidentiary COC

If samples are identified for legal/evidentiary purposes on the COC, Sample Control personnel, at login, will complete the custody seal, retain the shipping record with the COC, and initiate an internal COC for laboratory use by analysts and a sample disposal record.

23.2 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 and are discussed in detail in laboratory SOP No. IR-SC-LOGIN.

23.2.1 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 nonconformance, irregularity, or

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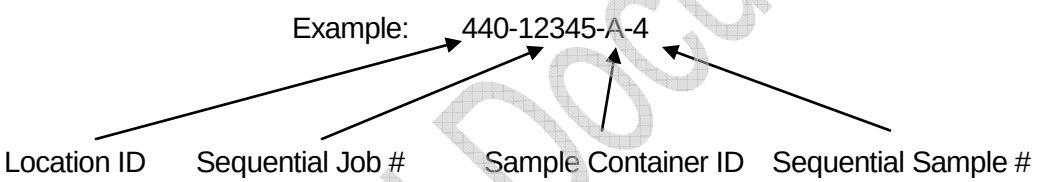
compromised sample receipt must be documented in the NCM program in the LIMS and brought to the immediate attention of the client. The COC, shipping documents, documentation of any nonconformance, irregularity, or compromised sample receipt, record of client contact, and resulting instructions become part of the project record.

23.2.1.1 Unique Sample Identification

All samples that are processed through the laboratory receive a unique sample identification to ensure that there can be no confusion regarding the identity of such samples at any time.

Using the LIMS, the laboratory assigns a unique identification code (i.e., Job) to a particular project/job occurrence. Each client sample is also identified by association with the Job and a unique sequential sample number.



The above example represents the complete Sample ID for the first container of the fourth sample received for Job 440-12345. The Job code includes the Location ID ('440' for the Irvine laboratory) and a sequential number.

With this system, a client sample can be tracked throughout the laboratory in every step from receipt to disposal.

23.3 SAMPLE ACCEPTANCE POLICY

The laboratory has a written Sample Acceptance Policy (Figure 23-2) that clearly outlines the circumstances under which samples shall be accepted or rejected. These include:

- COC filled out completely
- Samples properly labeled
- Proper sample containers with adequate volume for the analysis and necessary QC
- Samples preserved according to the requirements of the requested analytical method
- Sample holding time adhered to

The PM will be notified if any sample is received in damaged condition.

Data from samples that do not meet these criteria are flagged and the nature of the variation from policy is defined. Sample Control personnel shall include this copy with

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the sample container shipment to the client or the PM may e-mail the client a copy during project setup (prior to shipment of samples to the laboratory).

Once sample acceptance is verified, the samples are logged into the LIMS according to laboratory SOP No. IR-SC-LOGIN.

23.4 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 an organized manner in refrigerators or freezers suitable for the sample matrix (for analyses requiring thermal preservation) or in protected locations like secured shelvings in the sample receiving area for acid-preserved water containers requiring only metals analysis. 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, analyze the sample, and return the remaining sample or empty container to the refrigerator from which it originally came. All unused portions of samples, including empty sample containers, are returned to the Sample Control area. All samples are kept in the refrigerators for two to four weeks after analysis, which meets or exceeds most sample holding times. After two to four weeks, the samples are moved to dry room temperature Sample Archive area, where they are stored for an additional two to four weeks before they are disposed. This four to eight week holding period allows samples to be checked if a discrepancy or question arises. 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.

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.

23.5 HAZARDOUS SAMPLES AND FOREIGN SOILS

To minimize exposure to personnel and to avoid potential accidents, hazardous and foreign soil samples are stored in an isolated area designated for hazardous waste only. For any sample that is known to be hazardous at the time of receipt, the Sample Control personnel handling wastes clearly marks the sample with a red stamp, stamped on the sample label reading “HAZARDOUS” or “FOREIGN SOIL,” and places it in a colored and/or marked bag for easy identification. The Sample Control personnel handling wastes must completely fill out the Hazardous & Quarantine/Foreign Soil – Drum for Incineration Sample Notice (see Figure 23-4) and include a copy with the original COC

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and other sample receipt records that will be submitted to the PM. The original is retained by the Sample Control personnel handling wastes.

If after completion of analysis the analyst has determined a sample to be hazardous (based on action limits that are exceeded, as set up in the LIMS), the analyst will notify the Sample Control personnel handling wastes and submit to that personnel the original of the completed notification form (Figure 23-4) and a copy to the PM for archiving with the job records.

All hazardous samples are either returned to the client or disposed appropriately through a hazardous waste disposal firm that lab-packs all hazardous samples and removes them from the laboratory. Foreign soil samples are sent out for incineration by a USDA-approved waste disposal facility.

23.6 SAMPLE SHIPPING

In the event that the laboratory needs to ship samples, the samples are placed in coolers 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 (see Note). The COC form is signed by Sample Control and is 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 COC documentation and to keep the samples intact and on ice, if needed. Corporate EH&S Document No. CW-E-M-001 contains additional shipping requirements.

Note: If a client does not request trip blank analysis on the COC or other paperwork, the laboratory will not analyze the trip blanks that were supplied. However, in the interest of good client service, the laboratory will advise the client at the time of sample receipt that it was noted that they did not request analysis of the trip blank, and that the laboratory is providing the notification to verify that they are not inadvertently omitting a key part of regulatory compliance testing.

23.7 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 used up 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 laboratory SOP No. IR-EHS-WASTE. All procedures in the laboratory EH&S Manual are followed during disposal. Samples are normally maintained in the laboratory no longer than two months from receipt, unless otherwise requested. Unused

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portions of samples found or suspected to be hazardous according to state or federal guidelines may be returned to the client upon completion of the analytical work.

If a sample is part of a known litigation, the affected legal authority, sample data user, and/or submitter of the sample must participate in the decision about the sample's disposal. All documentation and correspondence concerning the disposal decision process must be kept on file. Pertinent information includes the date of disposal, nature of disposal (such as sample depletion, hazardous waste facility disposal, and return to client), and names of individuals who conducted the arrangements and physically completed the task. The laboratory will remove or deface sample labels prior to disposal, unless this is accomplished through the disposal method (e.g., samples are incinerated). A waste disposal record should be completed.

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Figure 23-1.

Example - Chain of Custody

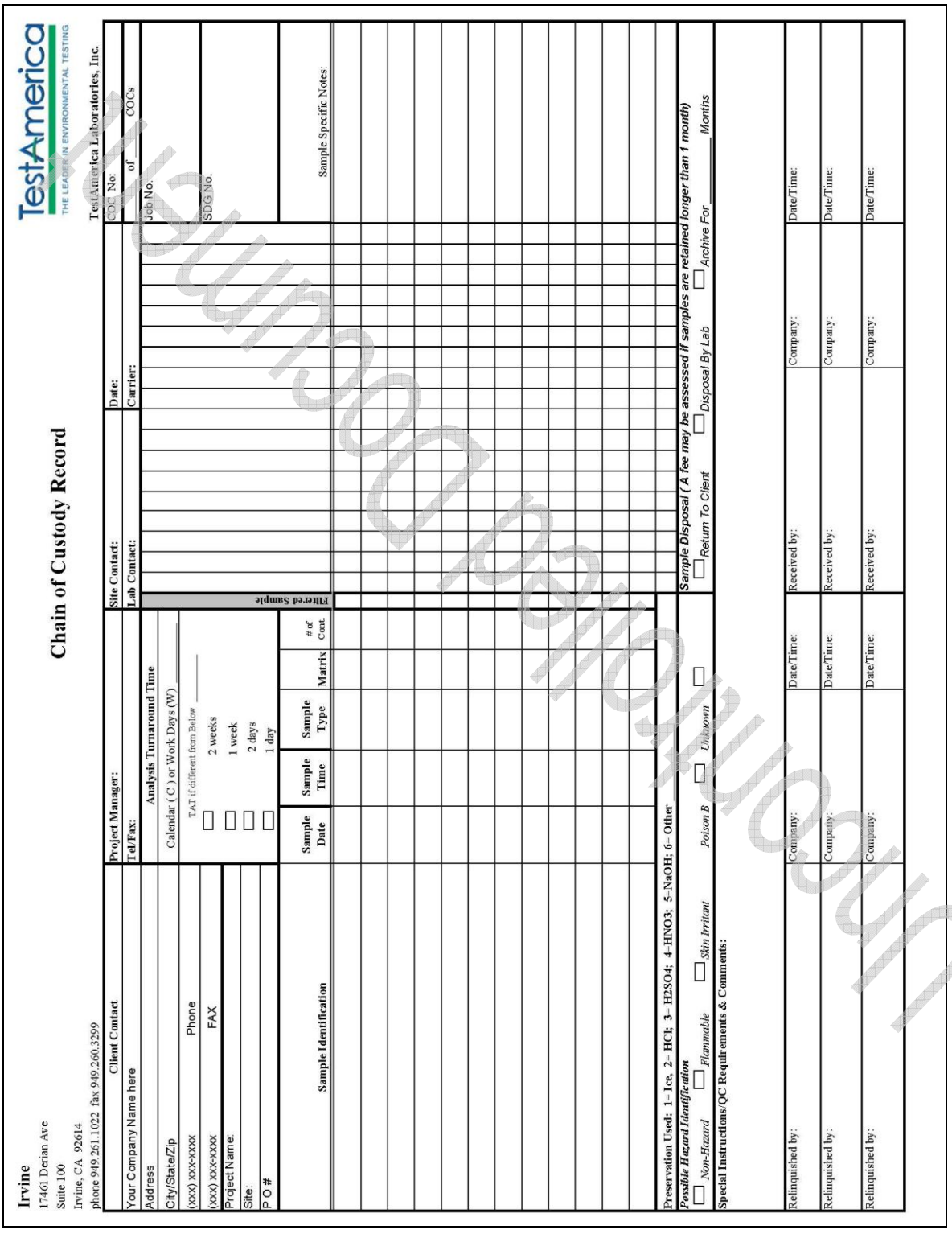

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Figure 23-2.

Example - Sample Acceptance Policy

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TestAmerica Sample Acceptance Policy

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

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

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

3) Proper sample containers with adequate volume for the analysis and necessary QC are required for each analysis requested. See TA Sample Container Guide.

4) Samples must be preserved according to the requirements of the requested analytical method (See TA Sample Container Guide). Most analytical methods require chilling samples to 4°C (other than water samples for metals analysis and samples for air analysis). For these methods, the criteria are met if the samples are chilled to below 6°C and above freezing (0°C). For methods with other temperature criteria (e.g. some bacteriological methods require ≤ 10°C), the samples must arrive within ± 2° C of the required temperature or within the method specified range. **Note:** Samples that are hand-delivered to the laboratory immediately after collection may not have had time to cool sufficiently. In this case the samples will be considered acceptable as long as there is evidence that the chilling process has begun (arrival on ice).

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- Chemical preservation (pH) will be verified at the time of analysis and the project manager will be notified immediately if there is a discrepancy. If analyses will still be reported, all affected results will be flagged to indicate improper preservation.

5) Sample Holding Times
   - TestAmerica will make every effort to analyze samples within the regulatory holding time. Samples must be received in the laboratory with enough time to perform the sample analysis. Except for short holding time samples (< 72hr HT) sample must be received with at least 48 hrs (working days) remaining on the holding time for us to ensure analysis.

   - Analyses that are designated as "field" analyses (pH, Dissolved Oxygen, Residual Chlorine, and Redox Potential) should be analyzed within 15 minutes. Dissolved Metals samples should be filtered in the field within 15 minutes. Dissolved Sulfide samples should be flocculated in the field within 15 minutes. The actual times of all "field" sample analyses are noted on the "Short Hold Time Detail Report" in the final report. If the analysis is performed at the laboratory, the data will be flagged on the final report with an 'HF' to indicate holding time is 15 minutes.

6) All samples submitted for Volatile Organic analyses should have a Trip Blank submitted at the same time. TestAmerica will supply a blank with the bottle order.

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

8) Recommendations for packing samples for shipment.

   - Pack samples in "wet" Ice rather than "Blue" ice packs.

   - Soil samples should be placed in plastic zip-lock bags. The containers often have dirt around the top and do not seal very well and are prone to intrusion from the water from melted ice.

   - Water samples would be best if wrapped with bubble-wrap or paper (newspaper, or paper towels work) and then placed in plastic zip-lock bags.

   - Fill extra cooler space with bubble wrap.

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Figure 23-3.

Example - Project Receipt Checklist

Project Receipt Checklist (PRC) **TestAmerica Irvine**

Section 1-Receipt

Cooler Received/Opened On Date/Time:_____/_____/_____ _____:_____ LIMS JOB #:_____-_____

Delivered by TA-Courier Fed Ex Client UPS Other _____

Tracking Number(s): _____,_____,_____,_____,_____

IR Thermometer ID#:_____ Correction Factor (CF):_____(must be <0.5C)

	(circle answer)
A . Does COC or sample appearance indicate "product" or otherwise hazardous matrix?	YES (NCM) -- NO
B. Are there any **SHORT HOLDS -- RUSHES (≤48HR)** – indicated on COC? **STANDARD**	CIRCLE ONE
C. Turn Around Time Requested: SAME DAY – 24-HOUR – 48-HOUR – 72-HOUR – STANDARD	
D. Are custody labels present? COOLER(S) – SAMPLE(S)	**YES (Intact/Compromised) - NO**
1. Cooler and samples appear to be uncompromised and not tampered with	**YES** -- NO (NCM) -- N/A
2. Samples were received on ice	**YES** -- NO (NCM) -- N/A
3. Cooler temp is: Uncorrected: _____ Corrected:_____	
4. Is temperature acceptable? ✓ Was a Temp Blank received…YES--NO-(temp taken from sample container)	**YES** -- NO (NCM) -- N/A
5. Temperature is recorded on both PRC and COC (raw and corrected temps)	**YES** -- NO (NCM) -- N/A
6. COC is present	**YES** -- NO (NCM) -- N/A
7. COC is filled out in ink and legible	**YES** -- NO (NCM) -- N/A
8. COC is filled out with pertinent information (signatures, contacts, etc.)	**YES** -- NO (NCM) -- N/A
9. Field Sampler's name is present on COC	**YES** -- NO (NCM) -- N/A

I certify that I received the cooler(s) and answered questions A,B,C & 1-9 :

_____ _____ _____

Initials Date NCM # (if written)

Section 2 - Cooler Breakdown

10. There are no discrepancies between containers received and the COC	**YES** -- NO (NCM) -- N/A
11. Samples are within Holding Time	**YES** -- NO (NCM) -- N/A
12. Samples have legible labels	**YES** -- NO (NCM) -- N/A
13. Containers are intact (not broken or leaking)	**YES** -- NO (NCM) -- N/A
14. Sample collection dates/times are provided	**YES** -- NO (NCM) -- N/A
15. Appropriate sample containers are supplied	**YES** -- NO (NCM) -- N/A
16. Sample bottles are adequately filled	**YES** -- NO (NCM) -- N/A
17. Sample preservation is Verified	YES -- NO (NCM) -- **N/A**
18. There is sufficient volume for all requested analyses, including requested MS/MSDs	**YES** -- NO (NCM) -- N/A
19. Containers requiring zero-headspace have <"pea-sized"(~1/4" or 6mm) bubble	**YES** -- NO (NCM) -- N/A
20. Multiphasic samples are not present	**YES** -- NO (NCM) -- N/A
21. Samples do not require splitting or compositing	**YES** – NO (require (circle one): splitting – compositing)
22. Residual chlorine checked	**YES** -- NO (NCM) -- N/A
23. Number of containers in cooler:_____	
24. Does # of containers in cooler agree with # of containers on COC?	**YES** -- NO (NCM) -- N/A
25. Were VOA vials received?	YES -- NO
26. Were Encores or Terracores received? ✓ IF YES, what date and time were they placed in freezer _____/_____/_____ _____:_____	YES -- NO
27. Were Trip Blank(s) received?	YES -- NO

I certify that I unloaded the cooler and answered questions 10-27:

_____ _____ _____

Initials Date NCM # (if written)

Section 3 - Labeling

I certify that I labeled the container(s) from this cooler(s): _____ _____ _____

Initials Date NCM # (if written)

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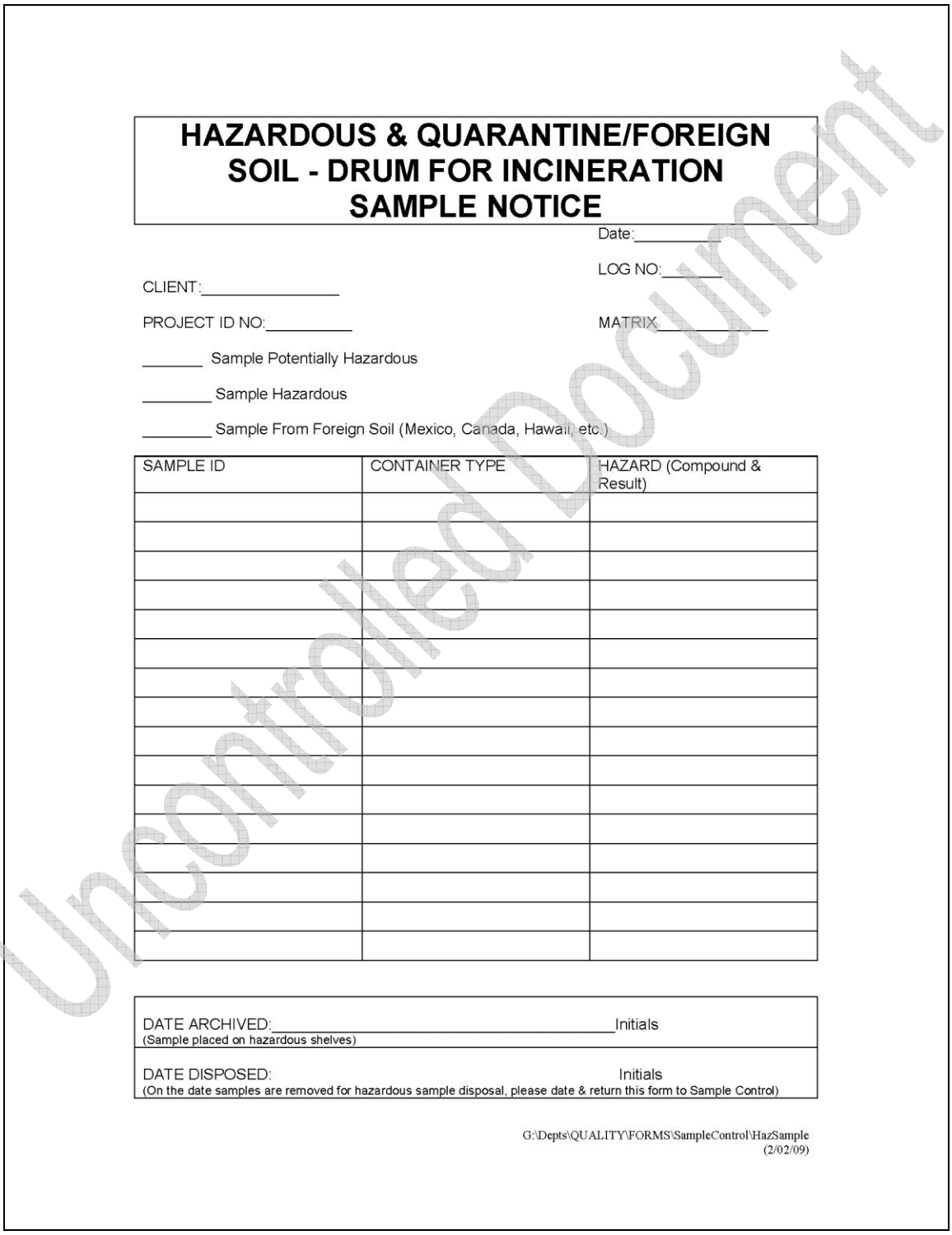
Figure 23-4.

Example - Hazardous & Quarantine/Foreign Soil - Drum for Incineration Sample Notice



HAZARDOUS & QUARANTINE/FOREIGN SOIL - DRUM FOR INCINERATION SAMPLE NOTICE

Date:_____

LOG NO:_____

CLIENT:_____

PROJECT ID NO:_____ MATRIX:_____

_____ Sample Potentially Hazardous

_____ Sample Hazardous

_____ Sample From Foreign Soil (Mexico, Canada, Hawaii, etc.)

SAMPLE ID	CONTAINER TYPE	HAZARD (Compound & Result)

DATE ARCHIVED:_____Initials
(Sample placed on hazardous shelves)

DATE DISPOSED: Initials
(On the date samples are removed for hazardous sample disposal, please date & return this form to Sample Control)

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SECTION 24

ASSURING THE QUALITY OF TEST RESULTS

24.1 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 20, but also by routine process QC measurements (e.g., blanks, LCS, MS, sample duplicates, surrogates, and internal standards). These QC checks are performed as required by the method or regulations to assess precision and accuracy. QC samples are to be treated in the exact same manner as the associated field samples being tested. In addition to the routine process QC samples, PT samples (concentrations unknown to laboratory) are analyzed to help ensure laboratory performance.

24.2 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.

24.3 NEGATIVE CONTROLS

Table 24-1. Example – Negative Controls

Control Type	Details
Method Blank	They are used to assess preparation and analysis for possible contamination during the preparation and processing steps.
	The specific frequency of use for method blanks during the analytical sequence is defined in the specific SOP for each analysis. Generally, it is one for each batch of samples; not to exceed 20 environmental samples.
	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. The method blank goes through all of the steps of the process (including as necessary: filtration, clean-ups, etc.).
	Re-analyze or qualify associated sample results when the concentration of a targeted analyte in the method blank is at or above the RL, as established by the method or by regulation, AND is greater than 1/10 of the amount measured in the sample.
Calibration Blanks	They 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.

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Control Type	Details
Instrument Blanks	They 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 preparation process. Instrument blanks may also be inserted throughout the analytical sequence to minimize the effect of carryover from samples with high analyte content.
Trip Blank [1]	They are required to be submitted by the client with each shipment of samples requiring aqueous volatiles analyses (or as specified in the client's project plan). A trip blank may be purchased (certified-clean) or 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.
Field Blanks [1]	They are sometimes used for specific projects by the field samplers. For example, a field blank is 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)
Equipment Blanks [1]	They are also sometimes created in the field for specific projects. 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 or TNI)
Holding Blanks	They are also referred to as refrigerator blanks or storage blanks and are used to monitor the sample storage units for volatile organic compounds during the storage of VOA samples in the laboratory.

[1] When known, these field QC samples 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, equipment blanks, or trip blanks with labels such as "FB", "EB", or "TB," respectively.

Evaluation criteria and corrective action for these controls are defined in the specific SOP for each analysis.

24.3.1 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:

Table 24-2. Negative Controls for Microbiology

Control Type	Details
Sterility Checks (Media)	They are analyzed for each lot of pre-prepared media, ready-to-use media, and for each batch of medium prepared by the laboratory.
Filtration Blanks	They are run at the beginning and end for each sterilized filtration unit used in a filtration series. For pre-sterilized single use funnels, a sterility check is performed on at least one funnel per lot.
Sterility checks (Sample Containers)	They are performed on at least one container per lot of purchased, pre-sterilized containers. If containers are prepared and sterilized by the laboratory, one container per sterilization batch is checked. Container sterility checks are performed using non-selective growth media.
Sterility Checks (Dilution Water)	They are performed on each batch of dilution water prepared by the laboratory and on each batch of pre-prepared dilution water. All checks are performed using non-selective growth media.

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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.

24.4 POSITIVE CONTROLS

Control samples (e.g., QC indicators) are analyzed with each batch of samples to evaluate data based upon (1) Method Performance (LCS or Blank Spike), which entails both the preparation and measurement steps; and (2) Matrix Effects (MS or sample duplicates), 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 the laboratory SOPs.

24.4.1 Method Performance Control – LCS

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.

The LCS 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. 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 is reported as the LCS. In some instances where there is no practical clean solid matrix available, aqueous LCSs may be processed for solid matrices; final results may be calculated as mg/kg or ug/kg, assuming 100% solids and a weight equivalent to the aliquot used for the corresponding field samples, to facilitate comparison with the field samples.

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.).

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The specific frequency of use for LCS during the analytical sequence is defined in the specific SOP for each analysis. It is generally one for each batch of samples, not to exceed 20 environmental samples.

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 LCS (and MS), 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.

- For methods that have 1-10 target analytes, spike all components.
- For methods that include 11- 20 target analytes, spike at least 10 or 80%, whichever is greater.
- For methods with more than 20 target analytes, spike at least 16 components.
- Exception: Due to analyte incompatibility in pesticides, Toxaphene and Chlordane are only spiked at client request based on specific project needs.
- 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.

24.4.2 Positive Controls for Microbiological Methods

- Each lot of pre-prepared media (including chromofluorogenic reagent) and each batch of laboratory prepared media is tested with a pure culture of known positive reaction.
- In addition, every analytical batch also contains a pure culture of known positive reaction.
- A pure culture of known negative reaction is also tested with each analytical batch to ensure specificity of the procedure.

24.5 SAMPLE MATRIX CONTROLS

Table 24-3. Sample Matrix Control

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Control Type	Details	
MS	Use	Used to assess the effect that the sample matrix of the spiked sample has on the precision and accuracy of the results generated by the method used.
	Typical Frequency[1]	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. 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 LCS and MS. Refer to the laboratory SOP for complete details.
	Description	Essentially, a sample fortified with a known amount of the test analyte(s).
Surrogate	Use	Measures method performance to sample matrix (organics only).
	Typical Frequency[1]	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. 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.
	Description	Similar to MS except the analytes are compounds with properties that mimic the analyte of interest and are unlikely to be found in environmental samples.
Duplicates[2]	Use	For a measure of analytical precision, with each matrix-specific batch of samples processed, a sample duplicate or LCSD is carried through the complete analytical procedure.
	Typical Frequency[1]	Duplicate samples are usually analyzed with methods that do not require MS analysis.
	Description	Performed by analyzing two aliquots of the same field sample independently or an additional LCS.
Internal Standard	Use	Corrects for matrix effects and helps troubleshoot variability in analytical response, and is assessed after data acquisition.
	Typical Frequency[1]	Spiked into all environmental and QC samples (including the ICAL). Added to all organic and ICP methods, as required by the analytical method.
	Description	A standard that is not present in environmental samples, elutes near the target analytes of concern, and is completely resolved from all of them. Possible sources of poor internal standard response are sample matrix, poor analytical technique, or instrument performance.

[1] See the specific laboratory SOP for type and frequency of sample matrix control samples.
[2] Recoveries for the duplicate samples must meet the same laboratory-established recovery limits for the 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 RPD. Poor precision between duplicates (except LCS/LCSD) may indicate non-homogeneous matrix or sampling.

24.6 ACCEPTANCE CRITERIA (CONTROL LIMITS)

As mandated by the test method and regulation, the individual analyte in the LCS, MS, or Surrogate Spike is evaluated against the control limits published in the test method. Where there are no established acceptance criteria, the laboratory calculates in-house control limits with the use of control charts or, in some cases, utilizes client project-specific control limits. 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.

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. Control limits are established per method, (as opposed to per instrument) regardless of the number of instruments utilized.

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Laboratory-generated percent 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).

- Regardless of the calculated limit, the control limit should be no tighter than those used in the Calibration Verification (ICV/CCV), unless the analytical method specifies a tighter limit.
- In-house limits cannot be any wider than those mandated in a regulated analytical method. Client- or contract-required control limits are evaluated against the laboratory's statistically derived control limits to determine if the DQOs can be achieved. If laboratory control limits are not consistent with DQOs, then alternatives must be considered, such as method improvements or use of an alternate analytical method.
- The lowest acceptable recovery limit will be 10% (the analyte must be detectable and identifiable). Exception: The lowest acceptable recovery limit for Benzidine will be 5% and the analyte must be detectable and identifiable.
- The maximum acceptable recovery limit will be 150%.
- The maximum acceptable RPD limit will be 35% for waters and 40% for soils. The minimum RPD limit will be 10%.
- If either the high or low end of the control limit changes by ≤5% from previous, the control chart is visually inspected and, using professional judgment, the control limits may be left unchanged if there is no effect on the laboratory's ability to meet the existing limits.

24.6.1 The laboratory 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 laboratory SOP No. IR-QA-CNTRLLIM.

- The QA Department e-mails the appropriate laboratory staff a table that contains the accuracy and precision limits for the spiked analytes for each method performed at the laboratory. Unless otherwise noted, the control limits within these tables are laboratory-generated. The table includes an effective date. The control limits are stored in the LIMS.
- When control limits are updated, the LIMS maintains in its database the previous control limits, so that historical control limits in effect for a specific time period may be retrieved for reference.

24.6.2 An 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 to be out of control and should be re-analyzed, if possible. If re-analysis 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 12) is also initiated if an LCS exceeds

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the acceptance limits. Sample results may be qualified and reported without re-analysis if:

- The analyte results are below the RL and the LCS is above the upper control limit.
- The analytical results are above the relevant regulatory limit, if known, and the LCS is below the lower control limit.

Marginal exceedence limits are not currently used in the laboratory. An effective means to determine randomness of failures, as required in the NELAC or TNI Standard, must first be put in place.

24.6.3 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 acceptance limits. If obvious preparation errors are suspected, or if requested by the client, unacceptable MS/MSDs are reprocessed and re-analyzed to prove matrix interference. A more detailed discussion of acceptance criteria and corrective action can be found in the laboratory SOPs and in Section 12.

24.6.4 If a surrogate standard falls outside the acceptance limits, if there is not obvious chromatographic matrix interference, re-analyze 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 re-analysis 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 re-analysis may be performed on a single sample rather than all of the samples, and if the surrogate meets the recovery criteria in the re-analysis, all of the affected samples would require re-analysis.

24.7 ADDITIONAL PROCEDURES TO ASSURE QUALITY CONTROL

The laboratory has written and approved SOPs to assure the accuracy of the test method, including calibration (see Section 20), use of certified reference materials (see Section 21), and use of PT samples (see Section 15).

A discussion regarding MDL, LOD, and LOQ can be found in Section 19.

Use of formulae to reduce data is discussed in the laboratory SOPs and in Section 20.

Selection of appropriate reagents and standards is included in Sections 9 and 21.

A discussion on selectivity of the test is included in Section 5.

Constant and consistent test conditions are discussed in Section 18.

The laboratory's sample acceptance policy is included in Section 23.

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SECTION 25

REPORTING RESULTS

25.1 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 conflict between client requests and laboratory ethics or regulatory requirements, the laboratory's ethical and legal requirements are paramount, and the laboratory will work with the client during project setup to develop an acceptable solution. Refer to Section 7.

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 (and this documentation must be kept with all other project information). There still must be enough information that would show any analyses that were out of conformance (e.g., 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 19.

25.2 TEST REPORTS

Analytical results are reported in a format that is satisfactory to the client and meets all requirements of applicable accrediting authorities and agencies. A variety of report formats are available to meet specific needs. The report is printed on laboratory letterhead, reviewed, and signed by the appropriate PM. At a minimum, the standard laboratory report shall contain the following information:

25.2.1 A report title (e.g., Analytical Report) with headers for the different information associated with a sample result (e.g., analyte name, data qualifiers, units, MDL, RL, dilution, date analyzed, instrument, analyst, and QC batch).

25.2.2 Each report cover page printed on company letterhead, which includes the laboratory name, address, and telephone number.

25.2.3 A unique identification of the report (e.g., job number) and on each page an identification to ensure the page is recognized as part of the report and a clear identification of the end.

Note: Page numbers of report are represented as Page # of ##, where the first number is the page number and the second is the total number of pages. Any addendum (that is not included in the report pagination) to the report must be identified in the case narrative (located in the front of the report) as being an integral part of the report, so it is a

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recognizable part of the report and cannot accidentally get separated from it (e.g., sampling information).

25.2.4 A copy of the COC

- Any COC involved with worksharing or subcontracting is included.
- All COCs associated with the report are included in the pagination.

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

25.2.6 Client PM or other contact

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

25.2.8 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.

25.2.9 Date reported or date of revision, if applicable.

25.2.10 Method of analysis including method code (EPA, ASTM, etc.)

25.2.11 RLs

25.2.12 MDLs, if requested

25.2.13 Definition of data qualifiers and reporting acronyms, e.g., ND

25.2.14 Sample results

25.2.15 QC data consisting of method blank, surrogate (if applicable), LCS, and MS/MSD recoveries and control limits

25.2.16 Condition of samples at receipt, including temperature (if applicable). Any nonconformance observed is reported in an NCM that is included with the final report to the client, as necessary.

25.2.17 A statement expressing the validity of the results, that the source methodology was followed, and that all results were reviewed for error.

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

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

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25.2.20 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 Laboratory Director.

25.2.21

25.2.22 When NELAC or TNI accreditation is required, the laboratory shall certify that the test results meet all requirements of NELAC or TNI or provide reasons and/or justification if they do not.

25.2.23

25.2.24 Where applicable, a narrative to the report that explains issues and concerns not already addressed in the NCM.

25.2.25 When soil samples are analyzed, a specific identification as to whether soils are reported on a "wet weight" or "dry weight" basis.

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

25.2.27 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 so in the report (e.g., partial report). A complete report must be sent once all of the work has been completed.

25.2.28 Any non-TestAmerica subcontracted analysis results are provided as a separate report on the official letterhead of the subcontractor. All TestAmerica subcontracting is clearly identified on the report as to which laboratory performed a specific analysis.

25.2.29 Non-accredited methods or tests performed shall be clearly identified in the case narrative when claims of accreditation to the NELAC or TNI Standard are made.

Note: Refer to Corporate Information Technology SOP No. CA-I-P-002 for details on internally applying electronic signatures of approval.

25.3 REPORTING LEVEL OR REPORT TYPE

The laboratory offers four levels of report packages. 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. Note that raw data presented in Level III and Level IV reports are in CLP-like format:

- Level I is a report with the features described in Section 25.2 above
- Level II is a Level I report plus summary information, including results for the method blank reported to the laboratory MDL (if required or applicable), percent recovery for LCS and MS samples, and the RPD values for all LCS/LCSD, MS/MSD, and sample duplicate analyses.
- Level III contains all the information supplied in Level II, plus all sample raw data but not raw data for tunes, calibrations, etc.

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- Level IV is the same as Level III with the addition of all tune and calibration data

In addition to hardcopy reports, the laboratory also provides reports in CD deliverable form when requested. Initial reports may be provided to clients by facsimile or e-mail or upload to TestAmerica's Total Access database. All faxed or other electronic reports are followed by hardcopy, when requested. Procedures used to ensure client confidentiality are outlined in Section 25.6.

25.3.1 Electronic Data Deliverables

EDDs are routinely offered as part of TestAmerica's services. TestAmerica Irvine offers a variety of EDD formats including, but not limited to, NAS, ADR, COELT EDF, EQuIS, GISKEY, Microsoft Excel, Locus EIM, Standard TestAmerica Format, FoxPro, and Terrabase.

PMs submit EDD specifications to Corporate IT for review. Once the laboratory 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 Corporate 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.

25.4 SUPPLEMENTAL INFORMATION FOR TEST

The laboratory 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 qualifier and/or a narrative or an NCM that will be attached to the final report to the client.

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

Where quality system requirements are not met, a statement of compliance/non-compliance with requirements and/or specifications is required, including identification of test results derived from any sample that did not meet NELAC or TNI sample acceptance requirements such as improper container, holding time, or temperature.

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

Opinions and Interpretations – In general, the test report contains objective

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information and does not contain subjective information such as opinions and interpretations. If such information is required by the client, the Laboratory Director will determine if a response can be prepared. If so, the Laboratory Director will designate the appropriate member of the management team to prepare a response. The response will be fully documented, and reviewed by the Laboratory Director, before release to the client. There may be additional fees charged to the client at this time, as this is a non-routine function of the laboratory.

When opinions or interpretations are included in the report, the laboratory provides an explanation as to the basis upon which the opinions and interpretations have been made. Opinions and interpretations are clearly noted as such and where applicable, a comment should be added suggesting that the client verify the opinion or interpretation with their regulator.

25.5 ENVIRONMENTAL TESTING OBTAINED FROM SUBCONTRACTORS

If the laboratory is unable to provide the client the requested analysis, the samples would be subcontracted following the procedures outlined in Corporate Legal Document No. CA-L-S-002.

Data reported from analyses performed by a subcontract laboratory are clearly identified as such on the analytical report provided to the client. Results from a subcontract laboratory outside of TestAmerica are reported to the client on the subcontract laboratory's original report stationery and the report includes any accompanying documentation.

25.6 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 accreditation body 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.

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:

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"CONFIDENTIALITY NOTICE: This e-mail communication, including any attachments, may contain privileged or confidential information for specific individuals and is protected by law. If you are not the intended recipient(s), you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited and you should delete this message and its attachments from your computer without retaining any copies. If you have received this communication in error, please reply to the sender immediately. We appreciate your cooperation."

25.7 FORMAT OF REPORTS

The format of reports is designed to accommodate each type of environmental test carried out and to minimize the possibility of misunderstanding or misuse.

25.8 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 12).

The revised report is retained in LIMS, as is the original report. The revised report is stored in LIMS under the job number along with a sequential revision number.

When the report is re-issued, a notation of "amended report" is placed on the cover/signature page of the report *or at the top of the narrative page* with a brief explanation of reason for the amendment and a reference back to the last final report generated. *For example*: *This final report, identified as Revision 1, was revised on 11/3/2014 to include toluene in sample NQA1504 per client's request. This final report replaces the final report identified as Revision 0.*

25.9 POLICIES ON CLIENT REQUESTS FOR AMENDMENTS

25.9.1 Policy on Data Omissions or RL Increases

Fundamentally, our policy is simply to not omit previously reported results (including data qualifiers) or to not raise RLs and report sample results as ND. This policy has few exceptions. They are as follows:

- 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

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change being interpreted as misrepresentation by anyone inside or outside of our company.

25.9.2 Multiple Reports

TestAmerica does not issue multiple reports for the same job 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 the QA Manager.

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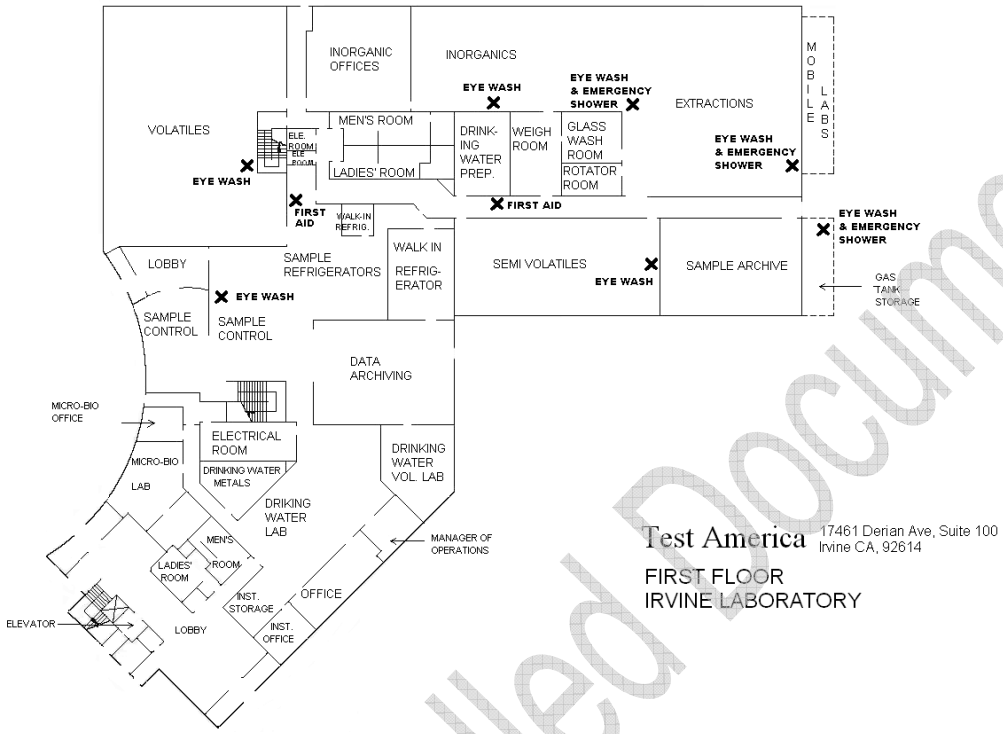
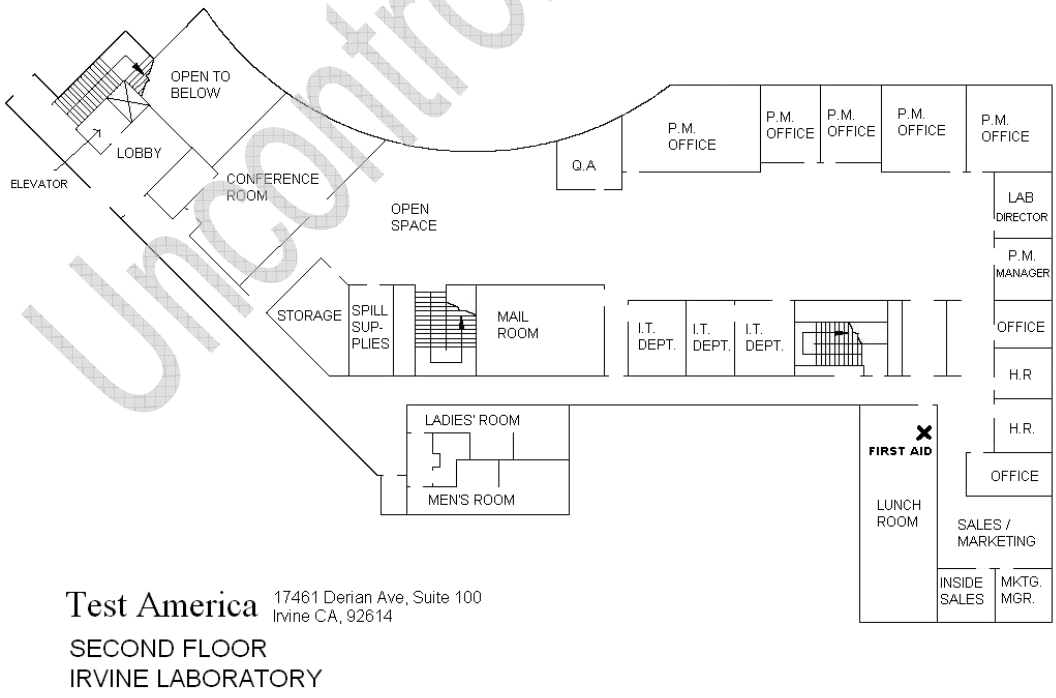
Appendix 1.

Laboratory Floor Plan





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Appendix 2. Glossary / Acronyms

Glossary:

Acceptance Criteria:
Specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQ)

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.

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.

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 QC to meet the required level of quality.

Analytical Uncertainty:
A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis. (TNI)

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 laboratory accreditation). (TNI)

Audit:
A systematic and independent examination of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management, and reporting aspects of a system to determine whether QA/QC and technical activities are being conducted as planned and whether these activities will effectively achieve quality objectives. (TNI)

Batch:
A set of environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents and within a defined period of time.

A preparation batch is composed of one to 20 environmental samples of the same quality systems 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) which are analyzed sequentially (no time gaps greater than 8 hours) as a group using the same calibration curve or factor, and meeting the method calibration check criteria (tune time or bracketing CCVs). An analytical batch can include prepared samples originating from various quality system matrices and can exceed 20 samples. (TNI)

NOTE: For methods that do not require a preparative step, the analytical batch must meet the same criteria as the preparation batch. Rerun of the same environmental sample is counted as part of the 20 in a batch. Field QC samples are included in the batch count.

A set of up to 20 environmental samples (reportable or not) of the same matrix processed using the same procedures and the same lot(s) of reagents within the same time period. A preparation batch is

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composed of one to 20 environmental samples of the same quality systems 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 calibration factor. The batch must be analyzed sequentially using the same instrument and instrument configuration within the same calibration event (i.e., the same calibration curve, calibration factors, or RFs must be in effect throughout the analysis). QC samples do not count towards the 20 samples in a batch. Rerun of the same environmental sample is counted as part of the 20 in a batch. Field QC samples are included in the batch count.

Bias**:**
The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value). (TNI)

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. (ASQ)

Calibration:
A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards. (TNI)

1) In calibration of support equipment, the values realized by standards are established through the use of reference standards that are traceable to the International System of Units.
2) In calibration according to methods, the values realized by standards are typically established through the use of Reference Materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications.

Calibration Curve:
The mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response. (TNI)

Calibration Standard:
A substance or reference material used to calibrate an instrument.

Certified Reference Material:
A reference material accompanied by a certificate having a value, measurement uncertainty, and stated metrological traceability chain to a national metrology institute. (TNI)

Chain of Custody:
Record that documents the possession of the samples from the time of collection to receipt at the laboratory. This record generally includes the number and types of containers, the mode of collection, the collector, time of collection, preservation, and requested analyses. (TNI)

Compromised Samples:
Those samples, which are improperly sampled, insufficiently documented (COC 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 requires analysis, the results must be appropriately qualified.

Confidential Business Information:

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Information that an organization designates as having the potential of providing a competitor with inappropriate insight into its management, operation, or products. TNI and its representatives agree to safeguard 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 clean-up procedures. (TNI)

Conformance:
An affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements. (ANSI/ASQ E1994)

Correction:
Action necessary to correct or repair analysis-specific nonconformances. The acceptance criteria for method-specific QC and protocols as well as the associated corrective actions. 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 to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence. (ISO 8402)

Data Audit:
A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality (i.e., they meet specified acceptance criteria).

Data Reduction:
The process of transforming the number of data by arithmetic or statistical calculations, standard curves, and concentration factors, and collation into a more useable form. (TNI)

Deficiency:
An unauthorized deviation from acceptable procedures or practices, or a defect in an item. (ASQ)

Demonstration of Capability:
A procedure to establish the ability of the analyst to generate analytical results of acceptable accuracy and precision. (TNI)

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. (ASQ)

Duplicate Analyses:
The analyses or measurements of the variable of interest performed identically on two sub-samples 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)

Equipment Blank:
Sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures.

External Standard Calibration:

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Calibrations for methods that do not utilize internal standards to compensate for changes in instrument conditions.

Field Blank:
Blank prepared in the field by filling a clean container with pure deionized water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA OSWER)

Field of Accreditation:
Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.

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)

Internal Standard:
A known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical test method. (TNI)

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 Detection Limit:
The minimum amount of a substance that can be measured with a specified degree of confidence that the amount is greater than zero using a specific instrument. The IDL is associated with the instrumental portion of a specific method only, and sample preparation steps are not considered in its derivation. The IDL is a statistical estimation at a specified confidence interval of the concentration at which the relative uncertainty is ± 100%. The IDL represents a range where qualitative detection occurs on a specific instrument. Quantitative results are not produced in this range.

Laboratory Control Sample (or 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 of the procedure, unless otherwise noted in a reference method. 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.

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 analysis of organic compounds and 0.995 for analysis of inorganic compounds.

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Limit(s) of Detection (LOD) [a.k.a., Method Detection Limit (MDL)]:
A laboratory's estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect in their facility. (TNI)

LOD Verification [a.k.a., MDL Verification]:
A processed QC sample in the matrix of interest, spiked with the analyte at no more than 3X the calculated MDL for single analyte tests and 4X the calculated MDL for multiple analyte tests and processed through the entire analytical procedure.

Limit(s) of Quantitation (LOQ) [a.k.a., Reporting Limit]:
The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence. (TNI)

Matrix Spike (spiked sample or fortified sample):
A sample prepared, taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a referenced method, by adding a known amount of target analyte to a specified amount of sample for which an independent test result of target analyte concentration is available. MS is used, for example, to determine the effect of the matrix on a method's recovery efficiency.

Matrix Spike Duplicate (spiked sample or fortified sample duplicate):
MS prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

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.

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)

Negative Control:
Measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results.

Non-conformance:
An indication, judgment, or state of not having met the requirements of the relevant specifications, contract, or regulation.

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.

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.

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. (TNI)

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Preservation:
Any condition under which a sample must be kept, in order to maintain chemical and/or biological integrity prior to analysis. (TNI)

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. (TNI)

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. (TNI)

Proficiency Testing Sample:
A sample, the composition of which is unknown to the laboratory and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria. (TNI)

Quality Assurance:
An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type of quality needed and expected by the client. (TNI)

Quality Assurance [Project] Plan:
A formal document describing the detailed QC 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 that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions, and ensuring that the results are of acceptable quality. (TNI)

Quality Control Sample:
A sample used to assess the performance of all or a portion of the measurement system. One of any number of samples, such as Certified Reference Materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking, intended to demonstrate that a measurement system or activity is in control. (TNI)

Quality Manual:
A document stating the management policies, objectives, principles, organizational structure, 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. (TNI)

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 activities. (TNI)

Quality System 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:

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Aqueous: Any aqueous sample excluded from the definition of Drinking Water or Saline/Estuarine. 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 & Emissions: 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. (TNI)

Range:
The difference between the minimum and the maximum of a set of values. (EPA-QAD)

Raw Data:
The documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, untabulated sample results, QC sample results, printouts of chromatograms, instrument outputs, and handwritten records. (TNI)

Record Retention**:**
The systematic collection, indexing, and storing of documented information under secure conditions.

Reference Material:
Material or substance, one or more properties of which are, sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. (TNI)

Reference Standard:
Standard used for the calibration of working measurement standards in a given organization or a given location. (TNI)

Sampling:
Activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure.

Second-Order Polynomial Curve (Quadratic):
The second-order order curves are a mathematical calculation of a slightly curved 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 second-order regression will generate a coefficient of determination (r^2) that is a measure of the "goodness of fit" of the quadratic curvature of the data. A value of 1.00

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indicates a perfect fit. In order to be used for quantitative purposes, r^2 must be greater than or equal to 0.99.

Selectivity:
The ability to analyze, distinguish, and determine a specific analyte or parameter from another component that may be a potential interferent or that may behave similarly to the target analyte or parameter within the measurement system. (TNI)

Sensitivity:
The capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. (TNI)

Spike:
A known mass of target analyte added to a blank, sample, or sub-sample; used to determine recovery efficiency or for other QC purposes.

Standard:
The document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of standard setting and meets the approval requirements of standard adoption organizations procedures and policies. (TNI)

Standard Operating Procedures:
A written document which details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps. SOPs are officially approved as the methods for performing certain routine or repetitive tasks. (TNI)

Storage Blank:
A blank matrix stored with field samples of a similar matrix (volatiles only) that measures storage contribution to any source of contamination.

Surrogate:
A substance with properties that mimic the analyte of interest. It is unlikely to be found in environmental samples and is added to them for QC 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.

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 Manager (or Technical Director):
A member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results.

Technology:
A specific arrangement of analytical instruments, detection systems, and/or preparation techniques.

Traceability:
The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection

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sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project. (TNI)

Trip Blank:
A blank matrix placed in a sealed container at the laboratory that is shipped, held unopened in the field, and returned to the laboratory in the shipping container with the field samples.

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.

Acronyms:

A2LA – American Association for Laboratory Accreditation
AE – Account Executive
ANSI – American National Standards Institute
APLAC – Asia-Pacific Laboratory Accreditation Cooperation
ASQ – American Society for Quality
ASTM – American Society for Testing and Materials
CBI – Confidential Business Information
CCV – Continuing Calibration Verification
CF – Calibration Factor
CFR – Code of Federal Regulations
COC – Chain of Custody
CQMP – Corporate Quality Management Plan
CSM – Customer Service Manager
DOC – Demonstration of Capability
DQO – Data Quality Objectives
ECO – Ethics and Compliance Officer
EDD – Electronic Data Deliverable
EH&S – Environmental Health and Safety
EPA-OSWER – Environmental Protection Agency–Office of Solid Waste and Emergency Response
EPA-QAD – Environmental Protection Agency–Quality Assurance Division
FID – Flame Ionization Detector
GC – Gas Chromatography
GC/MS – Gas Chromatography/Mass Spectrometry
GFAA – Graphite Furnace Atomic Absorption
HPLC – High Performance Liquid Chromatography
HVAC – Heating, Ventilation, and Air Conditioning
ICAL – Initial Calibration
iCAT – Incident/Complaint Activity Tracker
ICP – Inductively Coupled Plasma Atomic Emission Spectroscopy
ICP/MS – Inductively Coupled Plasma Mass Spectrometry
ICV – Initial Calibration Verification
IDL – Instrument Detection Limit
IDOC – Initial Demonstration of Capability
IEC – International Electrotechnical Commission
ILAC – International Laboratory Accreditation Cooperation
IR – Infrared
ISO – International Standards Organization
IT – Information Technology
LCS – Laboratory Control Sample
LCSD – Laboratory Control Sample Duplicate
LIMS – Laboratory Information Management System
LOD – Limit of Detection
LOQ – Limit of Quantitation

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MDL – Method Detection Limit
MDLV – Method Detection Limit Verification
MRA – Mutual Recognition Arrangement
MS – Matrix Spike
MSD – Matrix Spike Duplicate
MSDS – Material Safety Data Sheet
NCM – Nonconformance Memo
ND – Not Detected
NELAC – National Environmental Laboratory Accreditation Conference
NELAP – National Environmental Laboratory Accreditation Program
NIST – National Institute of Standards and Technology
NVLAP – National Voluntary Laboratory Accreditation
OSHA – Occupational Safety and Health Administration
PDF – Portable Document Format
PID – Photo Ionization Detector
PM – Project Manager
PMA – Project Manager Assistant
PT – Proficiency or Performance Testing
QA/QC – Quality Assurance/Quality Control
QAM – Quality Assurance Manual
QAPP – Quality Assurance Project Plan
QL – Quantitation Limit
QS – Quality System
RF – Response Factor
RFP – Request for Proposal
RL – Reporting Limit
RPD – Relative Percent Difference
RT – Retention Time
SAP – Sampling and Analysis Plan
SOP – Standard Operating Procedure
TAT – Turnaround Time
TCLP - Toxicity Characteristic Leaching Procedure
TDS – Total Dissolved Solids
TIC – Tentatively Identified Compound
TNI – The NELAC Institute
USDA – U.S. Department of Agriculture
VOA – Volatile Organic Analytes
VOC – Volatile Organic Compound

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Appendix 3.

Laboratory Certifications, Accreditations, Validations

TestAmerica Irvine maintains certifications, accreditations, and approvals 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 QAM, SOPs, MDLs, training records, etc. At the time of this QAM revision, the laboratory has accreditation/certification/licensing with the following organizations:

CERTIFICATION / ACCREDITATION STATUS
IRVINE LABORATORY (EPA ID CA01531)

State	Agency	Program	License Number	Latest Update	Expiration Date
CA	CDPH-NELAP	DW, WW, HW	01108CA	2/5/2013	01/31/14
CA	CDPH-ELAP	HW	2706	06/27/12	06/30/13
AK	DEC-DEH	DW	CA01531	11/06/12	6/30/13
AZ	DHS	DW, WW, HW	AZ0671	10/26/12	10/13/13
NV	DEP	DW, WW, RCRA	CA015312009A	10/2/12	07/31/13
HI	DOH	DW	--	3/8/13	01/31/14
CNMI	DEQ	DW	MP002	3/28/13	01/31/14
GUAM	EPA	DW	12-002r	6/13/13	01/23/14
NM	DWB	DW	--	5/1/2013	01/31/14
OR	ORELAP	DW	4005	9/11/12	9/12/13
--	CSDLAC	WW	10256	09/11/06	--
--	USDA	Foreign Soil	P330-09-00080	06/06/12	06/06/15
	EPA	UCMR3	CA01531	9/5/12	-----
--	EPA	ERLN/Water Laboratory Alliance (WLA)	--	8/26/11	--

The certificates and parameter lists (which may differ) are available upon request from a laboratory representative and may be found in the Corporate Intranet and in the laboratory's QA files.

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