

Quality Assurance Project Plan

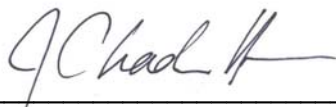
NERT Remedial Investigation – Downgradient Study Area
Nevada Environmental Response Trust Site
Henderson, Nevada

Final



Quality Assurance Project Plan

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Prepared By Chad Roper, PhD, Analytical Task Lead



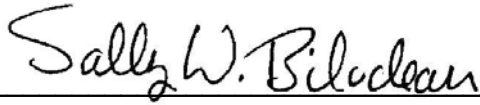
Reviewed By Lily Bayati, Project Chemist

Quality Assurance Project Plan (Rev 1)

NERT Remedial Investigation – Downgradient Study Area
Nevada Environmental Response Trust Site, Henderson, Nevada

Responsible Certified Environmental Manager (CEM) for this project

I hereby certify that I am responsible for the services described in this document and for the preparation of this document. The services described in this document have been provided in a manner consistent with the current standards of the profession and, to the best of my knowledge, comply with all applicable federal, state and local statutes, regulations and ordinances.



6/21/17

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List of Acronyms and Abbreviations

%R	percent recovery
µm	micrometer
BMI	Black Mountain Industrial
COPC	contaminant of potential concern
DI	deionized
DO	dissolved oxygen
DQO	data quality objective
DVSR	data validation summary report
EB	equipment blank
EDD	electronic data deliverable
EPA	U.S. Environmental Protection Agency
FB	field blank
FD	field duplicate
FS	Feasibility Study
HASP	health and safety plan
ICP	inductively coupled plasma
ID	identification
LCS	laboratory control sample
LCSD	laboratory control sample duplicate
LVW	Las Vegas Wash
MDL	method detection limit
MS	matrix spike
MSD	matrix spike duplicate
NDEP	Nevada Division of Environmental Protection
NELAC	National Environmental Laboratory Accreditation Conference
NERT	Nevada Environmental Response Trust
ORP	oxygen reduction potential
OSHA	Occupational Safety and Health Administration
PARCCS	precision, accuracy, representativeness, comparability, completeness, sensitivity
PID	photoionization detector
PM	Project Manager
PQL	practical quantitation limit
QA	quality assurance
QAPP	Quality Assurance Project Plan
QC	quality control
RI	Remedial Investigation
RPD	relative percent difference
RPM	Remedial Project Manager
SOP	standard operating procedure

Distribution List

This Quality Assurance Project Plan (QAPP) will be distributed electronically to the entities listed below. The QAPP may also be distributed to other project personnel including, but not limited to, client representatives and consultants, analytical laboratories, remediation contractors, and subcontractors, as needed.

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AECOM is responsible for ensuring that all project personnel have the most recent version of this QAPP.

1.0 Project Management

1.1 Introduction

On behalf of the Nevada Division of Environmental Protection (NDEP), AECOM has revised the existing Quality Assurance Project Plan (QAPP) for activities conducted in the Remedial Investigation (RI) of the Nevada Environmental Response Trust (NERT) – Downgradient Study Area located in Clark County, Nevada. This revised QAPP remains generally consistent in approach with the NDEP-approved QAPP prepared by Ramboll Environ (formerly known as ENVIRON) (Ramboll 2014). This revision serves to update the QAPP to reflect changes to the level of QA/QC as directed by NDEP (**Appendix A**). The changes involve the elimination of Stage 2B and Stage 4 data validation in favor of Stage 2A.

The purpose of this QAPP is to 1) describe the QA/QC procedures that the project team will follow during sampling and analysis; and 2) assure reporting of data that are representative of field conditions meet the established data quality objectives (DQOs), and are of acceptable quality to meet industry standards. The QAPP will be implemented in conjunction with the program-specific work plans that contain specific descriptions of the investigation activities to be performed.

This QAPP has been prepared in general accordance with the applicable elements of several U.S. Environmental Protection Agency (EPA) guidance documents, including *Guidance on Systematic Planning Using the Data Quality Objectives Process*, EPA QA/G-4 (EPA 2006); *EPA Requirements for Quality Assurance Project Plans*, EPA QA/R-5 (EPA 2001a and 2001b); and *Guidance for Quality Assurance Project Plans*, EPA QA/G-5 (EPA 2002).

Future plans will be incorporated into this QAPP by reference. Program-specific work plans will describe the specific objectives, sample locations and frequency, sample designations, analytical parameters, and test methods for the individual events.

1.2 QAPP Objectives and Use

QA/QC are activities undertaken to achieve the goal of producing data that accurately characterize the sites and materials that have been sampled. QA is generally understood to be more comprehensive than QC.

QC is the basic building block of data quality. It starts with activities whose purpose is to control quality at the source by finding problems and defects. At its simplest, QC is inspecting, testing or checking data to make sure it is correct, valid, or otherwise in accordance with established specifications. The intent is to identify data that is not correct, and either correct or eliminate it, to make sure it conforms to the specifications, and/or functions as required. QC does not ensure quality; it only finds instances where quality is absent or below established criteria.

QA can be defined as the integrated system of activities that ensures that a project meets defined standards. QA asserts that data quality can be improved by looking 'further up the line'. It is aimed at preventing nonconforming or invalid data. QA can be defined as the integrated system of activities that ensures that a project meets defined standards. QA still has QC at its core to control data quality, but it goes beyond testing or inspection to also consider related activities or processes (such as training, document control and audits) that may be resulting in systemic and recurring data quality issues.

The overall goal of the QA/QC procedures and specifications established in this QAPP is to ensure that comparable and representative data are produced during the implementation of the program-

specific work plans and that data quality is consistently assessed and documented with respect to its precision, accuracy, representativeness, comparability, completeness and sensitivity (PARCCS) parameters. The specific QAPP objectives are to:

- Provide standardized methods and quality specifications for all anticipated field sampling, analysis, and data review procedures;
- Provide guidance and criteria for selected field and analytical procedures; and
- Establish procedures for reviewing and documenting compliance with field and analytical procedures.

This QAPP documents the planning, implementation, and assessment procedures for the QA/QC program to be followed during implementation of the program-specific work plans. The QAPP will be expanded if further sampling work activities or analyses are identified. Similarly, should the list of chemicals of interest change, this QAPP will be modified to reflect those changes.

1.3 Project Schedule

The schedule for each groundwater or surface water sampling program will be specified in the program-specific work plans.

1.4 Project Organization/Roles and Responsibilities

Implementation of the approved QAPP requires the involvement of a wide range of individuals and organizations working together as a team. The project organization, and roles and responsibilities of the individuals involved, are defined in the QAPP to promote a clear understanding of the role that each party plays, and to provide the lines of authority and reporting for the project. Personnel assigned to the project will be required to familiarize themselves with pertinent protocols and procedures presented in this QAPP. Key project positions relate to project oversight, project management, sampling and analytical data acquisition management, data validation management, and database management.

AECOM, on behalf of NDEP, will be responsible for the direction and quality of all phases of the Groundwater Sampling Plan/Surface Water Sampling Plan implementation including QA/QC and will perform the scope of work as directed by NDEP. An organizational chart for the project is provided as **Figure 2**. The individuals participating in the project and their specific roles and responsibilities are discussed below:

Weiquan Dong, NDEP Remedial Project Manager: The NDEP Remedial Project Manager (RPM) has overall responsibility for regulatory oversight of all phases of the project and will be responsible for reviewing the QAPP.

Sally Bilodeau, PG, CEM, AECOM Project Manager: The AECOM Project Manager (PM) is responsible for technical decisions involving the project, including interaction and coordination with AECOM project staff and NDEP. The AECOM PM is also responsible for reviewing the sampling program(s) and associated field activities for compliance with the QAPP, including QA/QC, strategies, and review of all documents. The AECOM PM will have primary responsibility for project QA/QC and will evaluate and, if necessary, implement any corrective actions regarding data quality issues.

Leta Maclean, CHMM, AECOM Project QA/QC Officer: The QA/QC Officer will enforce implementation of QA/QC procedures during the field sampling program and is responsible for reviewing the project QA/QC program as it relates to the collection and completeness of data from

field and laboratory operations. After receiving analytical results, the QA/QC Officer will evaluate the field and laboratory data against the requirements of the QAPP.

AECOM Task Leaders: The AECOM Task Leaders are responsible for scope, cost, and technical considerations of the project; staff and task coordination; subcontractor coordination and implementation and review of overall project quality of the collection, completeness, and presentation of the data. If field conditions require modifications to protocol outlined in the QAPP, or if questions arise, the AECOM Task Leaders will be the primary contact for direction of field personnel. The AECOM Task Leaders will also be responsible for oversight and review of the QA/QC programs related to the compilation of data.

- **Carmen Caceres-Schnell, PG, AECOM Subsurface Investigation Task Leader:** This Task Leader is responsible for overall implementation of approved work plans, including work conducted by field subcontractors and general oversight of field activities.
- **Kristen Durocher, AECOM Surface Water Investigation Task Leader:** This Task Leader is responsible for overall implementation of approved work plans, including work conducted by the field subcontractors and general oversight of field activities.
- **Chad Roper, PhD, AECOM Analytical Task Leader:** This Task Leader is responsible for coordination with the analytical laboratories, review of analytical data, and tracking data through the data validation and reporting processes and will work with the other AECOM Task Leaders to ensure that work is conducted in compliance with project-specific objectives and applicable QA/QC procedures. During the contracting process the Analytical Task Leader will ensure that method control limits are sufficient to meet this QAPP and are adequate for the use of the data. The Analytical Task Leader is also responsible to generate the QAPP and update it as needed.

Laboratory Project Managers: Each Laboratory PM is the primary point-of-contact at the analytical laboratory for the project, and is responsible for ensuring project data meet the QA/QC objectives established herein. The Laboratory PM is also responsible for tracking the progress of testing in the laboratory and ensuring the timely delivery of data or other laboratory deliverables to the project team. The laboratories used for chemical surface water and groundwater testing will be certified by the State of Nevada for the analysis of interest. In the absence of Nevada certification for a particular analysis, National Environmental Laboratory Accreditation Conference (NELAC) certification will be considered an acceptable substitute.

- **Patty Mata, Laboratory PM at TestAmerica Laboratories, Inc. (TestAmerica):** The primary subcontracted laboratory for surface water and groundwater analysis for this project is TestAmerica's Irvine, California, location. The Laboratory PM will coordinate with individual laboratory managers for this project. The primary laboratory may also subcontract analyses to other certified laboratories that can meet the requirements of this QAPP upon written approval of the AECOM PM or AECOM Analytical Task Leader and following consultation with NDEP.

Data Management: The Analytical Task Leader (Chad Roper) is responsible for coordinating data validation and supervising database management. This includes review of data from the laboratory at the appropriate level, adding any qualifiers to call-out differences between guidelines and the reported data, and preparing the data for electronic submission to the database. AECOM will be conducting data validation and preparing data validation summary reports for this project.

Members of the project team are subject to change. A change in team members alone will not necessitate a revision to the QAPP.

1.5 Problem Definition and Background

The purpose of the investigation in the NERT RI Downgradient Study Area is to collect additional data to evaluate the nature and extent of perchlorate (and other NERT contaminants of potential concern [COPCs]) in groundwater, to support the Remedial Action Objectives as part of NERT's RI and Feasibility Study (FS). The Downgradient Study Area is believed to have been impacted from former Kerr-McGee/Tronox operations through off-site migration via groundwater and historic discharges to the former ditch conveyance system utilized by the Black Mountain Industrial (BMI) Complex companies. The Scope of Work includes planning for and implementation of RI activities within the Downgradient Study Area that covers the section of the Las Vegas Wash (LVW) from the Duck Creek to Lake Las Vegas and the area between Galleria Road and the LVW (**Figure 1**).

The investigation currently underway within the area referred to as the Downgradient Study Area has been the location of industrial operations since 1942 when it was developed by the U.S. government as a magnesium plant to support World War II operations (**Figure 1**). Following the war, this area continued to be used for industrial activities, including production of perchlorate, boron, and manganese compounds. Former industrial and waste management activities conducted at the NERT RI Study Area, as well as those conducted at adjacent properties, resulted in contamination of environmental media, including soil, groundwater, and surface water. Since 1979, the NERT RI Study Area has been the subject of numerous investigations and removal actions. Soil removal actions were conducted in 2010 and 2011 at the NERT RI Study Area to minimize potential health risks from impacted soil. Additional soil removal was performed in 2013 when the east end of the Beta Ditch was excavated. The soil removal activities and post-removal conditions are described in detail in the Revised Interim Soil Removal Action Completion Report (ENVIRON 2012). On-site groundwater removal actions include the installation of a groundwater extraction and treatment system, designed to capture and treat perchlorate and hexavalent chromium in shallow groundwater.

The distribution and concentration of perchlorate and other NERT COPCs in groundwater and surface water in the LVW within the Downgradient Study Area are the focus of this investigation. Groundwater data and surface water representing current target chemical concentrations within the Downgradient Study Area are needed to quantify the flux of perchlorate migrating from groundwater into the surface water flowing in the LVW and on to Lake Mead.

Tasks addressed by this QAPP include:

- Collecting surface water and groundwater samples,
- Conducting field analysis of water quality parameters,
- Labeling and shipping samples to laboratories,
- Documenting field activities on a daily basis,
- Subcontracting of laboratory services,
- Reviewing and validating laboratory data,
- Preparing data validation summary reports, and
- Submitting finalized validated data to NERT databases.

1.6 Project Description

The work to be completed includes surface water and groundwater chemical analyses to fill data gaps remaining from previous investigations, thereby providing additional information, including data regarding the magnitude and extent of selected chemicals in surface water and groundwater within

the Downgradient Study Area. The specific objectives, sample locations and frequency, sample designations, analytical parameters, and test methods for the individual events will be described in the program-specific work plans.

1.7 Data Quality Objectives

The overall goal of the QA/QC procedures and specifications established in this QAPP is to ensure that comparable and representative data are produced and that data quality is consistently assessed and documented in order to accomplish the objectives of the program-specific work plans. To achieve this goal, AECOM has followed a systematic approach in the planning of this project equivalent to the EPA DQO Process, as described in *Guidance on Systematic Planning Using the Data Quality Objectives Process*, EPA QA/G-4 (EPA 2006).

The DQO Process is a series of logical steps that guides users to a plan for the resource-effective acquisition of environmental data. It is used to establish performance and acceptance criteria, which serve as the basis for designing a plan for generating data of sufficient quality and quantity to support the goals of the study. The DQO Process consists of seven iterative steps; the iterative nature of the DQO Process allows one or more of these steps to be revisited as more information on the problem is obtained. The seven steps are as follows:

1. State the problem.
2. Identify the goal of the study.
3. Identify the information inputs.
4. Define the boundaries of the study.
5. Develop the analytical approach.
6. Specify performance of acceptance criteria.
7. Develop the detailed plan for obtaining data.

The DQO Process has driven the development of the Program-specific work plans, the choice of analytical methods, the establishment of relevant data validation procedures, and related aspects of the collection of environmental measurement data. The DQOs specify the data type, quality, quantity, and uses needed to make decisions and are the basis for designing data collection activities. The QA/QC procedures for this project require that the data meet minimum requirements of the PARCCS parameters. The procedures and minimum requirements are presented in the subsequent sections of this QAPP.

The primary and all other subcontracted laboratories will perform analytical work in accordance with this QAPP as well as with their internal standard operating procedures (SOPs) and QA Manuals, which comply with NELAC standards and EPA protocols established in *Test Methods for Evaluating Solid Waste, Physical Chemical Methods, SW-846*, dated June 1997, (SW-846) (EPA 1997). The QA Manuals include names of the responsible oversight individuals, QA manual review and update procedures, organization and responsibilities of various individuals, QA/QC objectives and reports, QA/QC policies and procedures including sampling and receiving policies, equipment calibrations and maintenance information, necessary reagents and standards, extraction and analysis methods, data review and reporting processes, system audits and corrective actions, certifications, recordkeeping and sample retention, sample disposal procedures, recent method detection limit (MDL) studies, and other QA/QC criteria relevant to the specific analytical methods.

The Analytical Task Leader will evaluate the field and laboratory data against the requirements of the QAPP. Each analytical laboratory will provide the most current QA/QC information, SOPs, and QA Manuals to the Analytical Task Leader that specify laboratory QA/QC samples and acceptance levels for each method. Laboratories contracted to perform analyses for this project are summarized on **Table 1**. The project specific MDLs, reporting limits, and QC limits for the analytes to be tested are provided in **Table 2**.

Project laboratories will either use the limits specified in this QAPP or propose equally or more stringent statistically calculated QC limits. Specific QA/QC samples will be analyzed to satisfy the DQOs. The QA/QC samples to be used and the minimum frequency of their analysis for this project are summarized in **Table 3**. The data obtained will conform to the QC requirements specified in this QAPP. The project Analytical Task Leader will be responsible for performing the data quality evaluations, the results of which will be included in the QA/QC sections of reports. A discussion of the measurement parameters and how they will be used to evaluate project analytical data follows.

This QAPP, and any QAPP addendum, collectively, will specify explicitly the data that are needed to meet the objectives of the project and how that data will be used. In addition, this QAPP discusses implementation of control mechanisms and standards that are used to obtain data of sufficient quality to meet all project DQOs. The project DQOs provide an internal means for control and review so the environmentally related measurements and data collected by the project team are valid, scientifically sound, and of known, acceptable, and documented quality.

1.7.1 Characteristics of Data Quality

The term “data quality” refers to the level of uncertainty associated with a particular data set. Data quality associated with environmental measurement is a function of the sampling plan rationale and procedures used to collect the samples, as well as of the analytical methods and instrumentation used in making the measurements. Uncertainty cannot be eliminated entirely from environmental data. However, QA programs effective in measuring uncertainty in data are employed to monitor and control excursions from the desired DQOs. Sources of uncertainty that can be traced to the sampling component include poor sampling plan design, incorrect sample handling, faulty sample transportation, and inconsistent use of SOPs. The most common sources of uncertainty that can be traced to the analytical component of the total measurement system are problems associated with calibration and contamination.

The purpose of this QAPP is to ensure that the data collected are of known and documented quality and useful for the purposes for which they are intended. The procedures described are designed to obtain data quality indicators for each field procedure and analytical method. To ensure that quality data continues to be produced, systematic checks must show that test results and field procedures remain reproducible and that the analytical methodology is actually measuring the quantity of analytes in each sample.

1.7.2 Measurement Performance Criteria

The primary measurement quality objective for the monitoring program relates to the precision and accuracy, including detections and QLs, for the analytical methods performed. All analytical results will be evaluated in accordance with PARCCS parameters to document the quality of the data and to ensure that the data are of sufficient quality to meet the project objectives. The following subsections describe each of the PARCCS parameters and how they will be assessed within this project.

Precision of the data is the measure of reproducibility or agreement among repeated measurements of the same sample under identical or substantially similar conditions. It is represented as either a range of values or as a standard deviation above the mean value. Precision goals vary for analytical data by the type of QC samples measured. Both laboratory and field QC samples are utilized to

measure precision. Precision may be expressed as a percentage of the mean of measurements, such as relative range or relative standard deviation.

Analytical precision is a measurement of the variability associated with duplicate or replicate analyses of the same sample in the laboratory. Analytical precision is determined by analysis of laboratory QC samples, such as matrix spike duplicates (MSD) or laboratory control sample duplicates (LCSD), or sample duplicates. These samples should contain concentrations of an analyte above the reporting limit. The most commonly used estimates of precision are percent relative standard deviation and the relative percent difference (RPD) when only two samples are used. RPDs for laboratory control samples (LCS) are listed in **Table 2** under matrix spike (MS) RPD and blank spike/LCS RPD. Percent relative standard deviation values are calculated when there are more than two replicates, and the values are comparable to RPD values. The objectives for field sample RPDs are ≤30 percent for aqueous samples. Field sample RPDs are listed in **Table 2** under duplicate RPDs. Samples outside the limits will be noted and reported with qualifiers.

Total precision is a measurement of the variability associated with the entire sampling and analytical process. It is determined by the analysis of duplicate samples, which measure variability introduced by the laboratory and field operations. Field duplicate (FD) samples are analyzed to assess field and analytical precision.

Table 3 sets forth the frequency with which laboratory duplicate samples (i.e., LCSD and MSD) will be analyzed as well as the allowable difference in results for laboratory QA/QC samples. If the precision goals indicated in this QAPP are not met, the data will be qualified for reporting purposes.

Accuracy of the data is the measure of the overall agreement of a measured value to the true value. It includes a combination of systematic error (bias) and random error (precision) components of sampling and analytical operations. It reflects the total error associated with a measurement. A measurement is considered accurate when the value reported does not differ from the true value or known concentration of a spike sample or standard beyond an acceptable margin. Field and laboratory activities are subject to accuracy checks.

To estimate the accuracy of the data, a selected sample is spiked with a known amount of a standard and is analyzed; these results are used to calculate percent recovery (%R). Accuracy of laboratory analyses will be assessed by comparing results to control limits for a surrogate standard, MS, or LCS, and initial and continuing calibration of instruments. Laboratory accuracy is expressed as the %R. If the %R is determined to be outside of the acceptance criteria, then the data will be flagged for reporting purposes. Accuracy goals vary for analytical data by the type of analysis employed. Laboratory goals are established as part of the laboratory QA/QC program as described in the laboratory QA Manual and SOPs.

Accuracy of field measured data will be maintained by keeping the field instruments in proper working condition and calibrating as specified by operation manuals. The specific maintenance and calibration procedures in the operation manuals will be followed. The results of calibrations will be evaluated against the limits established in operation manuals specific to each instrument and recorded in field logbooks. Field accuracy will also be assessed in part through adherence to all sample handling, preservation, and holding time requirements as described in this QAPP.

Representativeness is a qualitative term used to express the degree to which data accurately and precisely represent a characteristic of a population. It is mostly concerned with the proper design of the sampling program. Sample collection and handling methods, sample preparation, analytical procedures, holding times, and QA protocols developed for this project, and discussed in the subsequent sections of this document, have been established to ensure that the collected data are representative.

Completeness is defined as the percentage of measurements judged to be valid based on the number of planned analyses. The completeness goal is to generate a sufficient amount of valid data to meet project needs and is calculated and reported for each method, matrix, and analyte combination. Completeness describes the content of the data set once errors, if any, have been identified and qualified, and rejected data have been removed from the data set. Completeness may also be impacted when planned samples are not collected (e.g., caliche makes borehole advancement impossible) or collected samples are not analyzed (e.g., sample bottle broken in transit). The number of valid results divided by the number of planned results, expressed as a percentage, determines the completeness of the data set. The target completeness objective for this project is 90 percent for all types of samples; however, the actual completeness may be different, depending on the intrinsic nature of the samples. The data set will be considered complete if at least 90 percent of the data planned for collection in the field sampling plan is usable without meaningful qualifiers or errors. If the goal is not achieved, the rationale for the incompleteness will be assessed and reported. The data completeness will be evaluated during the data validation review process.

Comparability is a qualitative term used to express the confidence with which one data set can be compared to another data set. The objective for the QA/QC program is to produce data with the greatest possible degree of comparability. The number of matrices that are samples and the range of field conditions as encountered are considered in determining comparability. Data comparability will be sustained in this project through the use of defined procedures for sampling and analysis (sample collection and handling, sample preparation, and analytical procedures), reporting in standard units, normalizing results to standard conditions, and using standard and comprehensive reporting formats.

The data set will be considered comparable when EPA or other standard methods have been used for analyses, the data set is representative, and the field investigation is conducted in accordance with accepted industry standards. Laboratory analyses for surface water and groundwater will be performed in accordance with prescribed EPA protocols established in the document *Test Methods for Evaluating Solid Waste, Physical Chemical Method, SW-846*, dated June 1997 (EPA 1997), or other appropriate methods as required.

Sensitivity refers to the amount of analyte necessary to produce a detector response that can be reliably detected (MDL) or quantified (practical quantitation limit [PQL]) (NDEP 2008). The laboratory will strive to achieve reporting limits that are sufficiently low to allow for evaluation of the data with respect to the identified DQOs. Where practicable, to reduce the possibility of false negatives, the PQL of each COPC should be lower than the corresponding screening value. In cases where screening values are below PQLs, the MDLs can be used to evaluate the presence or absence of the analyte in environmental samples. Estimated concentrations detected below the PQL but above the MDL will be reported by the laboratory and flagged with a "J". Ideally, and to reduce the possibility of false positives, all blanks associated with project samples should be free of detectable contamination. The project specific MDLs, PQLs, and screening values for the analytes to be tested are summarized in **Table 2**.

1.8 Specific Training Requirements/Certification

The AECOM PM will be responsible for ensuring necessary training and certification requirements are met for field operations. The Laboratory PM will be responsible for ensuring NELAC certification is maintained for each analytical laboratory.

1.8.1 Training Requirements

Personnel conducting field activities will be required to have completed Occupational Safety and Health Administration (OSHA) Hazardous Waste Operations and Emergency Response 40-hour training with current refresher training as detailed in Title 29 of the Code of Federal Regulations Part

1910.120 for general site workers. Staff records documenting compliance with OSHA requirements are kept on file at AECOM.

A project-specific Health and Safety Plan (HASP), which addresses accident prevention, personnel protection, and emergency response procedures, has been developed for this project. The HASP establishes in detail the protocols necessary for protecting workers from the hazards associated with the contaminants at the Downgradient Study Area, and other physical hazards (such as slips, trips, and falls, electrical hazards, poisonous insects and plants, temperature hazards, etc.). All personnel will be provided access to the HASP prior to conducting work at the site. All field staff working at the Downgradient Study Area must comply with the HASP.

1.8.2 Certifications

All laboratory analytical data will be generated by a Nevada- or NELAC-certified laboratory and validated by AECOM. This applies to the primary laboratory and any laboratory subcontracted by the primary laboratory. Laboratories must have an in-place program for data reduction, validation, and reporting as discussed in this QAPP. Regularly scheduled analyses of known duplicates, standards, and spiked samples are a routine aspect of data reduction, validation, and reporting procedures.

Laboratories utilized for routine chemical testing of groundwater will be certified by the State of Nevada for the appropriate program of interest (i.e., Resource Conservation and Recovery Act Program, National Pollutant Discharge Elimination System Program, etc.) and the parameters of interest. In the absence of Nevada certification, National Environmental Laboratory Accreditation Program accreditation may be considered acceptable until Nevada offers certification for the parameter of interest. The laboratories must submit the necessary initial demonstration of capability and performance evaluation data to obtain certification from NDEP for all project parameters of interest and methods of interest that Nevada will certify. The primary laboratory and all subcontracted laboratories will maintain current NELAC and/or Nevada certification.

1.9 Documents and Records

This section includes information about the requirements for laboratory data packages.

Records that may be generated during field work include field logs and data sheets, photographic logs, sample chain-of-custody records, sample labels, equipment inspection/calibration records, and others as necessary. Units of measure for any field measurements and/or analyses will be clearly identified on the field forms and in notes and logs as necessary. The Analytical Task Leader, or other appropriate person designated by the AECOM PM, will review the field data to evaluate the completeness of the field records.

Analytical data will contain the necessary sample results and QC data to assure compliance with the DQOs defined for the project. Laboratory data will be provided in hard copy and electronic format in accordance with this QAPP.

The project files will be the central repository for all documents that constitute evidence relevant to sampling and analysis activities as described in this QAPP. The project files for a particular investigation, including all relevant records, reports, logs, field notebooks, pictures, subcontractor reports, and data reviews, should be maintained in a secured, limited access area and under custody of the PM.

The project files will include at a minimum:

- Field logbooks;

- Field data and data deliverables;
- Photographs;
- Drawings;
- Laboratory data deliverables;
- Reports (e.g., data validation, progress, quarterly, etc.); and
- Chain-of-custody documentation.

1.9.1 Field Notes

Field logbooks will provide the means of recording data collection activities at the time they take place. The logbooks will be bound field survey notebooks assigned to field personnel, but they will be stored with the project files in a centralized document repository at an AECOM office location when not in use. Activities will be described in as much detail as possible such that the activity being described can be reconstructed without reliance on memory. Entries will be made in language that is objective, factual, and free of personal opinions or terminology that might later prove unclear or ambiguous.

The cover of each logbook will be identified by the project name, project-specific document number, and the time period which the logbook describes (beginning and end dates). The title page of each logbook will have contact information for the AECOM PM. Entries into the logbook will contain a variety of project-specific information. At the beginning of each entry, the date, start time, weather, names of all team members present, level of personal protection being used, and the signature of the person making the entry will be entered. Names and affiliations of visitors to the site and the purpose of their visit will be recorded.

All entries will be made in ink signed and dated and no erasures will be made. If an incorrect entry is made, the information will be crossed out with a single strike mark, initialed, and dated by the user. Whenever a sample is collected or a measurement is made it will be recorded. Any photographs taken will be identified by number and a description of the photograph will be provided. All equipment used to conduct measurements will be identified including serial number and any calibration conducted will be recorded.

1.9.2 Field Data Sheets

Field data sheets will be completed by field personnel during sample collection activities. The types of field data sheets used include groundwater sampling logs, surface water sampling logs, well construction logs, and well development logs. If deemed necessary by the PM, electronic copies of the data sheets may be produced after sampling has been completed and these can be provided in the program-specific report, describing sampling conducted.

1.9.3 Photographs

Digital photographs will be taken if necessary to supplement and verify information entered into field logbooks. For each photograph taken, the following will be recorded in the field logbook:

- Date, time, and location;
- Number and brief description of the photograph; and
- Direction in which the photograph was taken, if relevant.

If a number of photographs are taken during a task, general notes will be sufficient on the group of photographs taken, so long as the information outlined above can be inferred from the information provided for each photograph.

1.9.4 Sample Labels

Sample labels will be provided with sample containers for laboratory analysis. Each sample collected will be assigned a unique identification (ID) number. All samples will be labeled in a clear and precise way for proper identification in the field, laboratory, and progress reports.

1.9.5 Chain-of-Custody Forms and Custody Seals

Completed original chain-of-custody forms will be sent with each sample shipment to document collection and shipment of samples for off-site laboratory analysis with copies to be maintained with the project files. The chain-of-custody form will identify the contents of each shipment and maintain the custodial integrity of the samples. A custody seal signed by the sampler will be used to maintain custodial integrity of the samples during collection and shipment to the laboratory.

1.9.6 Verification of Electronic Data

Electronic data are generally derived from automated data acquisition systems in an analytical laboratory setting. Analytical instruments are equipped with software that performs various manipulations, identifications, and calculations of data. Software calculations are verified manually during the data validation process. Other data generated by the analytical laboratories may consist of manually recorded results. This data may be documented in a logbook and may subsequently be entered in the form of electronic files. As a part of their periodic reviews of logbooks and deliverables, the analytical laboratories will review transcriptions to ensure accuracy. Any errors encountered will trigger further auditing until no transcription errors are encountered in the audit set, up to and including 100 percent review. Data formats will be consistent with NDEP guidance on electronic data deliverables (NDEP 2009d, NDEP 2009e, NDEP 2013).

Data can be reported in either hard copy form or electronic form. Screening level data are generally reported in summary form including sample ID information, results for the sample analyses, and a summary of the QC data including calibrations and verifications of precision, accuracy, and representativeness, where appropriate.

If data manipulation or reduction is performed electronically, outside of the raw data produced by purchased instrumentation, the formulae or macros employed for these purposes will be validated by comparing the results of a sample manual calculation to the result produced electronically. This validation will be documented and maintained in central files.

1.9.7 Electronic Data Deliverables (EDDs)

In addition to hard copy data reports provided by the contract laboratory, analytical data will be submitted to the AECOM Database Manager (**Figure 2**) as EDDs in the EQUiS® format. The names of analytical and preparation methods should be consistent with NDEP guidance (NDEP 2013). It is the responsibility of the analytical laboratory to ensure that the hard copy data and electronic data are identical. The data reported in EDDs and in the hard copy reports must correspond exactly, including significant digits and units. It is preferable that the hard copy and EDD are generated at approximately the same time from the same data source.

The laboratory will provide an EDD for each sample delivery group. The EDD should conform to AECOM's Laboratory EDD Format Specification, EQUiS Edition. At the discretion of the AECOM PM and the database administrator, an exception may be made to accept an alternative EDD format, which must contain the following information at a minimum:

- Sample ID,
- Sample Date,
- Sample Time,
- Laboratory Sample ID,
- Analytical Method,
- Analyte Name,
- Chemical Abstract Service Number,
- Result,
- Detect Flag (y/n),
- Laboratory Qualifier,
- Units,
- PQL,
- MDL,
- Sample Adjusted MDL,
- Spike Levels,
- %R,
- RPD,
- Control limits for %R and RPD,
- Extraction Method,
- Cleanup Method,
- Sample Receipt Date,
- Extraction Date,
- Analysis Date,
- Analysis Time,
- Dilution Factor,
- Result Reportable (y/n),
- Batch Number, and
- sample delivery group.

AECOM will compare 10 percent of electronic entries with hardcopy results to check for consistency as part of the data validation process.

1.9.8 Laboratory Documentation

The following section discusses general laboratory requirements for preparing data packages. Data packages provided by contract analytical laboratories will be at EPA Level 2 or equivalent. The Level 2 data package includes the following information:

- Sample and client information;
- Sampling time and date;

- Sample number;
- Analytical method;
- Environmental sample results or measurements;
- PQLs and MDLs;
- Chain-of-custody form;
- Sample receipt checklist;
- Summary of QA/QC results;
- Method blank results;
- LCS/LCSD results, recoveries, and control limits;
- MS/MSD results, recoveries and control limits;
- Duplicate results and RPD;
- Spike amount;
- Dilution factors;
- Initial sample aliquots (weights or volumes) and final sample volumes;
- Case narrative.

The case narrative will be written and the release of data will be authorized by the laboratory director or his/her designee. Items to be included in the case narrative are the field sample ID with the corresponding laboratory ID, parameters analyzed for in each sample and the methodology used (EPA method numbers or other citation), detailed description of all problems encountered and corrective actions taken, discussion of possible reasons for results exceeding the acceptable laboratory QA/QC results, and observations regarding any occurrences which may affect sample integrity or data quality.

Legible copies of the chain-of-custody forms for each sample will be maintained in the data package. Cooler log-in sheets will be associated with the corresponding chain-of-custody form/s. Any integral laboratory tracking document will also be included. Appendix B contains an example chain-of-custody form.

For each environmental sample analysis, this summary will include field ID and corresponding laboratory ID, sample matrix, collection date/time, laboratory receipt date/time, date of sample extraction (if applicable), date and time of analysis, identification of the instrument used for analysis, instrument specifications, weight or volume of sample used for analysis/extraction, dilution or concentration factor used for the sample extract, MDL or PQL, definitions of any data qualifiers used, and analytical results.

The following QA/QC results will be presented in summary form. Acceptance limits for all categories of QC criteria will be provided with the data. The summary of QA/QC results for analyses will include, but will not be limited, to the following:

- Method Blank Analyses – The concentrations of any analytes found in blanks will be reported even if the detected amounts are less than the PQL. The samples and QA/QC analyses associated with each method blank will be stated.
- MS/MSD – For MS/MSD analyses the sample results, spiked sample results, %R, and associated recovery and RPD control limits will be detailed. Parent sample results will also be included on the summary form.

- LCS/LCSD – For LCS/LCSD analyses the spiked sample results, %R, and associated recovery and RPD control limits will be detailed. LCS/LCSD analyses will also include: source of the sample(s), true value concentrations, found concentrations, %R for each element analyzed, and the date and time of analysis.
- Laboratory Duplicates – For laboratory duplicate analyses the sample results, RPD between duplicate analyses, and control limits will be reported, as applicable. For laboratory QC check and/or LCS analyses, the %R and acceptable control limits for each analyte will be reported. All batch QC information will be linked to the corresponding sample groups.

All data packages will be reviewed by the individual laboratory QA personnel to ensure accurate documentation of any deviations from sample preparation, analysis, and/or QA/QC procedures and descriptions. Any problems identified by the laboratory QA personnel will be documented in the narrative of the report.

Laboratory QA manuals for the laboratories currently performing work are included in **Appendix A**. When new or different laboratories are used, their manuals will be provided

1.9.9 Laboratory Record Retention

Raw data will be available for further inspection, if required, and maintained in each laboratory's central job file. Records related to the analytical effort (i.e., cost information, scheduling, custody) are maintained at the laboratories in a secured location. Moreover, analytical laboratories will have the ability to archive data and quality records in a secured area protected from fire and environmental deterioration. Electronic data should be protected against exposure to magnetic or electronic sources.

All records necessary to reproduce the analytical calculations and support the reported results must be maintained for at least 10 years. Types of records to be maintained for the project include, but are not limited to the following:

- Chain-of-custody forms, including: information regarding the sampler's name, date of sampling, type of sampling, sampling location and depth, number and type of sampling containers, signatures of sample custodians with transfer date and times noted, and sample receipt information including temperature and conditions upon arrival at the laboratory;
- Cooler receipt form documenting sample conditions upon arrival at the laboratory;
- Any discrepancy/deficiency report forms due to problems encountered during sampling, transportation, or analysis;
- Sample destruction authorization forms containing information on the manner of final disposal of samples upon completion of analysis;
- All laboratory notebooks including raw data readings, calibration details, QC checks, etc.;
- Hard copies of data system printouts (chromatograms, mass spectra, inductively coupled plasma [ICP] data files, etc.);
- Tabulation of analytical results with supporting QC information; and
- Sample preparation documents/records.

1.9.10 Field Document Retention

All field documentation generated during the implementation of the program-specific work plans, including any electronic files produced, will be kept on file in a secured central repository in an AECOM office in accordance with AECOM's document retention policy.

2.0 Measurement and Data Acquisition

This section discusses sampling process design; sampling methods; sample handling and custody; analytical methods; QC; instrument/equipment testing, inspection, maintenance, and calibration; inspection/acceptance of supplies; non-direct measurements, and data management.

2.1 Sampling Process Design

This QAPP is intended to cover surface water and groundwater sampling. Samples will be collected according to applicable NDEP guidelines and following the procedures described in the program-specific work plans. The design for these sampling plans is included in their specific work plans.

2.2 Sampling Methods

Sampling will be conducted in accordance with the procedures described in the program-specific work plans.

2.2.1 Sampling Procedures

Surface water and groundwater sampling procedures are discussed in the program-specific work plans. Field filtration (0.45 micrometer [μm]) of water samples is required for dissolved chromium (when required). Other analytes (hexavalent chromium, bromide, chloride, chlorate and perchlorate) can be lab filtered (0.45 μm). NDEP has indicated that sterile filtration (0.2 μm) is not required for this study.

2.2.2 QC Sample Collection

QC samples may include equipment blanks (EBs), field blanks (FBs), FDs, and MS/MSDs as needed for the individual sampling program. These samples will be collected as described below unless otherwise noted in the program-specific work plans.

Equipment blanks – EBs will be prepared by routing laboratory-grade and organic-free water (provided by the laboratory) through non-dedicated sampling equipment after equipment decontamination and before field sample collection. EBs will be collected at a frequency of one EB for every 20 primary samples for all aqueous samples collected with non-dedicated equipment, and will be analyzed for the same parameters as their associated samples unless otherwise specified in the program-specific work plans.

Field Blanks – FB samples are obtained by filling a clean sampling container with reagent-grade deionized (DI) water, in the field at a sample location. The sample is then analyzed in the same manner as the primary sample. FB samples will be collected at a frequency of one in every 20 samples and will be analyzed for the same suite of parameters as the primary sample to assess potential background contamination or errors in the sampling process.

Field Duplicates – FDs will be collected at a frequency of one FD for every 10 or less investigative samples. FDs will be collected by alternately filling two sets of identical sample containers from the interim container used to collect the sample. All FDs will be analyzed for the same parameters as their associated samples.

MS/MSDs – MS/MSD samples will be collected at a frequency of one for every 20 or less investigative samples and designated on the chain-of-custody forms.

2.3 Sample Handling and Custody

In general, the subcontracted analytical laboratories will handle samples in a manner to maximize data quality. Samples will be collected, handled, and stored in such a manner that they are representative of their original condition and chemical composition. Identification of samples and maintenance of custody are important elements that must also be utilized to ensure samples characterize Downgradient Study Area conditions. All samples will be properly identified and maintained under chain-of-custody protocol to protect sample integrity. The following sections discuss the sample handling and custody requirements in detail.

2.3.1 Sample Containers, Preservation, and Holding Times

Sample bottles and chemical preservatives will be provided by the laboratories. The containers will be cleaned by the manufacturer to meet or exceed all analyte specifications established in the latest EPA specifications and guidance for contaminant-free sample containers. Certificates of analysis will be provided with each lot of containers and maintained on file to document conformance to EPA specifications.

A summary of sample container, preservation, and holding time requirements is presented in **Table 4**.

2.3.2 Sample ID

To maintain consistency, a sample ID convention has been developed and will be followed throughout the program-specific work plans. The sample IDs will be entered onto the sample labels, field forms, chain-of-custody forms, logbooks, and other records documenting sampling activities.

The identification system for primary field samples will include groundwater well ID or the surface water location (usually as river mile – Las Vegas Wash [LW] mile to one decimal place) and the date in YYYYMMDD format. In the event that multiple samples are collected from a well or surface water location in a day, the time in a 24 hour format (-HH:MM) can be added as needed.

For example:

- A surface water sample collected from (LW5.7 on January 6, 2016 will be identified as LW5.7-20160106.
- A groundwater sample collected from monitoring well M-161D on July 1, 2016 will be identified as M-161D-20160701.

2.3.2.1 Field QA/QC Sample IDs

The field QC sample codes that may be applied include:

- EB for Equipment Blanks
- FB for Field Blanks
- FD for Field Duplicates

Field QA/QC sample codes will be appended to the end of the primary sample ID that is represented by the field QA/QC sample.

EBs should be named for the sample collected immediately prior to the collection of the EB.

The FB represents a group of samples: a batch of 20 for the FB. Thus, the FB should be named after the first sample of the batch.

The FD represents the primary sample that is being duplicated; thus, the FD should be named after the corresponding primary sample.

For example, the first sample to be placed in a cooler is MW-1-20140701. The sample is to be analyzed for volatile organic compounds, and a duplicate sample is collected. An EB is collected immediately following the collection of the groundwater sample (after decontamination of sampling equipment). The associated field QA/QC samples will be identified as:

- MW-1-20140701-EB
- MW-1-20140701-FB
- MW-1-20140701-FD

Field QA/QC samples and the frequencies of collection are summarized in **Table 3**.

2.3.2.2 Sample Labels

A sample label will be affixed to all sample containers sent to the analytical laboratory. Field personnel will complete an identification label for each sample with the following information written in waterproof, permanent ink:

- Client name ("NERT") and project number;
- Sample location and depth, if relevant;
- Unique sample ID;
- Date and time sample collected;
- Filtering performed, if any;
- Preservative used, if any;
- Name or initials of sampler; and
- Analyses or analysis code requested.

The use of pre-printed sample labels is preferred in order to reduce sample misidentification problems due to transcription errors. Sample labels must be completed and affixed to the sample container in the field at the time of sample collection.

If errors are made on a sample label, corrections will be made by drawing a single line through the error and recording the correct information. All corrections will be dated and initialed.

Immediately upon collection, each sample will be labeled with an adhesive label. Samples will be assigned unique sample IDs as described in the program-specific work plans.

Samples being designated for MS/MSD analysis will not include an identifier as part of the sample code, but will be identified on the chain-of-custody form.

2.3.2.3 Containers, Preservation, and Hold Time

The analytical methods, type of sample containers to be used for each sample type and analysis, preservation requirements for all samples, and holding times are provided in **Table 4**.

Each lot of preservative and sampling containers will be certified as contaminant-free by the provider and/or the laboratories. The laboratories will maintain certification documentation in their files. All preserved samples will be clearly identified on the sample labels and chain-of-custody forms. If

samples requiring preservation are not preserved, field records will clearly specify the reason for the discrepancy.

Surface water and groundwater sample containers will be placed in airtight plastic bags, if possible, and refrigerated or placed in a cooler with ice to chill and maintain a sample temperature of 4 ± 2 °C.

Chemical activity continues in the sample until it is either analyzed or preserved. Once the sample has been preserved, the sample may be held for a period of time before analysis. The time from the collection of the sample to the analysis is defined as the holding time.

2.3.3 Sample Handling and Transport

Proper sample handling techniques are used to ensure the integrity and security of the samples. Samples for field measured parameters will be analyzed immediately in the field by the sampling crew and recorded in the field logbook and field data sheets. Samples for laboratory analysis will be transferred immediately to appropriate laboratory supplied containers in accordance with the following sample handling protocols:

- Clean gloves will be donned before touching any sample containers, and care taken to avoid direct contact with the sample.
- Samples will be quickly observed for color, appearance, and composition and recorded as necessary.
- The sample container will be labeled before or immediately after sampling.
- Groundwater and surface water sample containers and liners will be capped with Teflon™-lined caps before being placed in Ziploc™-type plastic bags. The samples will be placed in an ice chest and cooled to 4 ± 2 degrees Celsius for transport to the laboratory.
- All sample lids will stay with the original containers, and will not be mixed.
- Sample bottles will be wrapped in bubble wrap as necessary to minimize the potential for breakage or damage during shipment.
- The chain-of-custody form will be placed in a separate plastic bag and taped to the cooler lid or placed inside the cooler. A custody seal will be affixed to the cooler.

The samplers are responsible for proper handling practices until receipt at the laboratories, or by the laboratory courier, at which time the Laboratory PM assumes responsibility of the samples through analysis and ultimately to the appropriate disposal of samples. Sample handling procedures specific to the laboratories are described in the individual laboratory QA Manuals.

2.3.4 Sample Custody

Standard sample custody procedures will be used to maintain and document sample integrity during collection, transportation, storage, and analysis. Custody documents must be written in waterproof, permanent ink. Documents will be corrected by drawing one line through the incorrect entry, entering the correct information, and initialing and dating the correction. The AECOM PM is responsible for proper custody practices so that possession and handling of individual samples can be traced from the time of collection until receipt at the laboratory, or by the courier. The Laboratory PM is responsible for establishing and implementing a control system for the samples in their possession that allows tracing from receipt of samples to disposal.

The chain-of-custody form provides an accurate written record that traces the possession of individual samples from the time of collection in the field until they are accepted at the analytical laboratories.

The chain-of-custody form also documents the samples collected and the analyses requested. The sampler will record the following information on the chain-of-custody forms:

- Client and project number;
- Name or initials and signature of sampler;
- Name of destination analytical laboratory;
- Name and phone number of PM in case of questions;
- Unique sample ID for each sample;
- Data and time of collection for each sample;
- Number and type of containers included for each sample;
- Analysis or analyses requested for each sample;
- Preservatives used, if any, for each sample;
- Sample matrix for each sample;
- Any filtering performed, if applicable, for each sample;
- Signatures of all persons having custody of the samples;
- Dates and times of transfers of custody;
- Shipping company identification number, if applicable; and
- Any other pertinent notes, comments, or remarks.

Unused lines on the form will be crossed out and initialed.

A sample is considered to be under the control of, and in the custody of, the responsible person if the samples are in their physical possession, locked or sealed in a tamper-proof container, or stored in a secure area.

The person who collects the sample is the initial custodian of the sample. Any transfers are documented on the chain-of-custody form by the individuals relinquishing and receiving the sample, along with their signature, and the date and time of transfer. This transfer must continue until the custody is released to a commercial carrier (i.e. FedEx), or the laboratory (either at the laboratory or to a laboratory employed courier). If relinquished to a commercial carrier, the carrier assumes custody through their shipping receipt. A copy of the shipping receipt should be attached to the chain-of-custody form as a permanent part of the custody control. If the sample is relinquished to a laboratory courier, the courier will then need to relinquish the sample to the laboratory upon arrival. Once the sample has arrived at the laboratory, it must be entered into the sample custody control system of the laboratory. If the sample is further transported to a subcontracted laboratory, the laboratory will produce an internal chain-of-custody form that will be available upon request. Chain-of-custody forms will be maintained in the project file by AECOM and at the analytical laboratories.

To discourage tampering during transport, a custody seal will be placed on each cooler after the samples are packed. These consist of a security tape or label with the date and initial of the sampler or person currently in possession of the sample. Receiving personnel at the laboratory will note on the cooler receipt form whether or not the custody seals are intact.

2.3.5 Shipping Procedures

If shipping samples using a commercial courier is necessary, each container sent will have a separate chain-of-custody form. Samples collected during the investigation will be identified as environmental

samples. Samples will be packed in the same manner as when being transported from the sampler to the laboratory, with the following changes:

- Dry ice is not allowed to be used to chill samples requiring commercial shipment.
- Extra packing material will be used to fill the coolers in order to limit movement within the container.
- Ice should be contained in zip-closure bags and the cooler should be lined with plastic as described below.
- Coolers containing ice and/or liquid samples should be lined with a plastic bag (such as a contractor garbage bag) to limit the potential for leaks in the event of ice bags leaking or sample container breakage. All necessary precautions must be taken to prevent any liquids leaking from sample coolers while in transit.
- Coolers will be closed and taped shut. If the cooler has a drain, it too will be closed and taped shut to prevent leaks.
- A minimum of two custody seals will be affixed to the front and side openings of the cooler so that the cooler cannot be opened without breaking a seal. The seals will be covered with wide clear tape so that the seals do not accidentally break in transit.
- Non-perishable samples collected on the weekend may be held for more than three days if there is no threat of exceeding hold times. If the samples require being chilled and maintained at a cool temperature, they will be stored under refrigeration and shipped the following work day.

2.3.6 Transport Container Receipt

Upon receipt of the transport container, the analytical laboratories will review the contents and sign and date the chain-of-custody forms. Additional information will also be added to the chain-of-custody form including the status of the custody seals; the temperature of the cooler, how it was evaluated, and whether or not the samples were on ice; the conditions of samples and identification of any broken sample containers; description of any discrepancies on the chain-of-custody forms; sample labels and/or requested analyses; and the pH of any preserved water samples.

The analytical laboratory will contact the AECOM Analytical Task Leader or other designated person regarding any discrepancies in paperwork and/or chemical or thermal sample preservation. Nonconformance and corrective actions will be documented in accordance with the laboratories QA/QC documents. After samples have been accepted, checked, and logged in, the laboratories will maintain them in a manner consistent with the custody and security requirements specified in the laboratory QA/QC documents.

2.4 Laboratories and Analytical Methods

Both field measurement methods and stationary analytical laboratory methods will be utilized to analyze samples during implementation of this QAPP. Analytical methods including MDLs and PQLs to be used are listed on **Table 2**. Laboratory SOPs for the listed methods have been developed and approved by the laboratories performing the analyses. The dates of the current SOPs are summarized for each laboratory on **Table 1**.

2.4.1 Field Methods

As specified in program-specific work plans, samplers may conduct in-field measurement for depth in the water column, depth to water, pH, conductivity, ferrous iron, sulfide, dissolved oxygen (DO), oxygen reduction potential (ORP), turbidity and temperature of groundwater samples. An appropriate

pH meter and standardization buffers as recommended by the instrument manufacturer will be used. All meter standardizations, QC, and sample results will be recorded on the appropriate field forms.

2.4.2 Laboratory Methods

The methods to be used are summarized in **Table 1**. Target analytes and target detection limits are provided in **Table 2**. The delegation of analyses to particular laboratories will be addressed in the program-specific work plans. The project will involve, at a minimum, the analysis of surface water and groundwater samples.

Each analytical laboratory used during implementation of this QAPP will be expected to provide a current statement of qualifications and laboratory QA/QC documents (including QA Manual and SOPs) for review by the Analytical Task Lead. In addition, analytical laboratories will be requested to provide current MDL studies, proposed PQLs and other sources that contain QC procedures, QC acceptance criteria, and corresponding corrective actions for the analytical methods to be used during implementation of the QAPP.

The laboratories will use analytical methods and QA/QC procedures in conformance with approved methods for all samples. Copies of the laboratory QA Manuals for all laboratories will be retained on file with AECOM. In the event that the listed procedures cannot be performed, the laboratory will notify the AECOM Analytical Task Leader of the conflict. The AECOM Task Leader or PM will notify the NDEP RPM for resolution. Unless specifically directed otherwise by the NDEP RPM, the standard or superseding test methods will govern. No changes in prescribed analytical methods will be made unless approved by the NDEP RPM.

PQLs compiled in **Table 2** are from a review of PQLs generally achieved by the laboratories used for implementation of this QAPP. It should be noted that the limits listed in **Table 2** are laboratory and sample dependent and may not always be achievable due to matrix effects, necessary dilution of the sample, and/or interferences.

2.5 Quality Control

There is potential variability in any sample collection, analysis, or measurement activity. QC activities are those technical activities routinely performed, not to eliminate or minimize errors, but to assess/demonstrate reliability and confidence in the measurement data generated. This section identifies QC checks for sample collection, field measurements, and laboratory analyses for data collected during implementation of the program-specific work plans.

2.5.1 Field

Field QA/QC samples that will be collected during the proposed investigation include FD samples, FBs, and EBs. The description and purpose of these samples is discussed in this section. The frequency of analysis of field QA/QC samples is summarized in **Table 5**. QC for field measurements will be limited to their calibrations.

Field QC samples will be collected during surface water and groundwater sampling to assess the accuracy and precision of the data. These samples may include FDs, MS/MSDs, FBs, and EBs as appropriate for the media and/or parameters being sampled. The QC samples specific to an individual sampling event will be identified in the program-specific work plan.

2.5.1.1 Field Duplicates

The FD is a replicate sample collected as close as possible to the same time that the primary sample is collected and from the same location, depth, or source, and is used to document analytical

precision. FD samples will be labeled and packaged in the same manner as primary samples but with “FD” appended to the sample ID. FDs will be collected at a frequency of one in every 10 primary samples and will be analyzed for the same suite of parameters as the primary sample. The RPD between the FD sample and the primary sample is evaluated to assess the homogeneity of the sample matrix and to assess the reproducibility of laboratory and field sample collection techniques.

2.5.1.2 Field Blanks

FB samples are used to assess the presence of contaminants arising from field sampling procedures. FB samples are obtained by filling a clean sampling container with reagent-grade DI water in the field at a sample location. The sample then is analyzed in the same manner as the primary sample. FB samples will be collected at a frequency of one in every 20 samples and will be analyzed for the same suite of parameters as the primary sample to assess potential background contamination or errors in the sampling process.

2.5.1.3 Equipment Blanks

EB samples are used to assess the effectiveness of decontamination procedures. EB samples are obtained by filling decontaminated sampling equipment with reagent-grade DI water, sampling this water, and submitting the sample for analysis. Alternatively, DI water can be poured over or through the decontaminated sampling equipment and then collected and submitted for analysis. EBs will be collected at a frequency of one in every 20 samples and will be analyzed for the same suite of parameters as the primary sample to assess the effectiveness of decontamination procedures.

2.5.2 Laboratory

The laboratory QA/QC program includes (i) performing analytical methods according to prescribed protocols and (ii) analyzing laboratory QA/QC samples to measure precision and accuracy of laboratory methods and equipment, instrument calibration and preventive maintenance. Laboratory QA/QC samples and parameters that will be analyzed during the implementation of the program-specific work plans include method blanks, LCS/LCSD, MS/MSD, laboratory duplicates, and surrogates. The acceptable limits of the laboratory QA/QC samples are provided in **Table 2**. The frequency of analysis of laboratory QA/QC samples is summarized in **Table 6**.

A detailed description of laboratory data management procedures is provided in the laboratory QA Manuals in **Appendix A**. Each Laboratory PM will be responsible for ensuring the established data management procedures are followed. The following are the laboratories and PMs that will be used on this project:

TestAmerica Laboratories, Inc.
Patty Mata
17461 Derian Avenue, Suite 100
Irvine, California 92614

Each analytical laboratory has a QC program in place to ensure the reliability and validity of the analysis performed at the laboratory. All analytical procedures are documented in writing as SOPs and each SOP includes the minimum requirements for the procedure. The internal QC checks differ slightly for each individual procedure but in general the QC requirements include the following:

- Blanks (method, reagent/preparation, instrument)
- MS/MSDs
- Surrogate spikes

- LCS/LCSDs
- Laboratory duplicates
- Interference checks (ICP analysis)
- Serial dilutions (ICP analysis)

Table 3 summarizes the essential QC for each method.

2.5.2.1 Method Blanks

A method blank is a sample of DI or distilled water prepared by and analyzed by the laboratory. It is used to assess potential contamination in the laboratory process (e.g., contaminated reagents, improperly cleaned or calibrated equipment). For each analytical method, the laboratory will analyze one per 20 primary field samples (one method blank per preparation batch), or 5 percent of the primary field samples for each analytical method, whichever is more frequent.

2.5.2.2 Laboratory Control Samples

An LCS is a known matrix (e.g., washed sea sand, reagent water, zero air) that has been spiked with a known concentration of specific target analytes. It is used to demonstrate the accuracy of the analytical process. For each analytical method, an LCS will be analyzed one per 20 primary field samples (for each analytical method there will be one LCS per preparation batch), or 5 percent of the primary field samples, whichever is more frequent.

2.5.2.3 Matrix Spikes and Blank Spikes

MS are performed by the analytical laboratory in order to evaluate the efficiency of the sample extraction and analysis procedures. MS samples are necessary because matrix interference may have a widely varying impact on the accuracy and precision of the extraction analysis. The MS is prepared by the addition of known quantities of specific target compounds to a primary sample. The sample is then extracted and analyzed. The results of the analysis are compared with the known additions and a MS recovery is calculated giving an evaluation of the accuracy of the extraction and analysis procedures. Typically, MS analyses are performed in duplicate in order to evaluate the precision of the procedures as well as the accuracy. MS recoveries (%R) are reviewed to check that they are within acceptable range. For applicable analytical methods, MS/MSDs will be analyzed by the laboratory at a frequency of at least one per 20 primary field samples, or 5 percent of the primary field samples (for applicable analytical methods there will be one per preparation batch), whichever is more frequent.

2.5.2.4 Laboratory Duplicates

Duplicate samples are used to assess precision in the analytical method. An additional aliquot is extracted from the primary sample and analyzed using the identical procedures as the primary sample. Then the results are compared to assess precision. There are three types of duplicates - sample duplicates, LCSDs, and MSDs. For applicable analytical methods, duplicates will be collected and analyzed in accordance the laboratory QA Manuals at a frequency of at least one per 20 primary field samples, or 5 percent of the primary field samples (for applicable analytical methods there will be one per preparation batch), whichever is more frequent.

2.5.2.5 Corrective Actions

Corrective actions may be initiated if precision or accuracy goals are not achieved. The initial step in corrective action will be to instruct the laboratory to examine its procedures to assess whether analytical or computational errors caused the anomalous results. At the same time, sample collection and handling procedures will be reviewed to assess whether they could have contributed to the

anomalous results. Based on this evaluation, the AECOM PM or Analytical Task Leader, together with the QA/QC Officer, will assess whether re-analysis or re-sampling is required or whether any protocol should be modified for future sampling events. Any changes in laboratory methods, or QA parameters or limits, require written approval by AECOM prior to implementation by the laboratory.

2.6 Instrument/Equipment Testing, Inspection, and Maintenance

2.6.1 Field Instrumentation

Equipment used in the collection of field measurements will be maintained according to the manufacturer's specifications, and will be inspected and calibrated prior to use. Field equipment requiring testing, inspection, and maintenance are:

- Organic vapor meter utilized for measuring total organic vapors in breathing zones;
- Particulate meter utilized for measuring particulate matter in breathing zones and air column;
- Water quality meter utilized to measure pH, temperature, and conductivity;
- A flow-through cell to measure DO and ORP of certain water samples;
- Turbidity meter utilized to measure turbidity of water samples;
- Electric water level meter utilized to measure depth to groundwater;
- Low-flow adjustable sampling pump utilized for collection of groundwater; and
- Pressure transducers for water level/temperature monitoring and data logging.

The operating manuals for each piece of field equipment used describe the procedures required for testing, inspecting, and maintaining this equipment. The types and frequencies of testing, calibration, and maintenance for field instruments are presented in **Table 5**. The results of testing, inspections, or maintenance conducted will be summarized in the field logbook or on separate field equipment forms (if available). Testing, inspection, and maintenance of field equipment and documentation of completion of these activities will be the responsibility of field personnel under the direction of the AECOM Field Team Lead.

Data that may be collected in the field primarily consist of field-measured water quality parameters (pH, conductance, temperature), depth to groundwater measurements, sample depth measurements, and information and measurements of the location of borings.

Upon generation, all field data will be immediately recorded in site-dedicated field logbooks. Calibration results will also be included in field logbooks and/or appropriate field forms. As necessary, field data from logbooks and field forms will be tabulated in spreadsheets to be included in reports. The Analytical Task Lead, or other appropriate person designated by the AECOM Field Team Lead will review the field data to evaluate the completeness and accuracy of the field records.

The field equipment for this project may include, but not be limited to, electronic water level indicators, water quality meters, and photoionization detectors (PIDs). The Field Team Lead will be responsible for ensuring that instruments are properly functioning. At a minimum, this will entail checking the instrument prior to shipment to the field and performing daily operational checks and calibration. Routine maintenance and trouble-shooting procedures will be performed as described in the manufacturer's instructions.

2.6.2 Laboratory Equipment

Routine testing and preventive maintenance are performed by each laboratory as part of their QA program. Details on the type of checks, frequencies, and corrective actions are included in the individual laboratory QA manuals (**Appendix A**).

2.7 Instrument/Equipment Calibration and Frequency

Instrument maintenance logbooks are maintained in the laboratories. In general, the logbooks contain a schedule of maintenance, as well as a complete history of past maintenance, both routine and non-routine, for that particular instrument.

Preventive maintenance is performed according to the procedures specified in the manufacturer's instrument manuals, including lubrication, source cleaning, and detector cleaning, and the frequency of such maintenance. Chromatographic carrier gas purification traps, injector liners, and injector septa are cleaned or replaced on a regular basis. Precision and accuracy data are examined for trends and excursion beyond control limits to determine evidence of instrument malfunction. The laboratory will ensure that maintenance is performed when an instrument begins to degrade as evidenced by the degradation of peak resolution, shift in calibration curves, decrease in sensitivity, or failure to meet one or another of the pre-determined QC criteria.

2.7.1 Field Calibration Procedures

Instruments requiring calibration include air monitoring equipment (e.g., PIDs, and multi-gas meters) and water quality meters (e.g., pH, DO, specific conductivity, and turbidity meters). Equipment that can be field calibrated will be calibrated at least once per day prior to beginning sampling activities, with calibration results documented on an Instrument Calibration Log or in the field logbook. Equipment that must be calibrated in a laboratory setting should be used only if a current calibration certificate is available (for example, a calibration certificate is provided with a piece of rental monitoring equipment). Calibration procedures should be consistent with manufacturer instruction manuals for each instrument. Calibration and maintenance procedures for field equipment are detailed in **Table 5**.

Calibration of field measurement instruments will be performed according to the manufacturer's instructions. All calibration procedures will be documented in the field records. Calibration records will include the date/time of calibration, name of the person performing the calibration, reference standard used, and the results of the calibration.

Calibration procedures for laboratory instruments will consist of initial calibrations, initial calibration verifications, and continuing calibration verifications. The SOP for each analysis performed in the laboratory describes the calibration procedures, their frequency, acceptance criteria, and the conditions that will require recalibration. This information is summarized in **Table 6** for major instrumentation.

2.7.2 Laboratory Calibration Procedures

The laboratory SOPs and QA Manuals address the calibration and frequency of calibration required for laboratory instruments as well as a description of documentation that will be completed. Laboratory QA Manuals are located in **Appendix A**. **Table 6** summarizes the minimum frequency and scope of laboratory checks and calibrations to be performed during this project. Laboratories may have more stringent requirements as part of their SOPs, but must meet these minimum requirements as well as satisfying specific requirements of the standard methods specified for this project.

Each Laboratory PM will be responsible for ensuring proper calibration and recordkeeping are conducted and will inform the AECOM Analytical Task Leader of any issues that may impact analytical results.

Each laboratory maintains documentation for each instrument, which includes the following information: instrument identification, serial number, date of calibration, analyst, calibration solutions, and the samples associated with these calibrations.

2.8 Inspection/Acceptance of Supplies and Consumables

A detailed description of the laboratory inspection and acceptance policy for supplies and consumables is provided in the laboratory QA Manual. A list of primary supplies and consumables necessary for each laboratory analysis are provided in the individual SOPs.

Each Laboratory PM will be responsible for ensuring supplies and consumables are inspected as described in their QA Manual and will inform the AECOM Analytical Task Leader of any issues that may impact analytical results.

Inspection will be conducted of field and laboratory supplies and consumables that may directly or indirectly affect the quality of results. Only supplies and consumables that have been determined to be acceptable will be utilized for the project.

Other field supplies and consumables to be used include items such as bailer cord, items related to field filtering (0.45 µm filters), calibration standards, disposable bladders for pumping, sample tubing, and DI or distilled water. These supplies will be inspected upon receipt in part to verify they are new and in their original packaging. If any defects are noted or suspected they will be properly discarded and replaced prior to use.

The supplies and consumables for this project will be handled and stored in a manner such that they will not compromise sampling results. This will involve keeping items in their original containers before use, sealing containers properly between uses, or storing items in new or dedicated plastic bags.

The AECOM Field Team Lead with assistance from field personnel will be responsible for inspecting and accepting field supplies and consumables and providing replacements as necessary. Field personnel will inventory critical supplies on a regular basis and report to the AECOM Field Team Lead to ensure that work will not be delayed unnecessarily. The AECOM Field Team Lead will in turn provide updates on a regular basis to the AECOM PM.

For this project, critical supplies for field activities will be tracked in the following manner:

Critical Supplies and Consumables	Inspection Requirements and Acceptance Criteria	Responsible Individual
Sample bottles	Visually inspected upon receipt for cracks, breakage, and cleanliness. Must be accompanied by certificate of analysis.	Field Team Lead
Chemicals and reagents	Visually inspected for proper labeling, expiration dates, and appropriate grade.	Field Team Lead
Field measurement equipment	Functional checks to ensure proper calibration and operating capacity.	Field Team Lead
Field test kits	Inspected for proper labeling, appropriate levels of calibration standards, and expiration dates.	Field Team Lead
Sampling equipment	Visually inspected for obvious defects, damage, and contamination.	Field Team Lead

Supplies and consumables not meeting acceptance criteria will initiate the appropriate corrective action. Corrective measures may include repair or replacement of measurement equipment, and/or notification of vendor and subsequent replacement of defective or inappropriate materials. All actions will be documented in the project files.

2.8.1 Laboratory Supplies and Consumables

A detailed description of the laboratory inspection and acceptance policy for supplies and consumables is provided in each laboratory's QA Manual. A list of primary supplies and consumables necessary for each laboratory analysis are provided in the individual SOPs.

Each Laboratory PM will be responsible for ensuring supplies and consumables are inspected as described in their QA Manual and will inform the AECOM Analytical Task Leader of any issues that may impact analytical results.

The laboratory system of inspection and acceptance of supplies and consumable is documented in the individual laboratory QA Manuals.

2.9 Non-Direct Measurements

The historic data were generated as part of previous investigations at the Downgradient Study Area. These data were evaluated during development of the program-specific work plans.

The sampling and analysis as described in the program-specific work plans and in this QAPP has been designed to generate data that will be comparable to the historic data and add to the Conceptual Site Model developed for the Downgradient Study Area.

Non-direct data (historical reports, maps, literature searches, and previously collected analytical data) will be reviewed prior to use to determine its acceptability based on the end use of the data.

2.10 Data Management

Data for this project will be generated in one of two ways; on site from sampling and measurement activities, and at the laboratory via analytical testing of surface water and groundwater samples. An

overview of the management and reporting of these data are described in the following sections. Data management operations include data recording, validation, transformation, transmittal, reduction, analysis, tracking, storage, and retrieval.

2.10.1 Field Data

Data that may be collected in the field primarily consist of; field-measured water quality parameters (pH, conductance, temperature), depth to groundwater measurements, sample depth measurements, and information and measurements of the location of borings.

Upon generation all field data will be immediately recorded in site-dedicated field logbooks. Calibration results will also be included in field logbooks and/or appropriate field forms. As necessary, field data from logbooks and field forms will be tabulated in spreadsheets to be included in reports. The Analytical Task Lead, or other appropriate person designated by the AECOM Field Team Lead will review the field data to evaluate the completeness and accuracy of the field records.

2.10.2 Laboratory Data

A detailed description of laboratory data management procedures is provided in the laboratory QA Manuals. Each Laboratory PM will be responsible for ensuring the established data management procedures are followed.

2.10.3 Data Management System

Data will be loaded into a “temporary” database until data validation is complete, at which time the database will be finalized. Any changes made to the database after finalization will be documented, including a description of the change, date of change, person responsible, and reason for change. Once all data quality checks are performed, the data will be exported to a variety of formats to meet project needs. The project database will be maintained on a secure network drive that is backed up regularly. Access to the database will be limited to authorized users and will be controlled by password access.

The data will be entered into an EQulS® database system maintained by AECOM. The database will be maintained on a secure, enterprise-level database server that is backed-up regularly. Access to the database will be restricted to authorized users.

EDDs provided by the laboratories should be in the EQulS 4-File EDD format as defined by the AECOM Laboratory EDD Format Specification, EQulS Edition. EDDs provided by the laboratories will be in the EQulS file format with project-specified valid values that will minimize manipulation of the data. The laboratories will check that their EDD submittals are consistent with lists of valid values provided by AECOM. Data collected in the field will also be entered into the system and integrated with laboratory data. Prior to loading into the database, EDDs will be reviewed for consistency with the file format and valid values.

The data validator will provide an EDD with data qualifiers, reason codes, and validation level columns appended to the data results. Data qualifiers and reason codes generated during data validation will be entered manually. The validation data will be applied to the results records in the EQulS database. Upon completion of data validation, an Access database consistent with NDEP specifications provided in Guidance on Unified Chemical Electronic Data Deliverable Format (NDEP 2013) will be created.

As data are loaded into the system, a variety of quality checks are performed to ensure data integrity. These checks include:

- Audits to ensure that laboratories reported all requested analyses;

- Checks that all analytes are consistently and correctly identified;
- Reviews to ensure that units of measurement are provided and are consistent;
- Queries to determine that any codes used in the database are documented properly;
- Reports to review sample definitions (depths, dates, locations);
- Proofing manually entered data against the hard-copy original; and
- Reports to review groupings of sampling locations and coordinate systems.

Records of the checks are maintained on file at the AECOM project office.

3.0 Assessment and Oversight

Assessment and oversight are designed to determine whether the QAPP is being implemented as approved, to increase confidence in the information obtained, and ultimately, to determine whether the information may be used for its intended purpose(s).

3.1 Assessment and Response Actions

3.1.1 Field Assessments and Response Actions

During the performance of the program-specific work plans, the QA/QC Officer, or other person designated by the PM, will perform periodic assessments of compliance with the QAPP. When problems or issues are identified, the field personnel will be notified of the issue and instructed as to how to proceed going forward. If a subsequent assessment reveals that the problem has not been corrected, a field audit will be conducted. In addition, periodic unannounced audits may be conducted of field operations. Such audits may include evaluation of the following actions: field procedures, sampling activities, field forms and logbooks, chain-of-custody procedures, field measurements, field equipment calibration procedures, and sample packaging and shipment. Additional routine audits may be conducted during the course of the program-specific work plans as deemed necessary by the AECOM Analytical Task Lead to verify conformance with corrective actions identified in a previous audit and/or to provide additional qualitative assessment of field procedures. The AECOM Field Team Lead, in consultation with the AECOM PM will be responsible for ensuring corrective actions identified by the audit are completed.

3.1.2 Laboratory Assessments and Response Actions

Each laboratory will be responsible for its own compliance with the QAPP. If an internal audit identifies a nonconformance that affects analytical results for this project, then the Laboratory PM will notify the AECOM Analytical Task Leader in writing describing the nonconformance, the impact to analytical results, and corrective actions implemented to respond to the nonconformance.

During the data validation process, AECOM will review selected elements of the laboratory performance as it relates to the QAPP. If non-compliance issues are identified, the laboratory will be notified as to what issue(s) has been identified and will be required to prepare a written response to AECOM regarding what corrective action will be taken to address the issue. If non-compliance problems persist, audits and/or further performance evaluation may be implemented.

3.2 Descriptions of Audits

Internal audits will be performed to review and evaluate the adequacy of the QAPP and to ascertain that it is being implemented.

A systems audit will include an evaluation of field and laboratory QA/QC procedures. If the systems audit shows a significant discrepancy from the program-specific work plans or the QAPP, the responsible party will remedy the situation before work continues. Each major system change will require a written summary to document the change made.

A performance audit will include a careful evaluation of field, laboratory, and data documentation and management procedures to determine accuracy. Upon discovery of significant deviation from the QAPP, the nature and extent of the deviation will be recorded. Corrective action will be taken to remedy the deviation as necessary.

The Analytical Task Lead has the responsibility of performing audits as deemed necessary and upon learning of any nonconformance. The AECOM PM may request an audit at any time. The AECOM PM and AECOM Task Leader(s) have ultimate responsibility for implementing corrective actions.

3.3 Response Actions

Corrective action is the process of identifying, recommending, approving, and implementing measures to counter unacceptable procedures or out-of-limit QC performance that can affect data quality. Corrective action can occur during field activities, laboratory analyses, data validation, or data assessment.

3.3.1 Field Corrective Action

Corrective action in the field may be needed when the sample network is changed (i.e., more/less samples, sampling locations other than those specified in the QAPP, etc.) or when sampling procedures and/or field analytical procedures require modification, etc., due to unexpected conditions. The field team may identify the need for corrective action. The Field Team Lead will approve the corrective action and notify the PM. The Field Team Lead will ensure that the corrective measure is implemented by the field team.

Corrective action resulting from internal field audits will be implemented immediately if data may be adversely affected due to unapproved or improper use of approved methods. The Analytical Task Lead will identify deficiencies and recommend corrective action to the PM. Implementation of corrective actions will be performed by the Field Team Lead and field team. Corrective action will be documented in QA reports to the project management team. Corrective actions will be implemented and documented in the field logbook. Documentation will include:

- A description of the circumstances that initiated the corrective action,
- The action taken in response,
- The final resolution, and
- Any necessary approvals.

3.3.2 Laboratory Corrective Action

Corrective action in the laboratory may occur prior to, during, and after initial analyses. A number of conditions such as broken sample containers, multiple phases in liquid samples, low/high pH readings, and potentially high concentration samples may be identified during sample log-in or analysis. Following consultation with laboratory analysts and supervisory personnel, it may be necessary for the Laboratory QA Coordinator to approve the implementation of corrective action. If the nonconformance causes project objectives not to be achieved, the AECOM PM will be notified.

These corrective actions are performed prior to release of the data from the laboratory. The corrective action will be documented in both the laboratory's corrective action files and in the narrative data report sent from the laboratory to the AECOM PM. If the corrective action does not rectify the situation, the laboratory will contact the AECOM PM, who will determine the action to be taken and inform the appropriate personnel.

Corrective Action during Data Validation and Data Assessment

The need for corrective action may be identified during either data validation or data assessment. Potential types of corrective action may include resampling by the field team or reinjection/reanalysis of samples by the laboratory. These actions are dependent upon the ability to mobilize the field team

and whether the data to be collected are necessary to meet the required QA objectives. If the data validator or data assessor identifies a corrective action situation, the AECOM PM will be responsible for informing the appropriate personnel.

3.4 Reports to Management

Upon completion of any audit, the AECOM QA/QC Officer will document and report the QA/QC results and the identified issues (i.e., laboratory and/or field) to the AECOM Task Leader(s). The AECOM Task Leader(s) will evaluate the impact of the QA/QC issues and determine if the deviations will result in an adverse effect on the project conclusions.

4.0 Data Validation and Data Usability

Data generated during performance of the Downgradient Study Area investigations will undergo two levels of review. The laboratories and AECOM will provide data verification. Data validation will be performed by AECOM. For purposes of this project, laboratory deliverables equivalent to EPA Level 2 will be required to support the DQOs. Per email communication dated March 7, 2017, the data will be validated to NDEP Stage-2A (**Appendix A**).

4.1 Data Review, Verification, and Validation Methods

4.1.1 Procedures Used for Verification of Field Data

Procedures to verify field data include checking for transcription errors and review of field logbooks at the time of data collection. Field sampling efforts as described in the field logbooks will be reviewed at the conclusion of each sampling event to confirm sampling procedures followed established procedures. If any significant nonconformance issues are noted, they will be reported with a description of the potential effect of the nonconformance to the data. This task will be the responsibility of the AECOM Field Team Lead, or designee.

Field data will be reviewed periodically by the AECOM Field Team Lead or his designate to ensure that the records are complete, accurate, and legible, and to verify that the sampling procedures are in accordance with the protocols specified in this QAPP.

Field records will be reviewed by the AECOM Field Team Lead or designee to ensure that:

- Logbooks and standardized forms have been filled out completely and that the information recorded accurately reflects the activities that were performed.
- Records are legible and in accordance with good recordkeeping practices (e.g., entries are signed and dated; data are not obliterated; changes are initialed, dated, and explained).
- Sample collection, handling, preservation, and storage procedures were conducted in accordance with the protocols described in this QAPP, and that any deviations were documented and approved by the appropriate personnel.
- All manually entered data (e.g., field data) will be proofed 100 percent against the original forms. Electronic data will be checked 100 percent after loading against laboratory data sheets for completeness and spot checked for accuracy.

4.1.2 Procedures Used for Verification and Validation of Laboratory Data

Initial data reduction, verification, and reporting will be performed by the laboratory as described in the laboratory QA Manuals (**Appendix B**). Prior to the release of any data from the laboratory, the data will be reviewed and approved by laboratory personnel. The review will consist of a tiered approach that will include reviews by the person performing the work, by a qualified peer, and by supervisory and/or QA personnel.

Each laboratory will perform in-house analytical data validation under the direction of their own QA personnel and the Laboratory PM. Each laboratory will be responsible for assessing data quality and advising of any data rated "preliminary", "unacceptable", or other notations that would caution the data user of possible nonconformance.

Laboratory QA personnel, at the direction of the Laboratory PM, will routinely audit preliminary reports and will decide if sample re-analysis is required. This data assessment will be based on the assumption that the sample was properly collected and handled.

Laboratory QA personnel will conduct a systematic review of the data for compliance with the established QC criteria based on spike, duplicate and blank results and an evaluation of data precision, accuracy, and completeness will be performed.

Data validation will be performed by AECOM using EPA National Functional guidelines (EPA 2017a and 2017b) and the Guidance on Data Validation from NDEP (NDEP 2006). The EPA guidelines, which were prepared for Contract Laboratory Program data, will be adapted to reflect the analytical methods and measurement quality objectives established for the individual sampling events. Additional guidance from NDEP specific to the BMI properties will be followed as appropriate (NDEP 2006, 2008, 2009a, 2009b, 2009c, 2009d, 2009e, 2012 and 2013). In the event of a conflict among guidance documents, NDEP documentation will take precedence.

All data collected will be validated to Stage 2A, which includes:

- Completeness check;
- Chain-of-custody review;
- Review of holding times;
- Review of sample specific QC summaries, including negative controls (blanks), positive controls (LCS), and sample specific controls (replicates, MS, tracers/yields);
- Review of Internal Standard recoveries;
- Interference Check Sample, ICP Serial Dilution, and PQLs;
- Project or sampling specific items that have been identified for review.

Upon completion of the validation, a report will be prepared. This report will summarize the samples reviewed, elements reviewed, any non-conformances with the established criteria, and validation actions (including application of data qualifiers). Data qualifiers employed will be consistent with EPA guidelines and modified if necessary on a project-specific basis.

4.2 Reconciliation with Data Quality Objectives

Analytical results obtained from the project will be reconciled with the requirements specified in this QAPP. Data validation and usability includes the final project checks to evaluate if the data obtained will conform to the project's objectives, and to estimate what the effect is if deviations occur. Assessment of data for precision, accuracy, and completeness will be performed according to the following quantitative definitions.

The QC results associated with each analytical parameter for each matrix will be compared to the measurement objectives as defined in the program-specific work plans. Only data generated in association with QC results meeting the stated acceptance criteria (i.e., data determined to be valid) will be considered usable for decision-making purposes.

4.2.1 Accuracy Assessment

One measure of accuracy will be %R, which is calculated for MS, surrogates, and LCSs. Percent recoveries for MS/MSD results will be determined according to the following equation:

$$\%R = \frac{(Amount\ in\ Spiked\ Sample - Amount\ in\ Sample)}{Known\ Amount\ Added} \times 100$$

%R for LCS and surrogate compound results will be determined according to the following equation:

$$\%R = \frac{Experimental\ Concentration}{Known\ Amount\ Added} \times 100$$

An additional measure of accuracy is blank contamination. The blanks associated with these sampling events include laboratory method blanks and FBs (e.g., equipment rinsate blanks, FBs). The results of the laboratory and FBs will be compared to the accuracy objectives as defined in the program-specific work plans. Failure to meet these objectives may indicate a systematic laboratory or field problem that should be investigated and resolved immediately. Associated data may be qualified and limitations placed on their use, depending on the magnitude of the problem.

4.2.2 Precision Assessment

The RPD between the MS and MSD, LCS and LCSD or sample and sample duplicate in the case of some of the inorganic parameters, and FD pair is calculated to compare to the precision objectives as defined in the program-specific work plans. The RPD will be calculated according to the following formula.

$$RPD = \frac{(Amount\ in\ Sample\ 1 - Amount\ in\ Sample\ 2)}{0.5 (Amount\ in\ Sample\ 1 + Amount\ in\ Sample\ 2)} \times 100$$

Failure to achieve precision objectives may result in the qualification of the associated data and limitations placed upon their use.

4.2.3 Completeness Assessment

Completeness is the ratio of the number of valid sample results to the total number of samples analyzed with a specific matrix and/or analysis. Following completion of the analytical testing, the percent completeness will be calculated by the following equation:

$$Completeness = \frac{(number\ of\ valid\ measurements)}{(number\ of\ measurements\ planned)} \times 100$$

Failure to meet the completeness objective will require an assessment to determine if the missing or invalid data are critical to achieving the project objectives. Corrective actions may include resampling or re-analysis, depending on the type of problem, logistical constraints, etc.

4.3 Data Submittals to NDEP

4.3.1 Data Validation Summary Report

After the data validation process is complete, a data validation summary report (DVSR) will be prepared. The DVSR will summarize the data reviewed, any non-conformances, and validation actions. Data qualifiers will be added based on this evaluation. The data qualifiers and reason codes may be modified on a project-specific basis, but will be consistent with the EPA guidelines. The DVSR will include tables of all qualified data, the reason for qualification, any DQOs not met, the value of the exceedance, and the criteria exceeded will be provided, per NDEP specifications (NDEP 2013; NDEP 2009c).

4.3.2 Electronic Data Deliverable

Following data validation, the EQulS database will be used to create an Access database consistent with current NDEP guidance (2013).

4.4 Reconciliation with Data User Requirements

AECOM will review the laboratory data and their validation results to determine if it is suitable to meet the objectives of the program-specific work plans. Project results that do not meet DQOs will be reviewed by the AECOM QA/QC Officer. Raw analytical data, laboratory notebooks, or other laboratory data may be obtained and examined as necessary. Corrective actions will begin with identifying the source of the problem. Potential problem sources may include failure to adhere to method procedures, improper data reduction, equipment malfunctions, or systemic contamination.

The first level of responsibility for identifying problems and initiating corrective action will be with the sampler or field personnel under the supervision of the AECOM Field Team Lead. The second level of responsibility will be with any person reviewing the data including the AECOM QA/QC Officer and /or AECOM Analytical Task Leader.

If critical data are found to not meet DQOs, the AECOM Analytical Task Leader will take appropriate action to obtain acceptable data as determined necessary. This may include re-analyzing existing samples, collecting new investigative samples, or other actions that will result in obtaining acceptable data. The specific course of action will be determined on a case-by-case basis based in part on the effect the nonconformance may have on the RI/FS objectives.

Data that provide useful information but are not critical for achieving RI/FS objectives will be appropriately documented if they do not meet QC objectives. However, resampling or re-analysis to address such data typically will not be necessary.

Other corrective actions may include more intensive training, equipment repair followed by a more intensive preventive maintenance program, or removal of the source of systemic problems. Any and all corrective actions will be reviewed by the AECOM Task Leader(s) for certainty that resolution was achieved. Once resolved, the corrective action procedure will be fully documented.

5.0 References

- ENVIRON International Corporation (ENVIRON). 2012. Revised Interim Soil Removal Action Completion Report, Nevada Environmental Response Trust Site, Henderson, Nevada, August 2010 – November 2011. January. Revised September 28. NDEP approved December 17, 2012.
- EPA. 1997. Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, SW-846. Third Edition. May 1986, revised June 1997 and all subsequent updates..
- EPA. 2001a. Quality Staff. EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5. March.
- EPA. 2001b. Region 9 Superfund Data Evaluation/Validation Guidance, EPA R9QA/006.1
- EPA. 2002. Quality Staff. EPA Requirements for Quality Assurance Project Plans, EPA QA/G5. December.
- EPA. 2006. Quality Staff. Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G4. December.
- EPA, 2017a. Contract Laboratory Program National Functional Guidelines for Inorganic Superfund Methods Data Review (**ISM02.4**), OLEM 9355.0-135, EPA 540-R-2017-001
- EPA, 2017b. Contract Laboratory Program National Functional Guidelines for Organic Superfund Methods Data Review (**SOM02.4**), OLEM 9355.0-136, EPA 540-R-2017-002
- NDEP. 2006. NDEP Guidance on Data Validation for the BMI Plant Sites and Common Areas Projects, Henderson Nevada. May.
- NDEP. 2008. NDEP Detection Limits and Data Reporting for the BMI Plant Sites and Common Areas Projects, Henderson, Nevada. December.
- NDEP. 2009a. NDEP Guidance on Uniform Electronic Deliverables for the BMI Plant Sites and Common Areas Projects, Henderson, Nevada. February 27,
- NDEP. 2009b. NDEP Supplemental Guidance on Data Validation for the BMI Plant Sites and Common Areas Projects, Henderson, Nevada. March 19.
- NDEP. 2009c. NDEP Supplemental Guidance on Data Validation for the BMI Plant Sites and Common Areas Projects, Henderson, Nevada. April 13.
- NDEP. 2009d. Unification of Electronic Data Deliverables (EDD), NDEP- Required EDD Format. Henderson, Nevada. May 11.
- NDEP. 2009e. Unification of Electronic Data Deliverables (EDD), NDEP-Required EDD Format Update. Henderson, Nevada. July 2.
- NDEP. 2012. Guidance on Qualifying Data Due to Blank Contamination, Rev 2. January 5.
- NDEP. 2013. Guidance on Unified Chemical Electronic Data Deliverable Format, BMI Plant Sites and Common Areas Projects, Henderson, Nevada. June 5.

Ramboll (Ramboll Environ [formerly Environ International]). 2014. Quality Assurance Project Plan, Revision 1. July 18.

Tables

**TABLE 1. ANALYTICAL METHODS AND LABORATORIES
 QUALITY ASSURANCE PROJECT PLAN
 Nevada Environmental Response Trust Site - Downgradient Study Area; Henderson, Nevada**

ANALYTES	MATRIX	ANALYTICAL METHOD	ANALYTICAL LABORATORY	SOPs REVIEW DATE⁽¹⁾
Metals (dissolved Chromium)	Water	EPA Method 200.7	TestAmerica (Irvine, CA)	May 17, 2013
Metals (dissolved Chromium) ⁽²⁾	Water	EPA Method 200.8	TestAmerica (Irvine, CA)	August 30, 2013
Hexavalent Chromium	Water	EPA Method 218.7	Silver State Analytical (Las Vegas, NV)	September 9, 2013
Inorganic Anions ⁽³⁾	Water	EPA Method 300.0	TestAmerica (Irvine, CA)	September 27, 2013
Chlorate	Water	EPA Method 300.1	TestAmerica (Irvine, CA)	September 30, 2013
Perchlorate	Water	EPA Method 314.0	TestAmerica (Irvine, CA)	October 2, 2013
Total Dissolved Solids (TDS)	Water	SM 2540C	TestAmerica (Irvine, CA)	September 30, 2013

Notes:

EPA = United States Environmental Protection Agency

SM = Standard Methods For The Analysis of Water and Wastewater

(1) The Standard Operating Procedures (SOPs) Review Date is the date of the laboratory's current approved SOPs that will be implemented for this project. Laboratories are responsible for notifying AECOM of any revisions to the SOPs referenced above. The use of revised SOPs are subject to approval.

(2) Dissolved chromium may be analyzed by EPA Method 200.8 to overcome matrix interference from saline groundwater and/or to achieve lower PQLs and MDLs.

(3) Chloride and bromide

Dissolved Chromium samples are to be field filtered with a 0.45 micron filter and samples are to represent dissolved constituents

**TABLE 2. GROUNDWATER AND SURFACE WATER ANALYTES AND ANALYTICAL QUALITY CONTROL CRITERIA
 QUALITY ASSURANCE PROJECT PLAN
 Nevada Environmental Response Trust Site - Downgradient Study Area; Henderson, Nevada**

ANALYTES	CAS Number	Screening Level	Screening Level Source ⁽¹⁾	Practical Quantitation Limit (PQL)	Method Detection Limit (MDL)	QUALITY CONTROL LIMITS ⁽²⁾						
						Surrogate %R	Duplicate RPD	Matrix Spike		Blank Spike/LCS		
								%R	RPD	%R	RPD	
Metals (µg/L)												
<i>EPA Method 200.7</i>												
Chromium (dissolved)	7440-47-3	100	MCL	5	2	--	--	30	75 - 125	20	80 - 120	20
<i>EPA Method 200.8</i>												
Chromium (dissolved)	7440-47-3	100	MCL	5	2	--	--	30	75 - 125	20	80 - 120	20
<i>EPA Method 218.7</i>												
Chromium (hexavalent)	18540-29-9	100	BCL	1	0.25	--	--	30	90 - 110	10	90 - 110	10
Others (µg/L)												
<i>EPA Method 300.0</i>												
Bromide	24959-67-9	--	--	500	250	--	--	30	80 - 120	20	90 - 110	20
Chloride	16887-00-6	250,000	2nd MCL	500	250	--	--	30	80 - 120	20	90 - 110	20
<i>EPA Method 300.1</i>												
Chlorate	7790-93-4	--	--	20	8	--	--	30	75 - 125	25	75 - 125	25
<i>EPA Method 314.0</i>												
Perchlorate	14797-73-0	18	BCL	4	0.95	--	--	30	80 - 120	20	85 - 115	15
<i>SM 2540C</i>												
Total Dissolved Solids	10-33-3	500,000	2nd MCL	10000	5000	--	--	30	--	--	90 - 110	10

**TABLE 2. GROUNDWATER AND SURFACE WATER ANALYTES AND ANALYTICAL QUALITY CONTROL CRITERIA
QUALITY ASSURANCE PROJECT PLAN
Nevada Environmental Response Trust Site - Downgradient Study Area; Henderson, Nevada**

ANALYTES	CAS Number	Screening Level	Screening Level Source ⁽¹⁾	Practical Quantitation Limit (PQL)	Method Detection Limit (MDL)	QUALITY CONTROL LIMITS ⁽²⁾					
						Surrogate %R	Duplicate RPD	Matrix Spike		Blank Spike/LCS	
								%R	RPD	%R	RPD

Notes:

-- = no value

µg/L = micrograms per liter

(1) Groundwater screening levels were selected according to the following hierarchy of criteria:

- (a) Maximum Contaminant Level (MCL): Primary United States Environmental Protections Agency (USEPA) maximum contaminant level (USEPA 40 CFR Part 141).
- (b) Basic Contaminant Level (BCL): Residential water basic comparison levels in NDEP August 2013 BCL Spreadsheet (NDEP 2013).
- (c) Regional Screening Level (RSL): Tap water regional screening levels in USEPA Pacific Southwest, Region 9, Regional Screening Levels Chemical Specific Parameters table, Nov 2013. The screening levels were selected as the minimal values of carcinogenic screening level and noncarcinogenic screening level (USEPA 2013a).
- (d) 2nd Maximum Contaminant Level (2nd MCL): National Secondary Drinking Water Regulations (USEPA, 40 CFR Part 143).

(2) QC Limits = Quality Control Limits for %R (Percent Recovery) of spiked compounds in Laboratory Control Samples (LCS) and surrogate compounds and Relative Percent Difference (RPD) between Matrix Spike (MS) and MS Duplicate (MSD) samples and LCS and LCS duplicate (LCSD) samples. Laboratory historical control limits are subject to change as a result of periodic re-evaluation. Limits in use at the time of sample analysis are available from the laboratory. Duplicate RPDs apply to sample duplicates and field duplicates.

Sources:

NDEP. 2013. User's Guide and Background Technical Document for NDEP Basic Comparison Levels (BCLs) for Human Health for the BMI Complex and Common Areas. Revision 12, August.

USEPA. 2013a. Regional Screening Levels (RSL) for Chemical Contaminants at Superfund Sites. November.

USEPA. National Primary Drinking Water Regulations. Code of Federal Regulations, 40 CFR Part 141.

USEPA. National Secondary Drinking Water Regulations. Code of Federal Regulations, 40 CFR Part 143.

**TABLE 3. FREQUENCY OF QA/QC SAMPLES
 QUALITY ASSURANCE PROJECT PLAN
 Nevada Environmental Response Trust Site- Downgradient Study Area; Henderson, Nevada**

SAMPLE TYPE	FREQUENCY OF ANALYSIS
Contamination Control Samples	
Laboratory Method Blank	One per each analytical method. One in every batch of samples (not to exceed 20 samples).
Equipment Blank	One per each analytical method. One in every batch of samples (not to exceed 20 samples).
Field Blank	One per each analytical method. One in every batch of samples (not to exceed 20 samples).
Accuracy Control Samples	
Laboratory Control Samples	One per each analytical method. One in every preparation batch (not to exceed 20 samples).
Matrix Spike Samples ⁽²⁾	Analyzed in each batch, where applicable to the method (not to exceed 20 samples).
Precision Control Samples	
Field Duplicate Sample	One per each analytical method. One in every batch of samples collected (not to exceed 10 samples).
Laboratory Control Sample Duplicates	One per each analytical method. One in every preparation batch (not to exceed 20 samples).
Matrix Spike Duplicate Samples ⁽²⁾	Analyzed in each batch, where applicable to the method (not to exceed 20 samples).

NOTE:

(1) Not all methods use surrogates.

(2) Not all analytical methods or sample matrices have Matrix Spikes.

**TABLE 4. SAMPLE PRESERVATION, CONTAINERS, AND HOLDING TIMES
 QUALITY ASSURANCE PROJECT PLAN
 Nevada Environmental Response Trust Site - Downgradient Study Area; Henderson, Nevada**

MATRIX	ANALYTES	ANALYTICAL METHOD	PRESERVATION	CONTAINER ⁽¹⁾⁽²⁾	TAT	HOLD TIME ⁽³⁾	
						Prior to pH adjustment	After pH adjustment
Water	Metals (dissolved chromium)	EPA Method 200.7	HNO ₃ to pH <2; 4 °C	500 mL HDPE	10d		180d
Water	Metals (dissolved chromium)	EPA Method 200.8	HNO ₃ to pH <2; 4 °C	500 mL HDPE	10d		180d
Water	Hexavalent chromium	EPA Method 218.7	Cool to <4 °C	500 mL HDPE	10d	24h	7d
Water	Inorganic anions ⁽⁴⁾	EPA Method 300.0	Cool to <4 °C	500 mL HDPE	10d		28d
Water	Chlorate	EPA Method 300.1	Cool to <4 °C	500 mL HDPE	10d		28d
Water	Perchlorate	EPA Method 314.0	Cool to <4 °C	500 mL HDPE	10d		28d
Water	Total Dissolved Solids (TDS)	SM 2540C	Cool to <4 °C	500 mL HDPE	10d		7d

Notes:

EPA = United States Environmental Protection Agency

TAT = Turnaround Time

HDPE = high-density polyethylene

HNO₃ = Nitric Acid

d = day(s)

h = hours

mL = milliliters

(1) Additional volume will be collected for MS/MSD samples.

(2) Laboratory may provide alternate containers as long as the containers meet the requirements of the method and allow the collection of sufficient volume to perform the analysis.

(3) Holding time begins from date of sample collection.

(4) Chloride and bromide

**TABLE 5. CALIBRATION AND MAINTENANCE OF FIELD EQUIPMENT
 QUALITY ASSURANCE PROJECT PLAN
 Nevada Environmental Response Trust Site - Downgradient Study Area; Henderson, Nevada**

INSTRUMENT	TASK	FREQUENCY
Organic Vapor Meter OVM ⁽¹⁾	(a) Inspect and calibrate (b) Charge batteries	(a) Daily (b) Each night prior to operation
Conductivity, Dissolved Oxygen (DO), Oxygen Reduction Potential (ORP), pH, and Temperature Meter ⁽²⁾	(a) Inspect and calibrate (b) Test batteries	(a) Daily (b) Each night prior to operation
Turbidity Meter ⁽³⁾	(a) Inspect and calibrate (b) Test batteries	(a) Daily (b) Each night prior to operation
Alkalinity Test Kit ⁽⁴⁾	(a) Inspect kit integrity	(a) Daily prior to testing
Water Level Indicator ⁽⁵⁾	(a) Inspect (b) Test batteries (c) Calibrate	(a) Daily (b) Each night prior to operation (c) Annually with steel tape
Low flow adjustable-rate sampling pump ⁽⁶⁾	(a) Change bladder (b) Change tubing ⁽¹¹⁾	(a) Each sample location (b) Each sample location
Low flow adjustable-rate sampling pump	(a) Inspect (b) Calibrate	(a) Individually prior to operation (b) Factory calibrated prior to shipment to site
Pressure Transducers ⁽⁷⁾	(a) Inspect data log (b) Check batteries and o-rings (c) Perform depth and drift tests (d) Calibrate	(a) Daily (b) Prior to installation (c) Prior to installation (d) Factory calibrated prior to shipment to site

Notes:

- (1) MiniRAE 2000 Photoionization Detector (PID) with 10.6 eV lamp or similar
- (2) YSI 556 MPS or similar
- (3) HACH 2100P Turbidity Meter or similar
- (4) HACH Digital Titrator or similar
- (5) Solinst Water Level Indicator or similar having gradations marked at 0.01-foot intervals.
- (6) QED Sample Pro or similar
- (7) In Situ Level Troll 500 vented water level/temperature monitor or similar.

**TABLE 6. ANALYTICAL LABORATORY CALIBRATION FREQUENCIES
 QUALITY ASSURANCE PROJECT PLAN
 Nevada Environmental Response Trust Site - Downgradient Study Area; Henderson, Nevada**

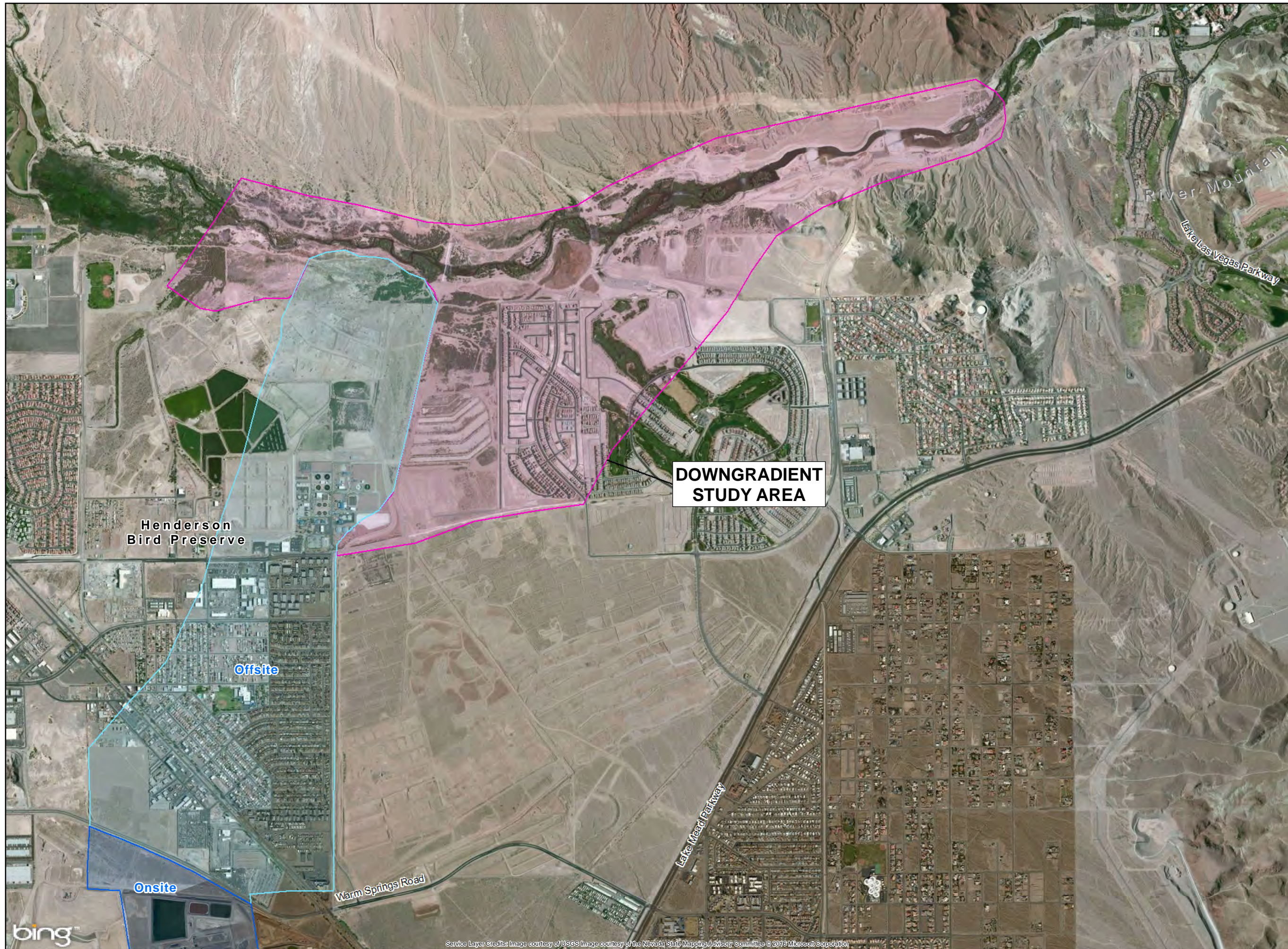
QUALITY CONTROL CHECK⁽¹⁾			
LABORATORY ANALYSIS	ANALYTICAL METHOD	Initial Calibration Type/Frequency	Continuing Calibration Type/Frequency
Metals by EPA Method 200.7	Inductively Coupled Plasma Atomic Emission Spectroscopy	Minimum two point and a blank calibration daily prior to analysis.	Standard analyzed at a minimum after every 10 samples and end of the sequence.
Metals by EPA Method 200.8	Inductively Coupled Plasma/ Mass Spectroscopy	Four point (three standard + blank) calibration daily prior to analysis.	Standard analyzed after every 10 samples.
Inorganic Anions by EPA Method 300.0 and 300.1	Ion Chromatography	Minimum three points plus a blank on an as needed basis with daily verification before sample analysis.	Standard analyzed after every 10 samples and end of sequence.
Hexavalent Chromium by EPA Method 218.7	Ion Chromatography	Minimum three points plus a blank on an as needed basis with daily verification before sample analysis.	Standard analyzed at least once every 10 samples and end of the sequence.
Perchlorate by EPA Method 314.0	Ion Chromatography	Minimum five points plus a blank on an as needed basis with daily verification before sample analysis.	Standard analyzed after every 10 samples and end of the sequence.
Total Dissolved Solids by SM2540	Gravimetric	Standard analyzed on an as needed basis with daily verification before sample analysis.	Balance calibration consistent with manufacturers recommendations

Notes:

EPA = United States Environmental Protection Agency
 SM = Standard Method

(1) These Quality Control checks are to be considered the minimum frequency and scope of checks and calibrations to be performed. Laboratories may have more stringent requirements as part of their Standard Operating Procedures.

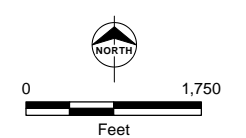
Figures



OVERVIEW MAP



- Legend**
- █ NERT Downgradient Study Area
 - █ NERT Off-site Study Area
 - █ NERT On-site Study Area



Scale 1:23,000
1 inch = 1,917 feet

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NERT
Remedial Investigation
Downgradient Study Area

**DOWNGRADIENT
STUDY AREA
LOCATION MAP**

Date: 2/22/2016 Project: 60477365

Quality Assurance Organization Chart



PRINCIPAL IN CHARGE
Harry Van Den Berg, PE

PROJECT MANAGER
Sally Bilodeau, PG, CEG, ChG, CEM

DEPUTY PROJECT MANAGER
Carmen Caceres-Schnell, PG
(CEM pending)

QA/QC OFFICER
Leta Maclean, CHMM

<p>SUBSURFACE INVESTIGATION TASK LEAD Carmen Caceres-Schnell, PG</p>	<p>ANALYTICAL TASK LEAD Chad Roper, PhD</p>	<p>SURFACE WATER SAMPLING TASK LEAD Kristen Durocher</p>
---	--	---

FIELD TEAM LEADS

Brian Ho, PG, CEM
Subsurface Investigations

Ryan McCarthy
Surface Water Investigations

DATA MANAGEMENT

Steve Cole
Project Chemist / Database Management

Lily Bayati
Project Chemist/ Data Validation

Grant Williams, PG
Data Visualization / GIS

Appendix A

Email Communication about Stage of Data Validation

Roper, Chad

From: Van Den Berg, Harry
Sent: Tuesday, March 07, 2017 1:15 PM
To: Caceres-Schnell, Carmen; Durocher, Kristen; Roper, Chad
Cc: Bilodeau, Sally
Subject: FW: Notification : Change in Groundwater Data Validation Guidance

FYI

Harry Van Den Berg, PE, CEM

Associate Vice President, Environment
Camarillo, CA
D +805-764-4045
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From: James Dotchin [<mailto:jdotchin@ndep.nv.gov>]
Sent: Tuesday, March 07, 2017 12:29 PM
To: Mark Paris (m paris@landwellco.com); richard.pfarrer@timet.com; Richards, Curt M CERG (CMRichards@olin.com); Jay A. Steinberg, President (trustee.president@lepetomaneinc.com); jkelly@montrosechemical.com; Elmendorf, Charles N (Charles.Elmendorf@astrazeneca.com) (Charles.Elmendorf@astrazeneca.com); Jeff Gibson (jeff.gibson@ampac.us)
Cc: 'Andrew Steinberg'; NDEP Industrial Site Cleanup; 'Alison Fong'; abaas@edgcomb-law.com; Allan DeLorme (adelorme@ramboll.com); Andrew Barnes (ABarnes@geosyntec.com); Kirk Stowers; Kurt Fehling (KFehling@thefehlinggroup.com); victoria tyson-bloyd (victoria@tysoncontracting.com); Paul Black (pblack@neptuneinc.org); Paul Hackenberry; Joanne Otani (jotani@thefehlinggroup.com); Brenda Pohlmann; Brian Waggle (BWAGGLE@HARGIS.COM) (BWAGGLE@HARGIS.COM); Share, David M CERG (DMShare@olin.com); Amidon, Derek; Ed Modiano (edm@demaximis.com) (edm@demaximis.com); Gary Carter (gary.carter@ampac.us); 'george.crouse@syngenta.com'; John Pekala (jpekala@ramboll.com); Kelly McIntosh (mcintosh_kelly@hotmail.com) (mcintosh_kelly@hotmail.com); Kimberly Schmidt Kuwabara (kkuwabara@ramboll.com); kyle.hansen@tetrattech.com; Anna Springsteen (aspringsteen@neptuneinc.org); Lee C. Farris (LFarris@LandwellCo.com); Ron Sahu (sahuron@earthlink.net); Michael Long (mlong@hargis.com); Nicholas Pogoncheff (NPogoncheff@pesenv.com); Patti Meeks (pmeeks@neptuneinc.org); steve.clough@nert-trust.com; Van Den Berg, Harry; 2- Kyle Gadley (KGadley@Geosyntec.com); Chris Ritchie
Subject: Notification : Change in Groundwater Data Validation Guidance

All,

The NDEP-BISC and its contractor have reviewed the current groundwater data validation requirements for the BMI and Surrounding Areas to determine the need for the BMI Plant Sites and Common Areas Projects and other Industrial Sites (The Companies) to continue to use the higher validation rates for groundwater samples. The review of existing groundwater data determined that the higher data validation rates did not change the outcomes of any of the Reports or Projects although they did significantly increase costs for the Companies.

The result of this review will be a coming change in guidance for data validation. As this change will take some time to complete I wanted to get this to the Companies before the spring groundwater sampling takes place.

Please use this e-mail as NDEP authorization to deviate from the existing validation guidance posted on NDEP's website at <http://ndep.nv.gov/bmi/technical.htm> under "Data Validation" related to groundwater and surface water samples. The required data validation stage will now be 2A for all groundwater and surface water sampling from March 1, 2017 forward. Please note that the data validation for soils has not changed and will remain the same.

Appendix B

Laboratory Quality Manual and EDD

Please contact me with any questions or comments about this notification, a letter will follow with an update to the guidance. Happy sampling.

Regards,
JD



James (JD) Dotchin
Chief, Bureau of Industrial Site Cleanup
Las Vegas Office Manager
Nevada Division of Environmental Protection
2030 E Flamingo Rd, Suite 230
Las Vegas, NV 89119
p: 702.486.2850 EXT 235 c: 775.443.5290 f: 702.486.2863
jdotchin@ndep.nv.gov
www.ndep.nv.gov
<http://ndep.nv.gov/bmi/index.htm>

May 19, 2017

Chad Roper, Ph.D
AECOM
1220 Avenida Acaso
Camarillo, CA 93012-8750

Subject: Authorization to Reproduce Laboratory QA Manual in QAPP

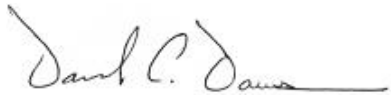
Dr. Roper:

TestAmerica Irvine hereby authorizes AECOM to include its laboratory Quality Assurance Manual (IR-QAM, revision 5, 03/14/2017) in the finalized NERT QAPP.

If you have any questions or require further information, please contact me at (949) 261-1022.

Sincerely yours,

TestAmerica Irvine



David C. Dawes
Quality Assurance Officer

Quality Assurance Manual Cover Page

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**Quality Assurance Manual
Approval Signatures**



Linda Scharpenberg
Laboratory and Technical Director

3-14-17

Date



Adriana Schow
Technical Director, Microbiology

3/14/17

Date



Kathryn Chang
Quality Assurance Manager

03/14/17

Date

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REFERENCED CORPORATE SOPs AND POLICIES

SOP / Policy Reference	Title
CA-I-P-002	Electronic Reporting and Signature Policy
CA-L-P-002	Contract Compliance Policy
CA-L-S-002	Subcontracting Procedures
CA-Q-M-002	Corporate Quality Management Plan
CA-Q-S-001	Solvent and Acid Lot Testing and Approval
CA-Q-S-002	Acceptable Manual Integration Practices
CA-Q-S-006	Detection Limits
CA-Q-S-009	Root Cause Analysis
CA-T-P-001	Qualified Products List
CW-E-M-001	Corporate Environmental Health & Safety Manual
CW-F-P-002	Company-Wide Authorization Matrix
CW-F-P-004	Procurement and Contracts Policy
CW-F-S-007	Capital Expenditure, Controlled Purchase Requests and Fixed Asset Capitalization
CW-L-P-004	Ethics Policy
CW-L-S-002	Internal Investigation
CW-Q-S-001	Corporate Document Control and Archiving

SOP / Policy Reference	Title
CW-Q-S-002	Writing a Standard Operating Procedure (SOPs)
CW-Q-S-003	Internal Auditing
CW-Q-S-004	Management Systems Review
CW-Q-S-005	Data Recall Process
CA-C-S-001	Work Sharing Process

REFERENCED LABORATORY SOPs

SOP Reference	Title
IR-QA-DOC	Document Control and Review
IR-QA-CNTRLLIM	Control Charts and Statistical Process Control
IR-QA-ARCH	Record Archiving
IR-IT-COMPUSEC	Computer Security and Software Maintenance
IR-QA-BAL	Balance Calibration, Verification and Documentation
IR-QA-THERMA	Thermometer Calibration, Temperature Monitoring, and Documentation
IR-QA-PIPET	Pipette, Syringe, and Dispenser Calibration
IR-MICRO-AUTOCLAVE	Microbiological Sterilization Equipment – Autoclave
IR-QA-TRAIN	Training and Documentation
IR-QA-MDL	Determination of Method Detection Limits
IR-QA-LOTTEST	Container and Reagent Verification by Lot Testing
IR-QA-STDCNTRL	Reagent and Standard Preparation, Control and Documentation
IR-SC-FIELD	Field Sampling and Testing
IR-QA-SUBSAMP	Subsampling, Compositing and Homogenization
IR-SC-LOGIN	Sample Login
IR-EHS-WASTE	Hazardous Waste Disposal

SECTION 3. INTRODUCTION, SCOPE AND APPLICABILITY

3.1 Introduction and Compliance References

TestAmerica Irvine's Quality Assurance Manual (QAM) is a document prepared to define the overall policies, organization objectives and functional responsibilities for achieving TestAmerica's data quality goals. 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 The NELAC Institute (TNI) Standard, dated 2009, Volume 1 Modules 2 and 4, and ISO/IEC Guide 17025:2005(E). In addition, the policies and procedures outlined in this manual are compliant with TestAmerica's Corporate Quality Management Plan (CQMP) 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:

- ANSI/ASQC, E4-1994, "Specifications and Guidelines for Quality Management Systems for Environmental Data Collection and Environmental Technology Programs" (American National Standard, January 5, 1995, or most recent version).
- "EPA Requirements for Quality Management Programs" (QA/R-2) (EPA/240/B-01/002, May 31, 2006).
- 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; Final Update V, August 2015.
- 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 Edition, 19th, 20th, 21st, and on-line Editions.**
- Toxic Substances Control Act (TSCA).

3.2 Terms and Definitions

A Quality Assurance Program is a company-wide system designed to ensure that data produced by 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 Standard Operating Procedures (SOPs) and quality control. The TestAmerica program is designed to minimize systematic error, encourage constructive, documented problem solving, and provide a framework for continuous improvement within the organization.

Refer to Appendix 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 Quality Assurance Program contains specific procedures and methods to test samples of differing matrices for chemical, physical and biological parameters. The Program also contains guidelines on maintaining documentation of analytical 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 the laboratory's network shared folder Irvine-QA. The approach of this manual is to define the minimum level of quality assurance and quality control necessary to meet these requirements. All methods performed by the laboratory shall meet these criteria as appropriate. In some instances, quality assurance project plans (QAPPs), project specific data quality objectives (DQOs) or local regulations may require criteria other than those contained in this manual. In these cases, the laboratory will abide by the requested criteria following review and acceptance of the requirements by the Laboratory Director and the Quality Assurance (QA) Manager. In some cases, QAPPs and DQOs may specify less stringent requirements. The Laboratory Director and the QA Manager must determine if it is in the lab's best interest to follow the less stringent requirements.

3.4 Management of the Manual

3.4.1 Review Process

The template on which this manual is based is reviewed annually by Corporate Quality Management Personnel to assure that 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 revised sections of the document. All updates will be reviewed by the senior laboratory management staff. The laboratory updates and approves such changes according to our Document Control and Review procedures (refer to SOP No. IR-QA-DOC).

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 and Chief Executive Officer (CEO), Chief Operating Officer (COO), Executive Vice President (VP) Operations, Corporate Quality, etc.). The laboratory operational and support staff work under the direction of the Laboratory Director. The organizational structure for both Corporate & TestAmerica Irvine is presented in Figure 4-1.

4.2 Roles and Responsibilities

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

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 person carries out his/her daily tasks in a manner consistent with the goals and in accordance with the procedures in this manual and the laboratory's SOPs. Role descriptions for Corporate personnel are defined in the CQMP. This manual is specific to the operations of TestAmerica's Irvine laboratory.

4.2.2 President and Chief Executive Officer (CEO)

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

4.2.3 Chief Operation Officer (COO)

The COO reports directly to the President and CEO of TestAmerica. The COO oversees the operations of all TestAmerica laboratories and the EMLab P&K business unit. The VP's of Operations report directly to COO.

4.2.4 Vice President of Operations

Each VP of Operations reports directly to the Executive VP of Operations and is a part of the Executive Committee. Each VP of Operations is responsible for the overall administrative and operational management of their respective laboratories. The VP's responsibilities include allocation of personnel and resources, long-term planning, goal setting, and achieving the financial, business, and quality objectives of TestAmerica. The VP's ensure timely compliance

with Corporate Management directives, policies, and management systems reviews. The VP's are also responsible for restricting any laboratory from performing analyses that cannot be consistently and successfully performed to meet the standards set forth in this manual.

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

The Vice President (VP) of QA/EHS reports directly to the President and CEO. With the aid of the Executive Committee, Laboratory Directors, Quality Directors, Safety Manager, EH&S Coordinators and QA Managers, the VP-QA/EHS has the responsibility for the establishment, general overview and Corporate maintenance of the Quality Assurance and EH&S Programs within TestAmerica. Additional responsibilities include:

- Review of QA/QC and EHS aspects of Corporate SOPs & Policies, national projects and expansions or changes in services.
- Work with various organizations outside of TestAmerica to further the development of quality standards and represent TestAmerica at various trade meetings.
- Preparation of a monthly report that includes quality metrics across the analytical laboratories and a summary of any quality related initiatives and issues.
- Preparation of a monthly report that includes EH&S metrics across the analytical laboratories and a summary of any EH&S related initiatives and issues.
- Work with various organizations outside of TestAmerica to further the development of quality standards and represent TestAmerica at various trade meetings.
- With the assistance of the Corporate Senior Management Teams and the EHS Director, development and implementation of the TestAmerica Environmental, Health and Safety Program.

4.2.6 Vice President of Client Service

The VP of Client Services leads the Client Service Organization (CSO) and is responsible for client satisfaction, driving operational excellence and improving client responsiveness. The VP provides direction to the Client Service Directors, Programs Managers and Project Managers.

4.2.7 Quality Assessment Director

The Quality Assessment Director reports to the VP-QA/EHS. The Quality Assessment Director has QA oversight of laboratories; responsible for the internal audit system, schedule and procedure; monitors laboratory internal audit findings; identifies common laboratory weaknesses; and monitors corrective action closures. Together with the Quality Compliance Director, the Quality Systems Director, and the VP-QA/EHS, the Quality Assessment Director has the responsibility for the establishment, general overview and maintenance of the Analytical Quality Assurance Program within TestAmerica.

4.2.8 Quality Compliance Director

The Quality Compliance Director reports to the VP-QA/EHS. The Quality Compliance Director has QA oversight of laboratories; monitors and communicates DoD/DoE requirements; develops corporate tools for ensuring and improving compliance; develops corporate assessment tools;

identifies common laboratory weaknesses; and monitors corrective action closures. Together with the Quality Assessment Director, Quality Systems Director and the VP-QA/EHS, the Quality Compliance Director has the responsibility for the establishment, general overview and maintenance of the Analytical Quality Assurance Program within TestAmerica.

4.2.9 Quality Systems Director

The Quality Systems Director reports to the VP-QA/EHS. The Quality Systems Director has QA oversight of laboratories; develops quality policies, procedures and management tools; monitors and communicates regulatory and certification requirements; identifies common laboratory weaknesses; and monitors corrective action closures. Together with the Quality Assessment Director, Quality Compliance Director and the VP-QA/EHS, the Quality Systems Director has the responsibility for the establishment, general overview and maintenance of the Analytical Quality Assurance Program within TestAmerica.

4.2.10 Quality Information Manager

The Quality Information Manager is responsible for managing all company official documents (e.g., Policies, Procedures, Work Instructions), the company's accreditation database, intranet websites, external laboratory subcontracting, regulatory limits for clients on the company's TotalAccess website; internal and external client support for various company groups (e.g., Client Services, EH&S, Legal, IT, Sales) for both quality and operational functions. The Quality Information Manager reports to the VP-QA/EHS; and works alongside the Quality Assessment, Quality Compliance and Quality System Directors and EHS Managers to support both the Analytical Quality Assurance and EHS Programs within TestAmerica.

4.2.11 Technical Services Director

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

4.2.12 Ethics and Compliance Officers (ECOs)

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

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

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

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

4.2.13 Chief Information Officer (CIO)

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

4.2.14 Environmental Health and Safety Managers (Corporate)

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

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

4.2.15 Laboratory Director

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

Specific responsibilities include, but are not limited to:

- Provide one or more technical managers for the appropriate fields of testing. If the Technical Manager is absent for a period of time exceeding 15 consecutive calendar days, the Laboratory Director must designate another full time staff member meeting the qualifications of the Technical Manager to temporarily perform this function. If the absence exceeds 65 consecutive calendar days, the primary accrediting authority must be notified in writing.
- Ensure that all analysts and supervisors have the appropriate education and training to properly carry out the duties assigned to them and ensure that this training has been documented.
- Ensure that personnel are free from any commercial, financial and other undue pressures which might adversely affect the quality of their work.
- Ensure TestAmerica's human resource policies are adhered to and maintained.
- Ensure that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory.
- Ensure that appropriate corrective actions are taken to address analyses identified as requiring such actions by internal and external performance or procedural audits. Procedures that do not meet the standards set forth in the QAM or laboratory SOPs may be temporarily suspended by the Laboratory Director.
- Review and approve all SOPs prior to their implementation and ensures all approved SOPs are implemented and adhered to.
- Pursue and maintain appropriate laboratory certification and contract approvals. Support ISO 17025 requirements.
- Ensure client specific reporting and quality control requirements are met.
- Captain the management team, consisting of the QA Manager and the Technical Manager(s) as direct reports.
- 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 QA Manager and in compliance with regulatory requirements.
- Ensure that scheduled instrument maintenance is completed.
- Manage efficient utilization of supplies.
- Constantly monitor and modify the processing of samples through the departments.

4.2.16 Quality Assurance (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 their

Corporate Quality Director. This position is able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence. Corporate QA may be used as a resource in dealing with regulatory requirements, certifications and other quality assurance related items. The QA Manager also directs the activities of the QA officers.

Specific responsibilities include, but are not limited to:

- Serve as the focal point for QA/QC in the laboratory.
- Have functions independent from laboratory operations for which he/she has quality assurance oversight.
- Maintain and update this Quality Assurance Manual (QAM).
- Monitor and evaluate laboratory certifications; scheduling proficiency testing samples.
- Monitor and communicate regulatory changes that may affect the laboratory to the management.
- Train and advise the laboratory staff on quality assurance/quality control procedures that are pertinent to their daily activities.
- 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).
- Arrange for or conduct internal audits on quality systems and the technical operation.
- Maintain records of all ethics-related training, including the type and proof of attendance.
- Maintain, improve, and evaluate the corrective action database and the corrective and preventive action systems.
- Notify the 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 procedures outlined in Section 12 and if deemed necessary may be temporarily suspended during the investigation.
- Objectively monitor standards of performance in quality control and quality assurance without outside (e.g., managerial) influence.
- Coordinate document control of SOPs, MDLs, control limits, and miscellaneous forms and information.
- Review a percentage of all final data reports for internal consistency. Review Chain of Custody (COC) records, correspondence with the analytical request, batch QC status, and completeness of any corrective action statements. Evaluate manual calculations, format, holding time, sensibility and completeness of the project file contents.
- Review external audit reports and data validation requests.
- Follow-up with audits to ensure regulatory and/or client QAPP requirements are met.
- Establish reporting schedule and prepare various quality reports for the Laboratory Director, clients and/or Corporate QA.

- Develop suggestions and recommendations to improve quality systems.
- Research current state and federal requirements and guidelines.
- Captain the QA team to enable communication and to distribute duties and responsibilities.
- Communicate and monitor standards of performance to ensure that systems are in place to produce the level of quality as defined in this document.
- Notify the 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 are temporarily suspended following the procedures outlined in Section 12.
- Evaluate the thoroughness and effectiveness of training.
- Ensure compliance with ISO 17025 (where applicable).

4.2.17 Technical Manager or Designee

The Technical Manager(s) report(s) directly to the Laboratory Director. The Technical Manager is accountable for all analyses and analysts under their experienced supervision and for compliance with the ISO 17025 Standard. 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.

Specific responsibilities include, but are not limited to:

- Exercise day-to-day supervision of laboratory operations for the appropriate field of accreditation and reporting of results. Coordinate, write, and review the preparation of all test method SOPs with regard to quality, integrity, regulatory and optimum and efficient production techniques, and subsequent analyst training and interpretation of the SOPs for implementation and unusual project samples. Ensures that the SOPs are properly managed and adhered to at the bench. Develop standard costing of SOPs to include supplies, labor, overhead, and capacity (design vs. demonstrated versus first-run yield) utilization.
- 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. This procedure addresses the adequate definition of methods to be used for analysis and any limitations, the laboratory's capability and resources, and the client's expectations. Differences are resolved before the contract is signed and work begins. A system documenting any significant changes is maintained, as well as pertinent discussions with the client regarding their requirements or the results of the analyses during the performance of the contract. All work subcontracted by the laboratory must be approved by the client. Any deviations from the contract must be disclosed to the client. Once the work has begun, any amendments to the contract must be discussed with the client and so documented.
- Monitor the validity of the analyses performed and data generated in the laboratory. This activity begins with reviewing and supporting all new business contracts, ensuring data quality, analyzing internal and external non-conformances to identify root cause issues and implementing the resulting corrective and preventive actions, facilitating the data review process (training, development, and accountability at the bench), and providing technical and troubleshooting expertise on routine and unusual or complex problems.

- Provide training and development programs to applicable laboratory staff as new hires and, subsequently, on a scheduled basis. Training includes instruction on calculations, instrumentation management, troubleshooting and preventive maintenance.
- Enhance efficiency and improve quality through technical advances and improved LIMS utilization. Perform capital forecasting and instrument life cycle planning for second generation methods and instruments as well as asset inventory management.
- Coordinate sample management from “cradle to grave,” and ensure no time is lost in locating samples.
- Schedule all QA/QC related requirements for compliance, e.g., MDLs, etc.
- Captain department personnel to communicate quality, technical, personnel, and instrumental issues for a consistent team approach.
- Coordinate audit responses with the QA Manager.
- Ensure compliance with ISO 17025 (where applicable).

4.2.18 Hazardous Waste Coordinator

The Hazardous Waste Coordinator reports directly to the Laboratory Director.

Specific responsibilities include, but are not limited to:

- Stay current with the hazardous waste regulations.
- Continue training on hazardous waste issues.
- Review and update annually the Hazardous Waste Contingency Plan in the Environmental Health & Safety Manual.
- Audit the staff with regard to compliance with the Hazardous Waste Contingency Plan.
- Contact the hazardous waste subcontractors for review of procedures and opportunities for minimization of waste.

4.2.19 Supervisors

Supervisors report to the Technical Managers.

Specific responsibilities include, but are not limited to:

- Ensure that analysts in their department adhere to applicable SOPs and the QA Manual. They perform frequent SOP and QA Manual review to determine if analysts are in compliance and if new, modified, and optimized measures are feasible and should be added to these documents.
- Participate in the selection, training (as documented in Section 8.1), development of performance objectives and standards of performance, appraisal (measurement of objectives), scheduling, counseling, discipline, and motivation of analysts, and document these activities in accordance with systems developed by the QA and Personnel

Departments. Evaluate staffing sufficiency and overtime needs. Conduct trainings consisting of familiarization with SOP, QC, safety, and computer systems.

- Encourage the development of analysts to become cross-trained in various methods and/or operate multiple instruments efficiently while performing maintenance and documentation, self-supervise, and function as a department team.
- Provide guidance to analysts in resolving problems encountered daily during sample preparation/analysis in conjunction with the Technical Manager, Operations Manager, and/or QA Manager. Each is responsible for 100% of the data review and documentation, non-conformance and CPAR issues, the timely and accurate completion of performance evaluation samples and MDLs, for his/her department.
- Ensure all logbooks are maintained, current, and properly labeled or archived.
- Report all non-conformance conditions to the QA Manager, Technical Manager, Operations Manager, and/or Laboratory Director.
- Ensure that preventive maintenance is performed on instrumentation as detailed in the QA Manual or SOPs. Develop and implement a system for preventive maintenance, troubleshooting, and repairing or arranging for repair of instruments.
- Maintain adequate and valid inventory of reagents, standards, spare parts, and other relevant resources required to perform daily analysis.
- Achieve optimum turnaround time on analyses and compliance with holding times.
- Conduct efficiency and cost control evaluations on an ongoing basis to determine optimization of labor, supplies, overtime, first-run yield, capacity (designed vs. demonstrated), second- and third-generation production techniques/instruments, and long-term needs for budgetary planning.
- Develop, implement, and enhance calibration programs.
- Provide written responses to external and internal audit issues.

4.2.20 Laboratory Analysts

Laboratory analysts are responsible for conducting analysis and performing all tasks assigned to them by the group leader or supervisor. Specific responsibilities include, but are not limited to:

- Perform analyses by adhering to analytical and quality control protocols prescribed by current SOPs, this QA Manual, and project-specific plans honestly, accurately, timely, safely, and in the most cost-effective manner.
- Document standard and sample preparation, instrument calibration and maintenance, data calculations, sample matrix effects, and any observed non-conformance on worklists, benchsheets, lab notebooks and/or the Non-Conformance Database.
- Report all non-conformance situations, instrument problems, matrix problems and QC failures, which might affect the reliability of the data, to their supervisor, the Technical Manager, and/or the QA Manager or member of QA staff.

- Perform 100% review of the data generated prior to entering and submitting for secondary level review.
- Suggest method improvements to their supervisor, the Technical Manager, and the QA Manager. These improvements, if approved, will be incorporated. Ideas for the optimum performance of their assigned area, for example, through the proper cleaning and maintenance of the assigned instruments and equipment, are encouraged.
- Work cohesively as a team in their department to achieve the goals of accurate results, optimum turnaround time, cost effectiveness, cleanliness, complete documentation, and personal knowledge of environmental analysis.
- Work Cell: A “work cell” is considered to be all those individuals who see a sample through the complete process of preparation, extraction, and analysis. To ensure that the entire preparation, extraction, and analysis process is completed by a group of capable individuals, the laboratory shall ensure that each member of the work cell (including a new member entering an already existing work cell) demonstrates capability in his/her area of responsibility in the sequence. Even though the work cell operates as a “team,” the demonstration of capability at each individual step in the sequence, as performed by each individual analyst/team member, remains of utmost importance. A work cell may NOT be defined as a group of analysts who perform the same step in the same process (for example, extractions for Method 8270), represented by one analyst who has demonstrated capability for that step.

4.2.21 Safety Officer or EHS Coordinator

The Safety Officer reports to the Laboratory Director and ensures that systems are maintained for the safe operation of the laboratory.

Specific responsibilities include, but are not limited to:

- Conduct ongoing, necessary safety training and conduct new employee safety orientation.
- Assist in developing and maintaining the Chemical Hygiene/Safety Manual.
- Administer dispersal of all Safety Data Sheet (SDS) information.
- Perform regular chemical hygiene and housekeeping instruction.
- Give instruction on proper labeling and practice.
- Serve as chairman of the laboratory safety committee.
- Provide and train personnel on protective equipment.
- Oversee the inspection and maintenance of general safety equipment – fire extinguishers, safety showers, eyewash fountains, etc. and ensure prompt repairs as needed.
- Supervise and schedule fire drills and emergency evacuation drills.
- Determine what initial and subsequent exposure monitoring, if necessary to determine potential employee exposure to chemicals used in the laboratory.
- When determined necessary, conduct exposure monitoring assessments.

- Determine when a complaint of possible over-exposure is “reasonable” and should be referred for medical consultation.
- Assist in the internal and external coordination of the medical consultation/monitoring program conducted by TestAmerica’s medical consultants.

4.2.22 Sample Control Manager

The Sample Control Manager reports to the Laboratory Director and is responsible for the daily activities within the Sample Control department.

Specific responsibilities include, but are not limited to:

- Supervise the courier scheduling, initiation of container lot testing, sample container order preparation, sample receiving and tracking, shipping, login, and other sample management activities.
- Ensure timely and correct shipment of sample containers, including proper preservatives and instructions, to clients. Maintain accurate records of sample container shipments.
- 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.

4.2.23 Manager of Project Management (MPM)

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

Specific responsibilities include, but are not limited to:

- 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.

- Prepare price quotes or project bids.

4.2.24 Project Manager (PM)

The PM reports to the Manager of Project Management (MPM) and serves as the interface between the laboratory's technical departments and clients. There is an entire staff of Project Managers that makes up the Project Management team with the overall goal of total client satisfaction.

Specific responsibilities include, but are not limited to:

- Ensure that clients receive the proper sampling supplies.
- Is accountable for response to client inquiries concerning sample status.
- Assist clients regarding the resolution of problems concerning COC.
- Ensure that client specifications, when known, are met by communicating project and quality assurance requirements to the laboratory.
- Notify the supervisors of incoming projects and sample delivery schedules.
- Is accountable to clients for communicating sample progress in daily status meeting with agreed-upon due dates.
- Discuss with client any project-related problems, resolve service issues, and coordinate technical details with the laboratory staff.
- Is responsible for staff familiarization with specific quotes, sample log-in review, and final report completeness.
- Monitor the status of all data packages in-house to ensure timely and accurate delivery of reports.
- Inform clients of data package-related problems and resolve service issues.
- Coordinate requests for sample containers and other services (data packages).

4.2.25 Sample Archiving/Disposal Technician

The Sample Archiving/Disposal Technician reports to the Laboratory Director.

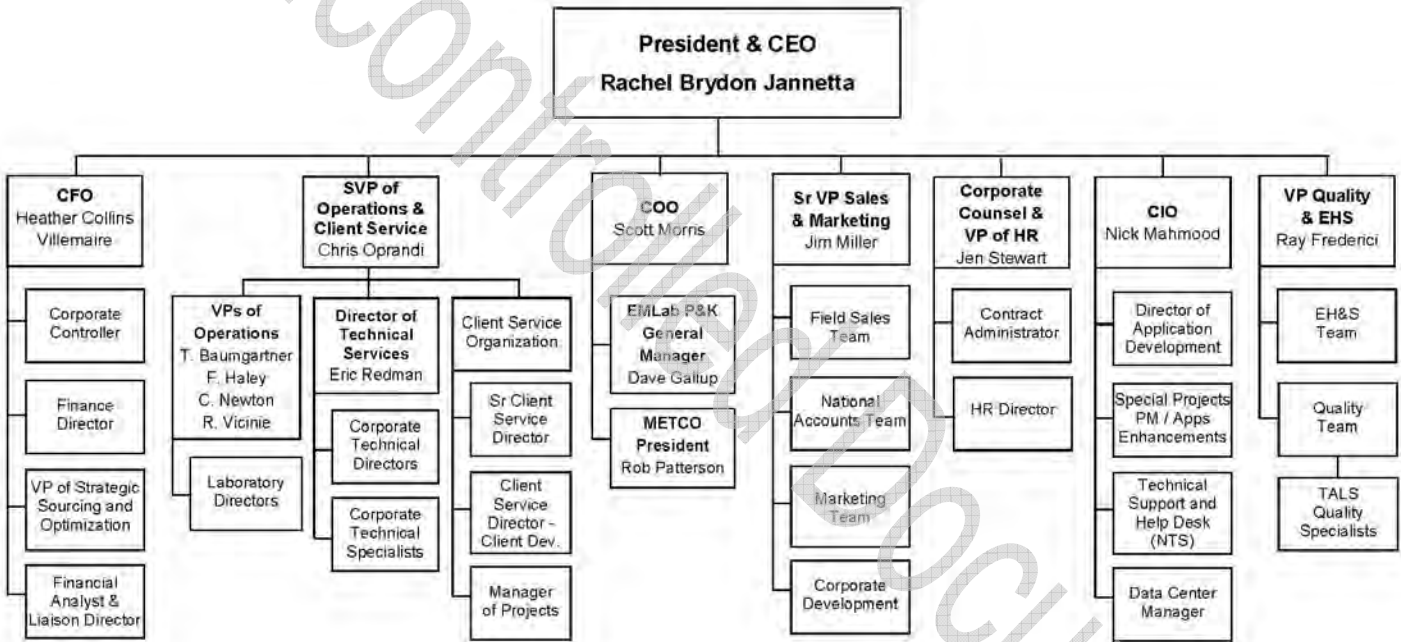
Specific responsibilities include, but are not limited to:

- Manage facility maintenance.
- Supervise the organized storage and appropriate climate control of samples.
- Supervise the disposal of samples in accordance with the Waste Disposal SOP, the Hazardous Waste Contingency Plan in the Chemical Hygiene/Safety Manual, and the U. S. Department of Agriculture requirements.

4.3 Deputies

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

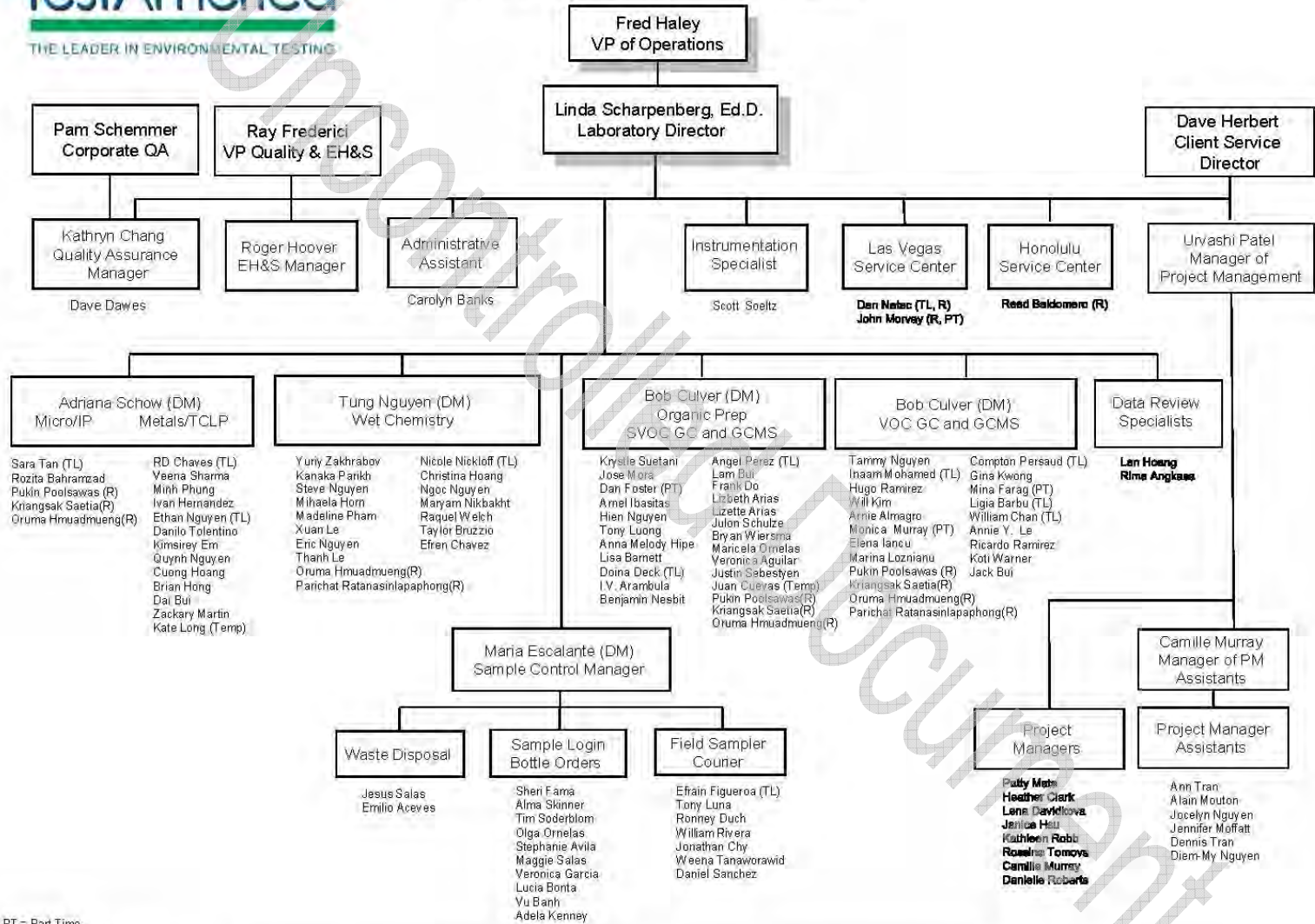
Key Personnel	Deputy
Linda Scharpenberg Laboratory Director	Fred Haley VP Operations, West Region
Kathryn Chang Quality Assurance Manager	David Dawes Quality Assurance Specialist
Robert Culver Volatiles Department Manager	Compton Persaud Volatiles Department Supervisor
Robert Culver Semi-Volatile Department Manager	Robert Culver Volatiles Department Manager
Adriana Schow Metals Department Manager	Ethan Nguyen Metals Department Supervisor
Adriana Schow Microbiology Department Manager	Sarah Tan Microbiology Department Supervisor
Tung Nguyen Wet Chemistry Department Manager	Nicole Nickloff Wet Chemistry Department Supervisor
Roger Hoover Environmental Health and Safety Manager	Linda Scharpenberg Laboratory Director
Urvashi Patel Manager of Project Management	Camille Murray Manager of Project Management Assistants



February 27 2017

Figure 4-1. Corporate and Laboratory Organization Charts

Irvine Laboratory Organization



Note: QA Manager and EH&S Manager have a direct reporting relationship to both operations leadership and corporate functional leadership.

Effective March 6, 2017

PT = Part Time
Temp – Temporary Employee
TL = Technical Lead/Supervisor
R = Remote Employee

Company Confidential & Proprietary

Figure 4-1. Corporate and Laboratory Organization Charts (Cont.)

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 quality assurance 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.
- ❖ To comply with the ISO/IEC 17025:2005(E) International Standard, the 2009 TNI Standard and to continually improve the effectiveness of the management system.

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

5.2 Ethics and Data Integrity

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

- An Ethics Policy (Corporate Policy No. CW-L-P-004) and Employee Ethics Statements.
- Ethics and Compliance Officers (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 SOP No. CW-L-S-002).
- Procedures and guidance for recalling data if necessary (Corporate SOP No. CA-Q-S-005).
- Effective external and internal monitoring system that includes procedures for internal audits (Section 15).
- Produce results, which are accurate and include QA/QC information that meets client pre-defined Data Quality Objectives (DQOs).
- Present services in a confidential, honest and forthright manner.

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

5.3 Quality System Documentation

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

- Quality Assurance Manual – Each laboratory has a lab-specific quality assurance manual.
- Corporate SOPs and Policies – Corporate SOPs and Policies are developed for use by all relevant laboratories. They are incorporated into the laboratory's normal SOP distribution, training and tracking system. Corporate SOPs may be general or technical.
- Work Instructions – A subset of procedural steps, tasks or forms associated with an operation of a management system (e.g., checklists, preformatted bench sheets, forms).
- Laboratory SOPs – General and Technical.
- 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:

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

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's QAM shall take precedence over the CQMP in those cases.

5.4 QA/QC Objectives for the Measurement of Data

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

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

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

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

5.4.1 Precision

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

5.4.2 Accuracy

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

5.4.3 Representativeness

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

documented by the relative percent difference between separately procured, but otherwise identical samples or sample aliquots.

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

5.4.4 Comparability

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

The comparability objective is documented by inter-laboratory studies carried out by regulatory agencies or carried out for specific projects or contracts, by comparison of periodically generated statements of accuracy, precision and reporting limits with those of other laboratories.

5.4.5 Completeness

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

5.4.6 Selectivity

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

5.4.7 Sensitivity

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

5.5 Criteria for Quality Indicators

The laboratory maintains a Quality Control Limit Summary that contains tables (or however named) that summarize the precision and accuracy acceptability limits for performed analyses.

This summary includes an effective date, is updated each time new limits are generated and are managed by the laboratory's QA department. Unless otherwise noted, limits within these tables are laboratory generated. Some acceptability limits are derived from US EPA methods when they are required. Where US EPA method limits are not required, the laboratory has developed limits from evaluation of data from similar matrices. Criteria for development of control limits is contained in the laboratory SOP No. IR-QA-CNTRLLIM.

5.6 Statistical Quality Control

Statistically-derived precision and accuracy limits are required by selected methods (such as SW-846) 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 laboratory (dated and approved by the Technical Manager and QA Manager) and entered into the Laboratory Information Management System (LIMS). The Quality Assurance department maintains an archive of all limits used within the laboratory *via the LIMS historical limit group database*. If a method defines the QC limits, the method limits are used.

If a method requires the generation of historical limits, the lab develops such limits from recent data in the QC database of the LIMS following the guidelines described in Section 24. All calculations and limits are documented and dated when approved and effective. On occasion, a client requests 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 rerun or re-extracted/rerun or if a comment should be added to the report explaining the reason for the QC outlier.

5.6.1 QC Charts

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 to determine if adjustments need to be made or for corrective actions to methods. All findings are documented and kept on file. Refer to laboratory SOP No. IR-QA-CNTRLLIM 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.

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, 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 Quality Assurance Manual
- Laboratory Standard Operating Procedures (SOP)
- 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, Corporate Document Control and Archiving. The laboratory's internal document control procedure is defined in the laboratory SOP No. IR-QA-DOC.

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

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

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

Controlled documents are authorized by the QA Department. In order to develop a new document, the Department Manager or Supervisor submits an electronic draft to the QA Department for suggestions and approval before use. Upon approval, QA personnel add the identifying version information to the document and retains 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 QA Manual, refer to the procedure outlined in Section 3.4 of this manual. Uncontrolled copies must not be used within the laboratory. Previous revisions and back-up data are stored by the QA department. Electronic copies are stored on the Public server in the QA folder (or define location) for the applicable revision.

For changes to SOPs, refer to Corporate SOP No. CW-Q-S-002, Writing a Standard Operating Procedure SOP and the laboratory SOP No. IR-QA-DOC. The SOPs identified above also defines the process of changes to SOPs.

Forms, worksheets, work instructions and information are organized in the file cabinet of the QA department. Electronic versions are kept in the network shared folder Irvine-QA. The procedure for the care of these documents is in the laboratory SOP No. IR-QA-DOC.

6.4 Obsolete Documents

All invalid or obsolete documents are removed, or otherwise prevented from unintended use. The laboratory has specific procedures as described above to accomplish this. In general, obsolete documents are collected from employees according to distribution lists and are marked obsolete on the cover or destroyed. At least one copy of the obsolete document is archived according to the laboratory SOP No. IR-QA-ARCH.

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 lab'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 clients' requirements may be proposed by the lab. A review of the lab's capability to analyze non-routine analytes is also part of this review process.

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

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

Electronic or hard copy deliverable requirements are evaluated against the 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 lab 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 acceptance of the contract. It is necessary that the contract be acceptable to both the laboratory and the client. Amendments initiated by the client and/or TestAmerica, are documented in writing.

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

The 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 Project Manager (PM) is considered adequate. The PM confirms that the laboratory has any required certifications, that it can meet the clients' data quality and reporting requirements and that the laboratory has the capacity to meet the clients' turn around needs. It is recommended that, where there is a sales person assigned to the account, an attempt should be made to contact that sales person to inform them of the incoming samples.

For new, complex or large projects, the proposed contract is given to the Client Relationship Manager or Proposal Team, 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 TestAmerica's Corporate SOP No. CA-L-P-002, Contract Compliance Policy.

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

- Contract Administrator
- VP of Operations
- Laboratory Manager of Project Management
- Laboratory Project Manager
- Laboratory and/or Corporate Technical Managers
- Laboratory and/or Corporate Information Technology Managers
- Account Executives
- Laboratory and/or Corporate Quality
- Laboratory and/or Corporate Environmental Health and Safety Managers/Directors
- The Laboratory Director reviews the formal laboratory quote and makes final acceptance for their facility.

The Sales Director, Contract Administrator, Account Executive or Proposal Coordinator then submits the final proposal to the client.

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

The Contracts Department maintains copies of all signed contracts. A copy is also maintained by the assigned Laboratory Project Manager.

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 Project Manager.

The contract will be distributed to and maintained by the appropriate sales/marketing personnel and the Account Executive. A copy of the contract and formal quote will be filed with the laboratory Project Manager 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 Project Manager keeps a phone log or e-mail documentation of conversations with the client. These documentations are kept on file 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, a PM is assigned to each client. It is the PM's responsibility to ensure that project-specific technical and QC requirements are effectively evaluated and communicated to the laboratory personnel before and during the project. QA department involvement may be needed to assist in the evaluation of custom QC requirements.

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

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

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 during production meetings. Such changes are updated to the project notes or work instructions and are introduced to the managers at these meetings. The laboratory staff is then introduced to the modified requirements via the PM or the individual laboratory Technical Manager. After the modification is implemented into the laboratory process, documentation of the modification is made in the case narrative of the data report(s).

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 (Section 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

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

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

7.6 Reporting

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 develops laboratory and client specific surveys to assess client satisfaction.

SECTION 8. SUBCONTRACTING OF TESTS

8.1 Overview

For the purpose of this quality manual, the phrase subcontract laboratory refers to a laboratory external to the TestAmerica laboratories. The phrase "work sharing" 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 project scope, changes in laboratory capabilities, capacity or unforeseen circumstances, we must be assured that the subcontractors or work sharing laboratories understand the requirements and will meet the same commitments we have made to the client. Refer to TestAmerica's Corporate SOP's on Subcontracting Procedures (CA-L-S-002) and the Work Sharing Process (CA-C-S-001).

When outsourcing analytical services, the laboratory will assure, to the extent necessary, that the subcontract or work sharing laboratory maintains a program consistent with the

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

Project Managers (PMs), Client Relationship Managers or Account Executives (AE) (or others as defined by the laboratory) for the Export Lab (TestAmerica laboratory that transfers samples to another laboratory) are responsible for obtaining client approval prior to subcontracting any samples. The laboratory will advise the client of a subcontract arrangement in writing and when possible approval from the client shall be retained in the project folder. Standard TestAmerica Terms & Conditions include the flexibility to subcontract samples within the TestAmerica laboratories. Therefore, additional advance notification to clients for intra-laboratory subcontracting is not necessary unless specifically required by a client contract.

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

8.2 Qualifying and Monitoring Subcontractors

Whenever a PM [or Account Executive (AE) or Client Relationship Manager, etc.] becomes aware of a client requirement or laboratory need where samples must be outsourced to another laboratory, the other laboratory(s) shall be selected based on the following:

- The first priority is to attempt to place the work in a qualified 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 project folder;
- Firms listed as pre-qualified and currently under a subcontract with TestAmerica. A listing of all approved subcontracting 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., on the subcontractors TNI, A2LA accreditation 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;
- TNI or A2LA accredited laboratories.
- In addition, the firm must hold the appropriate certification to perform the work required.

All TestAmerica laboratories are pre-qualified for work sharing provided they hold the appropriate accreditations, can adhere to the project/program requirements, and the client approved sending samples to that laboratory. The client must provide acknowledgement that the samples can be sent to that facility (an e-mail is sufficient documentation or if acknowledgement is verbal, the date, time, and name of person providing acknowledgement must be documented). The originating laboratory is responsible for communicating all technical,

quality, and deliverable requirements as well as other contract needs. (Corporate SOP No. CA-C-S-001, Work Sharing Process).

When the potential subcontract laboratory has not been previously approved, Account Executives or PMs may nominate a laboratory as a subcontractor based on need. The decision to nominate a laboratory must be approved by the Laboratory Director. The Laboratory Director requests that the QA Manager or PM begin the process of approving the subcontract laboratory as outlined in Corporate SOP No. CA-L-S-002, Subcontracting Procedures.

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 the Corporate Quality Information Manager (QIM) for review. Once all documents are reviewed for completeness, the Corporate QIM will forward the documents to the Purchasing Manager for formal signature and contracting with the laboratory. The approved vendor will be added to the approved subcontractor list on the intranet site and the finance group is concurrently notified for JD Edwards.

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.

8.1.1

8.2.3 The status and performance of qualified subcontractors will be monitored periodically by the Corporate Contracts and/or Corporate Quality Departments. Any 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 are posted using the Vendor Performance Report.
- Information shall be updated on the intranet when new information is received from the subcontracted laboratories.
- Subcontractors in good standing will be retained on the intranet listing. CSO Personnel 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 CSO Personnel, 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 work orders relating to individual projects. A standard subcontract and the Lab Subcontractor Vendor Package (posted on the intranet) can be used to accomplish this, and Corporate Counsel can tailor the document or assist with negotiations, if needed. The PM (or EDS, AEs or CSM, etc.) responsible for the project must advise and obtain client

consent to the subcontract as appropriate, and provide the scope of work to ensure that the proper requirements are made a part of the subcontract and are made known to the subcontractor.

Prior to sending samples to the subcontracted laboratory, the PM confirms their certification status to determine if it's current and scope-inclusive. The information is documented within the project records. 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 subcontracted laboratory.

All subcontracted samples must be accompanied by a TestAmerica Chain of Custody (COC). A copy of the original COC sent by the client must be available in TestAmerica LIMS (TALS) for all samples workshared within TestAmerica. Client COCs are only forwarded to external subcontractors when samples are shipped directly from the project site to the subcontractor lab. Under routine circumstances, client COCs are not provided to external subcontractors.

Through communication with the subcontracted 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.

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

Reports submitted from subcontractor laboratories are not altered and are included in their original form in the final project report. This clearly identifies the data as being produced by a subcontractor facility. If subcontract laboratory data is incorporated into the laboratories EDD (i.e., imported), the report must explicitly indicate which laboratory produced the data for which methods and samples. A copy of the subcontracting laboratory's report must be included in the originating laboratory's final report, regardless of whether the subcontract laboratory's results are inserted into the originating laboratory's report.

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

8.4 Contingency Planning

The Laboratory Director may waive the full qualification of a subcontractor process temporarily to meet emergency needs; however, this decision & justification must be documented in the project files, and the 'Purchase Order Terms And Conditions For Subcontracted Laboratory Services' must be sent with the samples and Chain-of-Custody. 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.

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 TestAmerica's Capital Expenditure, Controlled Purchase Requests and Fixed Asset Capitalization, SOP No. CW-F-S-007.

Contracts will be signed in accordance with TestAmerica's Company-Wide Authorization Matrix Policy, Policy No. CW-F-P-002. Request for Proposals (RFP's) will be issued where more information is required from the potential vendors than just price. Process details are available in TestAmerica's Corporate Procurement and Contracts Policy (Policy No. CW-F-P-004). RFP's allow TestAmerica to determine if a vendor is capable of meeting requirements such as supplying all of the TestAmerica facilities, meeting required quality standards and adhering to necessary ethical and environmental standards. The RFP process also allows potential vendors to outline any additional capabilities they may offer.

9.2 Glassware

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

9.3 Reagents, Standards & Supplies

Purchasing guidelines for equipment, consumables, and reagents must meet the requirements of the specific method and testing procedures for which they are being purchased. Solvents and acids are pre-tested in accordance with TestAmerica's Corporate SOP on Solvent & Acid Lot Testing & Approval, SOP No. CA-Q-S-001. Approval information for the solvents and acids tested under SOP CA-Q-S-001 is stored on the TestAmerica Sharepoint, under Solvent Approvals. A master list of all tested materials, as well as the certificates of analysis for the materials, is stored in the same location. Procedures for laboratory tested materials are outlined in the laboratory SOP No. IR-QA-LOTTEST.

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 method SOP. The analyst completes the Material Request Sheet when requesting reagents, standards, or supplies. The analyst may check the item out of the on-site consignment system that contains items approved for laboratory use.

The analyst must provide the master item number (from the master item list that has been approved by the Technical Manager), item description, package size, catalogue page number, and the quantity needed. If an item being ordered is not the exact item requested, approval must be obtained from the Technical Manager prior to placing the order. The Technical Manager or Laboratory Director places the order.

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 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. This is documented through the addition of the received date and initials to the information present on the daily order log.

The supervisor or analyst verifies the lot numbers of received solvents and acids against the pre-approval lists. If a received material is listed as unapproved, or is not listed, it is sequestered and returned to the vendor. Alternatively, the laboratory may test the material for the intended use, and if it is acceptable, document the approval on the approval list. Records of any testing performed locally are maintained in the shared "public" folder on the computer network.

Materials may not be released for use in the laboratory until they have been inspected, verified as suitable for use, and the inspection/verification has been documented.

Safety Data Sheets (SDSs) 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 time noted in a method SOP. 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 SOPs expiration date unless 'verified' (refer to item 3 listed below).

- An expiration date **cannot** be extended if the dry chemical/solvent is discolored or appears otherwise physically degraded, the dry chemical/solvent must be discarded.
- Expiration dates can be extended if the dry chemical/solvent is found to be satisfactory based on acceptable performance of quality control samples (Continuing Calibration Verification (CCV), Blanks, Laboratory Control Sample (LCS), etc.).
- If the dry chemical/solvent is used for the preparation of standards, the expiration dates can be extended 6 months if the dry chemical/solvent is compared to an unexpired independent source in performing the method and the performance of the dry chemical/solvent is found to be satisfactory. The comparison must show that the dry chemical/solvent meets CCV limits. The comparison studies are maintained in the shared "public" folder on the computer network.

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- $\mu\text{mho/cm}$ (or specific resistivity of greater than 1.0 megohm-cm) at 25°C. The specific conductivity is checked and recorded daily. If the water's specific conductivity is greater than the specified limit, the Facility Manager and appropriate Technical Managers must be notified immediately in order to notify all departments, decide on cessation (based on intended use) of activities, and make arrangements for correction.

The laboratory may purchase reagent grade (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 is documented.

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

Purchased 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 maintained.

Records of manufacturer's certification and traceability statements are maintained in files or binders in each laboratory section or uploaded to TestAmerica LIMS (TALS) Reagent program. These records include date of receipt, lot number (when applicable), and 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 are per the Corporate Environmental Health & Safety Manual (Corp. Doc. No. CW-E-M-001) and method SOPs or manufacturer instructions.

9.4 Purchase of Equipment / Instruments / Software

When a new piece of equipment is needed, either for additional capacity or for replacing inoperable equipment, the analyst or supervisor makes a supply request to the Technical Manager and/or the Laboratory Director. If they agree with the request, the procedures outlined in TestAmerica's Corporate Policy No. CA-T-P-001, Qualified Products List, are followed. A decision is made as to which piece of equipment can best satisfy the requirements. The appropriate written requests are completed and purchasing places the order.

Upon receipt of a new or used piece of equipment, an identification name is assigned and added to the equipment list. IT must also be notified so that they can synchronize the instrument for back-ups. Its capability is assessed to determine if it is adequate or not for the specific application. For instruments, a calibration curve is generated, followed by MDLs, Demonstration of Capabilities (DOCs), and other relevant criteria (refer to Section 19). For software, its operation must be deemed reliable and evidence of instrument verification must be retained by the IT Department or QA Department. Software certificates supplied by the vendors are filed with the IT Department. The manufacturer's operation manual is retained at the bench.

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 and/or Technical Managers. The service providers that perform the services are approved by the Technical Manager and the Laboratory Director.

Analytical balances are serviced and calibrated annually in accordance with SOP IR-QA-BAL. The calibration and maintenance services are performed on-site, and the balances are returned to use immediately following successful calibration. When the calibration certificates are received (usually within two weeks of the service), they are reviewed, and documentation of the review is filed with the certificates. If the calibration was unsuccessful, the balance is immediately removed from service and segregated pending either further maintenance or disposal.

Calibration services for support equipment such as thermometers, weight sets, autopipettors, etc., are obtained from vendors with current and valid ISO 17025 accreditation for calibration of the specific piece of equipment. Prior to utilizing the vendor's services, the vendor's accreditation status is verified. Once the equipment has been calibrated, the calibration

certificates are reviewed by the QA department, and documentation of the review is filed with the calibration certificates. The equipment is then returned to service within the laboratory.

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 the Procurement & Contracts Policy (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.

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

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

9.6.1 New Vendor Procedure

TestAmerica employees who wish to request the addition of a new vendor must complete a J.D. Edwards Vendor Add Request Form.

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

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., communications, responsiveness, data, reports, invoicing and other functions) expressed by any party, whether received verbally or in written form. Client inquiries, complaints or noted discrepancies are documented, communicated to management, and addressed promptly and thoroughly.

The laboratory has procedures for 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 (Corrective Actions). The laboratory utilizes the TestAmerica LIMS (TALS) Non-Conformance Memo (NCM) program or the Incident/Corrective Action Tracker (iCAT) database, as appropriate, to document complaints and the corrective action performed.

10.2 External Complaints

An employee that receives a complaint initiates the complaint resolution process by first documenting the complaint in the TALS NCM program or the iCAT database 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 shall 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:

- 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 non-conformances, training issues, internal audit findings, and deviations from methods. Corrective actions may be initiated by any staff member who observes a nonconformance and shall follow the procedures outlined in Section 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 and 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 Review (Section 16).

SECTION 11. CONTROL OF NON-CONFORMING 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 Supervisor or Department Manager for resolution. The Supervisor or Department Manager may elect to discuss it with the QA Manager and the Technical Manager. Depending on the nature of the departure, the Laboratory Director or the PM may contact the client to decide on a logical course of action. Once an approach is agreed upon, the analyst documents it using the laboratories corrective action system described in Section 12. This information can then be supplied to the client in the form of a footnote or a case narrative with the report.

Project Management may encounter situations where a client may request that a special procedure be applied to a sample that is not standard laboratory practice. Based on a technical evaluation, 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. The client may request that the compound be reported based only on the calibration. Such a request would need to be approved by the Technical Manager and QA Manager, documented and included in the project folder. Deviations **must** also be noted on the final report with a statement that the compound is not reported in compliance with TNI (or the analytical method) requirements and the reason. Data being

reported to a non-TNI state would need to note the change made to how the method is normally run.

11.2 Responsibilities and Authorities

Under certain circumstances, the Laboratory Director, a Technical Manager, or a member of the QA team 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 reanalyze, etc. In most cases, the client will be informed of the departure prior to the reporting of the data. Any departures must be well documented using the laboratory's corrective action procedures. 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 within 24-hours. The Senior Management staff is comprised of the Laboratory Director, the QA Manager, and the Technical Managers. The reporting of issues involving alleged violations of the company's Data Integrity or Manual Integration procedures must be conveyed to an ECO (e.g., the VP-QA/EHS) and the laboratory's 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, QA Manager, ECOs, VP of Operations 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 SOP entitled Data Recalls (CW-Q-S-005) is the procedure to be followed when it is discovered that erroneous or biased data may have been reported to clients or regulatory agencies.

Corporate SOP entitled Internal Investigations (CW-L-S-002) is the procedure to be followed for investigation and correction of situations involved alleged incidents of misconduct or violation of the company's ethics policy.

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 TestAmerica's Corporate SOP No. CW-Q-S-005.

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 non-conformances to determine if any nonconforming work 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 persons 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 or test fully back on line. In some cases, that may not be necessary if all appropriate personnel have already agreed there is a problem and there is agreement on the steps needed to bring the method, target or test fully back on line. The QA Manager will also initiate a corrective action report as described in Section 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 VP of Operations and member of Corporate QA. This fax/e-mail acts as notification of the incident.

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

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

SECTION 12. CORRECTIVE ACTION

12.1 Overview

A major component of TestAmerica's Quality Assurance (QA) Program is the problem investigation and feedback mechanism designed to keep the laboratory staff informed on quality

related issues and to provide insight to problem resolution. When nonconforming work or departures from policies and procedures in the quality system or technical operations are identified, the corrective action procedure provides a systematic approach to assess the issues, restore the laboratory's system integrity, and prevent reoccurrence. Corrective actions are documented using TALS NCM program and iCAT database (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, proficiency testing (PT) performance, client complaints, staff observation, etc.

The purpose of a corrective action system is to:

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

12.2.1 Non-Conformance Memo (NCM) Program

The TALS NCM program is used to document the following types of corrective actions:

- Deviations from an established procedure or SOP
- QC outside of limits (non-matrix related)
- Isolated reporting / calculation errors
- Client complaints
- Discrepancies in materials / goods received vs. manufacturer packing slips.

12.2.2 Incident/Corrective Action Tracker (iCAT) Database

The iCAT database is used to document the following types of corrective actions:

- Questionable trends that are found in the review of NCMs.
- Issues found while reviewing NCMs that warrant further investigation.
- Internal and external audit findings.
- Failed or unacceptable PT results.
- Corrective actions that cross multiple departments in the laboratory.
- Systematic reporting / calculation errors.
- Client complaints.

- Data recall investigations.
- Identified poor process or method performance trends.
- Excessive revised reports.
- Health and safety violations.

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 non-conformance event, the event must be defined and documented. An NCM or iCAT must be initiated, someone is assigned to investigate the issue and the event is investigated for cause. Table 12-1 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 Technical Manager, Laboratory Director, or QA Manager (or QA designee) is 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 iCAT is used for this documentation.

12.3.3 Root Cause Analysis

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. Corporate SOP Root Cause Analysis (No. CA-Q-S-009) describes the procedure.

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 5 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 Technical Manager and 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. Technical Managers are accountable to the Laboratory Director to ensure final acceptable resolution is achieved and documented appropriately.

Each NCM and iCAT is entered into a database for tracking purposes and a monthly summary of all corrective actions is reviewed to aid in ensuring that the corrective actions have taken effect.

TestAmerica laboratories began using the Incident/Corrective Action Tracker (iCAT) database developed by the company in 2015. An incident is an event triggering the need for one or more corrective actions as distinct from a corrective action, a potential deficiency stemming from an incident that requires investigation and possibly fixing. The database is independent of TALS, available to all local and corporate managers, and capable of notifying and tracking multiple corrective actions per event, dates, and personnel. iCAT allows associated document upload, categorization (such as, external/internal audit, client service concerns, data quality issues, proficiency testing, etc.), and trend analysis. Refer to Figure 12-2.

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.

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 compliance with its own policies and procedures, or on its compliance 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.)

12.4 Technical Corrective Actions

In addition to providing acceptance criteria and specific protocols for technical corrective actions in the method SOPs, the laboratory has general procedures to be followed to determine when departures from the documented policies and procedures and quality control have occurred (refer to Section 11). The documentation of these procedures is through the use of an NCM or iCAT database.

Table 12-1 includes examples of general technical corrective actions. For specific criteria and corrective actions, refer to the analytical methods or specific method SOPs. The laboratory may also maintain Work Instructions on these items that are available upon request.

Table 12-1 provides some general guidelines for identifying the individual(s) responsible for assessing each QC type and initiating corrective action. The table also provides general guidance on how a data set should be treated if associated QC measurements are unacceptable. Specific procedures are included in Method SOPs, Work Instructions, QAM 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 quality control measures are acceptable. If the deficiency does not impair the usability of the results, data will be reported with an appropriate data qualifier and/or the deficiency will be noted in the case narrative. Where sample results may be impaired, the Project Manager is notified by an NCM and appropriate corrective action (e.g., reanalysis) 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 initialed (or signed) and dated by the person making the correction. In the case of records stored electronically, the original "uncorrected" file must be maintained intact and a second "corrected" file is created.

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

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

Figure 12-1. Example – TALS NCM Program

The screenshot shows the 'NCM Create/Edit' window. At the top is a menu bar with options: New, Edit, Copy, Delete, Print, Find, Doc's, NCM #, and Set to Ready. Below the menu bar is a 'Description' section with fields for NCM ID, Lab Section, NCM Type, NCM Category, Date Opened, Date Closed, Status, and Created By. There is a checkbox for 'Need Corrective Action'. Below this is a 'Narrative' section with a rich text editor and a toolbar. To the right of the narrative is an 'Affected Items' table with columns for Description and Final Report, and a 'Notifications' section with a table for Verification Type, User Name, and Notice Level. At the bottom is a 'Detail/History' section with a table for #, Entry Date, and User Name.

Figure 12-2. Example – iCAT Database

The screenshot shows the 'incident/Corrective Action Tracker (iCAT)' interface. The main heading is 'Record New Incident/Complaint'. Below this is a form with the following fields: Created By, Created On, Incident/Audit Date, Date Report Received, Incident Group (dropdown), Subject, Client, Contact/Auditor Name, Contact/Auditor Phone, Contact/Auditor Email, Project (if applicable), and Date Response Due (required). At the bottom is a large text area for 'Describe the incident/complaint: (required)'. The interface includes a navigation bar with Home, Help, ADD NEW, QA, and Admin.

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 same response, determine cause of contamination: reagents, environment, instrument equipment failure, etc.
Initial Calibration Standards (Analyst, Technical Manager(s))	- Correlation coefficient > 0.99 or standard concentration value. - % Recovery within acceptance range. - See details in Method SOP.	- Reanalyze standards. - If still unacceptable, remake standards and recalibrate instrument.
Independent Calibration Verification (Second Source) (Analyst, Technical Manager(s))	- % Recovery within control limits.	- Remake and reanalyze standard. - If still unacceptable, then remake calibration standards or use new primary standards and recalibrate instrument.
Continuing Calibration Standards (Analyst, Data Reviewer)	- % Recovery within control limits.	- Reanalyze standard. - If still unacceptable, then recalibrate and rerun affected samples.
Matrix Spike / Matrix Spike Duplicate (MS/MSD) (Analyst, Data Reviewer)	- % Recovery within limits documented in TALS Method Limit Groups.	- 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.

QC Activity (Individual Responsible for Initiation/Assessment)	Acceptance Criteria	Recommended Corrective Action
Laboratory Control Sample (LCS) (Analyst, Data Reviewer)	- % Recovery within limits specified in TALS Method Limit Groups.	- Batch must be re-prepared and re-analyzed. This includes any allowable marginal exceedance. When not using marginal exceedances, 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 with data qualifying codes. Note: If there is insufficient sample or the holding time cannot be met, contact client and report with flags.
Surrogates (Analyst, Data Reviewer)	- % Recovery within limits of method or within three standard deviations of the historical mean.	- Individual sample must be repeated. Place comment in TALS. - Surrogate results outside criteria shall be reported with qualifiers.
Method Blank (MB) (Analyst, Data Reviewer)	< Reporting Limit ^{1,2}	- Reanalyze blank. - If still positive, determine source of contamination. If necessary, reprocess (i.e. digest or extract) entire sample batch. Report blank results. - Qualify the result(s) if the concentration of a targeted analyte in the MB is at or above the reporting limit AND is > 1/10 of the amount measured in the sample.
Proficiency Testing (PT) Samples (QA Manager, Technical Manager(s))	- Criteria supplied by PT Supplier.	- Any failures or warnings must be investigated for cause. Failures may result in the need to repeat a PT sample to show the problem is corrected.

QC Activity (Individual Responsible for Initiation/Assessment)	Acceptance Criteria	Recommended Corrective Action
Internal / External Audits (QA Manager, Technical Manager(s), Laboratory Director)	- Defined in Quality System documentation such as SOPs, QAM, etc.	- Non-conformances must be investigated through iCAT database and necessary corrections must be made.
Reporting / Calculation Errors (Depends on issue – possible individuals include: Analysts, Data Reviewers, Project Managers, Technical Managers, QA Manager, Corporate QA, Corporate Management)	- SOP CW-Q-S-005, Data Recall.	- Corrective action is determined by type of error. Follow the procedures in SOP CW-L-S-002.
Client Complaints (Project Managers, Lab Director/Manager, Sales and Marketing)	- QAM.	- 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, Lab Director/Manager, Technical Manager(s))	- QAM, SOPs.	- Corrective action is determined by the type of issue. For example, CARs for the month are reviewed and possible trends are investigated.
Health and Safety Violation (Safety Officer, Lab Director/Manager, Technical Manager(s))	- Environmental Health and Safety (EHS) Manual.	- Non-conformance is investigated and corrected through iCAT database.

Note:

¹ Program or project specific requirements may dictate that method blank must not contain target analytes greater than ½ the reporting limit (RL).

² Except as noted below for certain compounds, the method blank should be below the detection limit. Concentrations up to five times the reporting limit 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 samples. This allowance presumes that the detection limit is significantly below any regulatory limit to which the data are to be compared and that blank subtraction will not occur. For benzene and ethylene dibromide (EDB) and other analytes for which regulatory limits are extremely close to the detection limit, the method blank must be below the method detection limit (MDL).

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, the laboratory continually strives to improve customer service and client satisfaction through continuous improvements to laboratory systems.

Opportunities for improvement may be discovered through any of the following:

- review of the monthly QA Metrics Report,
- trending NCMs,
- review of control charts and QC results,
- trending proficiency testing (PT) results,
- performance of management system reviews,
- trending client complaints,
- review of processing operations, or
- staff observations.

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. The metrics report is reviewed monthly by the laboratory management, Corporate QA and TestAmerica's Executive Committee. These metrics are used to evaluate the management and quality system performance on an ongoing basis and provide a tool for identifying areas for improvement.

Items identified as continuous improvement opportunities to the management system may be issued as goals from the annual management systems review, recommendations from internal audits, white papers, Lesson Learned, Technical Services audit report, Technical Best Practices, or as Corporate or management initiatives.

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 non-compliance event. Historical review of corrective action and non-conformances provides a valuable mechanism for identifying preventive action opportunities.

13.1.1 The following elements are part of a preventive action/process improvement system:

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

13.1.2 Any Preventive Actions/Process Improvement 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. The types of changes covered under this system include: Facility Changes, Major Accreditation Changes, Addition or Deletion to Division's Capabilities or Instrumentation, Key Personnel Changes, Laboratory Information Management System (LIMS) changes.

TestAmerica Irvine has not implemented the Management of Change process at the time of the effective date of this QAM.

SECTION 14. CONTROL OF RECORDS

The laboratory maintains a records management system appropriate to its needs and that complies with applicable standards or regulations as required. The system produces unequivocal, accurate records that document all laboratory activities. The laboratory retains all original observations, calculations and derived data, calibration records and a copy of the analytical report for a minimum of five years after it has been issued. Exceptions for programs with longer retention requirements are discussed in Section 14.1.2.

14.1 Overview

The laboratory has established procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. A record index is listed in Table 14-1. Quality records are maintained by the QA department in a local or network server,

which is backed up as part of the regular laboratory backup. Records are of two types; either electronic or hard copy paper formats depending on whether the record is computer or hand generated (some records may be in both formats). Technical records are maintained by the 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	<ul style="list-style-type: none"> - Raw Data - Logbooks ² - Standards - Certificates - Analytical Records - MDLs/IDLs/DOCs - Lab Reports 	5 Years from analytical report issue*
Official Documents	<ul style="list-style-type: none"> - Quality Assurance Manual (QAM) - Work Instructions - Policies - SOPs - Policy Memorandums - Manuals 	5 Years from document retirement date*
QA Records	<ul style="list-style-type: none"> - Internal & External Audits/Responses - Certifications - Corrective/Preventive Actions - Management Reviews - Method & Software Validation / Verification Data - Data Investigation 	5 Years from archival* Data Investigation: 5 years or the life of the affected raw data storage whichever is greater (beyond 5 years if ongoing project or pending investigation)
Project Records	<ul style="list-style-type: none"> - Sample Receipt & COC Documents - Contracts and Amendments - Correspondence - QAPP - SAP - Telephone Logbooks - Lab Reports 	5 Years from analytical report issue*
Administrative Records	Finance and Accounting	10 years
	EH&S Manual, Permits	7 years
	Disposal Records	Indefinitely
	Employee Handbook	Indefinitely
	Personnel files, Employee Signature & Initials, Administrative Training Records (e.g., Ethics)	Refer to HR Manual
	Administrative Policies Technical Training Records	7 years

¹ Record Types encompass hardcopy and electronic records.

² Examples of Logbook types: Maintenance, Instrument Run, Preparation (standard and samples), Standard and Reagent Receipt, Archiving, Balance Calibration, Temperature (hardcopy or electronic records).

* Exceptions listed in Table 14-2.

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 an offsite location that provides a suitable environment to prevent damage or deterioration and to prevent 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. The procedures for record archiving and retrieval are outlined in the laboratory SOP No. IR-QA-ARCH.

Access to the data is limited to laboratory and company employees and shall be documented with an access log. Records archived off-site are stored in a secure location where a record is maintained of any entry into the storage facility. Whether on-site or off-site storage is used, logs are maintained in each storage box to note removal and return of records. Retention of records are maintained on-site at the laboratory for at least 1 year after their generation and moved offsite for the remainder of the required storage time. Records are maintained for a minimum of five years unless otherwise specified by a client or regulatory requirement.

For raw data and project records, record retention shall be calculated from the date the project report is issued. For other records, such as Controlled Documents, QA, or Administrative Records, the retention time is calculated from the date the record is formally retired. Records related to the programs listed in Table 14-2 have lengthier retention requirements and are subject to the requirements in Section 14.1.3.

14.1.2 Programs with Longer Retention Requirements

Some regulatory programs have longer record retention requirements than the standard record retention time. These are detailed in Table 14-2 with their retention requirements. In these cases, the longer retention requirement is enacted. If special instructions exist such that client data cannot be destroyed prior to notification of the client, the container or box containing that data is marked as to who to contact for authorization prior to destroying the data.

Table 14-2. Example – Special Record Retention Requirements

Program	Retention Requirement ¹
Drinking Water – All States	5 years (project records) 10 years - Radiochemistry (project records)
Drinking Water Lead and Copper Rule	12 years (project records)
Commonwealth of MA – All environmental data 310 CMR 42.14	10 years
FIFRA – 40 CFR Part 160	Retain for life of research or marketing permit for pesticides regulated by EPA
Housing and Urban Development (HUD) Environmental Lead Testing	10 years
Alaska	10 years
Louisiana – All	10 years

Program	Retention Requirement ¹
Michigan Department of Environmental Quality – all environmental data	10 years
Navy Facilities Engineering Service Center (NFESC)	10 years
NY Potable Water NYCRR Part 55-2	10 years
Ohio VAP	10 years and State contacted prior to disposal
TSCA - 40 CFR Part 792	10 years after publication of final test rule or negotiated test agreement

Note:

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

14.1.3 The laboratory has procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records. All analytical data is maintained as hard copy or in a secure readable electronic format. For analytical reports that are maintained as copies in PDF format, refer to Section 19.14.1 and the laboratory's SOP No. IR-IT-COMPUSEC for more information.

14.1.4 The record keeping system allows for historical reconstruction of all laboratory activities that produced the analytical data, as well as rapid recovery of historical data. (Records stored off site should be accessible within 2 days of a request for such records). The history of the sample from when the laboratory took possession of the samples must be readily understood through the documentation. This shall include inter-laboratory transfers of samples and/or extracts.

- The records include the identity of personnel involved in sampling, sample receipt, preparation, or testing. All analytical work contains the initials (at least) of the personnel involved. The laboratory's copy of the COC is scanned and stored with the invoice and the work order sheet generated by TALS in the designated project folder. If a correction was made to a COC at any time before the final report is issued, the corrected COC is scanned and stored with the first scanned copy in the same folder. The chain of custody would indicate the name of the sampler. If any sampling notes are provided with a work order, they are kept with this package.
- All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification are documented.
- The record keeping system facilitates the retrieval of all working files and archived records for inspection and verification purposes (e.g., set format for naming electronic files, set format for what is included with a given analytical data set, etc.). Instrument data is stored sequentially by instrument. A given day's analyses are maintained in the order of the analysis. Run logs are maintained for each instrument or method; a copy of each day's run log or instrument sequence is stored with the data to aid in re-constructing an analytical sequence. Where an analysis is performed without an instrument, bound logbooks or bench

sheets are used to record and file data. Standard and reagent information is recorded in logbooks or entered into the TALS Reagent program for each method as required.

- 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 reason for a signature or initials on a document is clearly indicated in the records such as “sampled by,” “prepared by,” “reviewed by”, or “analyzed by”.
- All generated data except those that are generated by automated data collection systems, are recorded directly, promptly and legibly in permanent dark ink.
- Hard copy data may be scanned into PDF format for record storage as long as the scanning process can be verified in order to ensure that no data is lost and the data files and storage media must be tested to verify the laboratory’s ability to retrieve the information prior to the destruction of the hard copy that was scanned.
- Also refer to Section 19.14.1 ‘Computer and Electronic Data Related Requirements’.

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 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 run logs, include:

- Laboratory sample ID code;
- Date of analysis; Time of Analysis is also required if the holding time is seventy-two (72) hours or less, or when time critical steps are included in the analysis (e.g., drying times, incubations, etc.); instrumental analyses have the date and time of analysis recorded as part of their general operations. Where a time critical step exists in an analysis, location for such a time is included as part of the documentation in a specific logbook or on a benchsheet.
- Instrumentation identification and instrument operating conditions/parameters. Operating conditions/parameters are typically recorded in instrument maintenance logs where available.
- Analysis type;

- All manual calculations and manual integrations;
- Analyst's or operator's initials/signature;
- Sample preparation including, but are 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;
- Quality control protocols and assessment;
- Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries; and
- Method performance criteria including expected quality control requirements. These are indicated both in the LIMS and on specific analytical report formats.

14.2.4 All logbooks used during receipt, preparation, storage, analysis, and reporting of samples or monitoring of support equipment shall undergo a documented supervisory or peer review on a monthly basis.

14.3 Laboratory Support Activities

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

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

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

14.4 Administrative Records

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

14.5 Records Management, Storage and Disposal

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.

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.

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

The 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 are issued on a per analysis basis, and are numbered sequentially. All data are recorded sequentially within a series of sequential notebooks. Bench sheets are filed sequentially. Standards are maintained in the TALS Reagent program – no logbooks are used to record that data. Records are considered archived when noted as such in the records management system (a.k.a., document control).

14.5.1 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.

14.5.2 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.

SECTION 15. AUDITS

15.1 Internal Audits

Internal audits are performed to verify that laboratory operations comply with the requirements of the lab's quality system and with the external quality programs under which the laboratory operates. Audits are planned and organized by the QA staff. 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 the TestAmerica Corporate SOP on performing Internal Auditing, SOP No. CW-Q-S-003. 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 staff.

Table 15-1. Types of Internal Audits and Frequency

Description	Performed by	Frequency
Quality Systems Audits	QA Department, QA approved designee, or Corporate QA	All areas of the laboratory annually
Method Audits QA Technical Audits	Joint responsibility: a) QA Manager or designee b) Technical Manager or designee (Refer to CW-Q-S-003)	QA Technical Audits Frequency: 50% of methods annually
SOP Method Compliance	Joint responsibility: a) QA Manager or designee b) Technical Manager or designee (Refer to CW-Q-S-003)	SOP Compliance Review Frequency: Every 2 years, except for all SOPs affecting Drinking Water analyses (including QA and administrative SOPs)

Description	Performed by	Frequency
Special Audits	QA Department or designee	Surveillance or spot checks performed as needed, e.g., to confirm corrective actions from other audits
Performance Testing	Analysts with QA oversight	Two successful per year for each 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, 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, quality controls, preventive action and corrective action. The completeness of earlier corrective actions is assessed for effectiveness & sustainability. The audit is divided into sections for each operating or support area of the lab, 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 assess data authenticity and analyst integrity. These 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 run 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. All analysts should be reviewed over the course of a two year period through at least one QA Technical Audit.

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, or annually for methods, QA, and administrative SOPs related to the Drinking Water program. It is also recommended that the work of each newly hired analyst is assessed within 3 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 3 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 semi-annually in performance audits conducted through the analysis of PT samples provided by a third party. The laboratory generally participates in the following types of PT studies: Drinking Water (WS), Non-potable Water (WP), 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 unique problems, in the regular production process they may need to be treated differently, as would any special or unique request submitted by any client. The QA Manager must be consulted and in agreement with any decisions made to treat a PT sample differently due to some special circumstance.

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. Laboratory supervisors are responsible for providing corrective actions to the QA Manager who coordinates the response for any deficiencies discovered during an external audit. Audit responses are due in the time allotted by the client or agency performing the audit. When requested, a copy of the audit report and the labs 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 (CBI) Considerations

During on-site audits, auditors may come into possession of information claimed as business confidential. A business confidentiality claim is defined as "a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality or a request for a determination that such information is entitled to such treatment." When information is claimed as business confidential, the laboratory must place on (or attach to) the information at the time it is submitted to the auditor, a cover sheet, stamped or typed legend or other suitable form of notice, employing language such as "trade secret", "proprietary" or "company confidential". Confidential portions of documents otherwise non-confidential must be clearly identified. CBI may be purged of references to client identity by the responsible laboratory official at the time of removal from the laboratory. However, sample identifiers may not be obscured from the information. Additional information regarding CBI can be found in within the 2009 TNI standards.

15.3 Audit Findings

Audit findings are documented using the corrective action process and database. The laboratory's corrective action responses for both types of audits may include action plans that could not be completed within a predefined 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 Technical 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 labs 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.

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, Technical Managers, their Quality Director as well as the VP of Operations. 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, VP of Operations or Corporate QA may request that additional information be added to the report.

On a monthly basis, Corporate QA 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 VPs of Operations.

16.2 Annual Management Review

The senior lab management team (Laboratory Director, Technical Managers, QA Manager, and the Manager of Project Management) conducts a review annually of its quality systems and LIMS to ensure its continuing suitability and effectiveness in meeting client and regulatory requirements and to introduce any necessary changes or improvements. It will also provide a platform for defining goals, objectives and action items that feed into the laboratory planning system. Corporate Operations and Corporate QA personnel is be included in this meeting at the discretion of the Laboratory Director. The LIMS review consists of examining any audits,

complaints or concerns that have been raised through the year that are related to the LIMS. The laboratory will summarize any critical findings that cannot be solved by the lab and report them to Corporate IT.

This management systems review (Corporate SOP No. CW-Q-S-004 and Work Instruction No. CW-Q-WI-003) 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 reissue requests.
- Review of client feedback and complaints.
- Issues arising from any prior management or staff meetings.
- Minutes from prior senior lab management 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. Including 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 VP of Operation and the Quality Director. The report includes, but is not limited to:

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

Changes to the quality systems requiring update to the laboratory QA Manual shall be included in the next revision of the QA Manual.

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. TestAmerica's Corporate Internal Investigations SOP shall be followed (SOP No. CW-L-S-002). All investigations that result in finding of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients.

TestAmerica's President and CEO, Executive VP of Operations, VP of Client & Technical Services, VPs of Operations and Quality Directors receive a monthly report from the VP-QA/EHS summarizing any current data integrity or data recall investigations. The VPs of Operations are also made aware of progress on these issues for their specific labs.

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 chart in Figure 4-1.

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

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

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

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

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

17.2 Education and Experience Requirements for Technical Personnel

The laboratory makes every effort to hire analytical staffs that possess a college degree (AA, BA, BS) in an applied science with some chemistry in the curriculum. Exceptions can be made based upon the individual's experience and ability to learn. Selection of qualified candidates for laboratory employment begins with documentation of minimum education, training, and experience prerequisites needed to perform the prescribed task. Minimum education and training

requirements for TestAmerica employees are outlined in job descriptions and are generally summarized for analytical staff in the table below.

The laboratory maintains job descriptions for all personnel who manage, perform or verify work affecting the quality of the environmental testing the laboratory performs. Job Descriptions are located on the TestAmerica intranet site's Human Resources web-page (Also see Section 4 for position descriptions/responsibilities).

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

As a general rule for analytical staff:

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

Specialty	Education	Experience
Technical Managers – <u>Microbiology</u>	Bachelor’s degree in applied science with at least 16 semester hours in general microbiology and biology An advanced (MS, PhD.) degree may substitute for one year of experience	And 2 years of relevant experience

When an analyst does not meet these requirements, they can perform a task under the direct supervision of a qualified analyst, peer reviewer or Technical 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

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 various areas of required employee training:

Required Training	Time Frame	Employee Type
Environmental Health & Safety	Prior to lab 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
Quality Assurance	90 days of hire	All
Ethics – Comprehensive Refresher	Annually	All
Initial Demonstration of Capability (DOC)	Prior to unsupervised method performance	Technical

The laboratory maintains records of relevant authorization/competence, education, professional qualifications, training, skills and experience of technical personnel (including contracted personnel) as well as the date that approval/authorization was given. These records are kept on file at the laboratory. Also refer to “Demonstration of Capability” in Section 19.

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

- Each employee must have documentation in their training file that they have read, understood and agreed to follow the most recent version of the laboratory QA Manual and SOPs in their area of responsibility. This documentation is updated as SOPs are updated.

- Documentation from any training courses or workshops on specific equipment, analytical techniques or other relevant topics are maintained in their training file.
- Documentation of proficiency (refer to Section 19).
- An Ethics Agreement signed by each staff member (renewed each year) and evidence of annual ethics training.
- A Confidentiality Agreement signed by each staff member signed at the time of employment.
- Human Resources maintains documentation and attestation forms on employment status & records; benefit programs; timekeeping/payroll; and employee conduct (e.g., ethics 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 technical training for individual technologies, and particularly for people cross-trained.
- Analysts' knowledge to refer to QA Manual 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 of the laboratory's training program are described in the Laboratory Training 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 1 week of hire followed by technical data integrity training within 30 days, comprehensive training within 90 days, and an annual refresher for all employees. Senior management at each facility performs the ethics training for their staff.

In order to ensure that all personnel understand the importance TestAmerica places on maintaining high ethical standards at all times; TestAmerica has established a Corporate Ethics Policy (Policy No. CW-L-P-004) and an Ethics Statement. All initial and annual 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, etc., accepting/offering kickbacks, illegal accounting practices, unfair competition/collusion).
- Internal monitoring. Investigations and data recalls.
- Consequences for infractions including potential for immediate termination, debarment, or criminal prosecution.
- Importance of proper written narration / data qualification by the analyst and project manager with respect to those cases where the data may still be usable but are in one sense or another partially deficient.

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

SECTION 18. ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS

18.1 Overview

The laboratory is a 45,000 ft² secure laboratory facility with controlled access and designed to accommodate an efficient workflow and to provide a safe and comfortable work environment for employees. All visitors sign in and are escorted by laboratory personnel. Access is controlled by various measures.

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

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

The laboratory is separated into specific areas for sample receiving, sample preparation, volatile organic sample analysis, non-volatile organic sample analysis, inorganic sample analysis, microbiological sample analysis, and administrative functions.

18.2 Environment

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

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

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

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

Environmental conditions of the facility housing the computer network and 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, including 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 area. Work areas include:

- Access and entryways to the laboratory.
- Sample receipt areas.
- Sample storage areas.
- Chemical and waste storage areas.

- Data handling and storage areas.
- Sample processing areas.
- Sample analysis areas.

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

- Standard Methods, 9020B, Sec. 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 the laboratory. In addition to signing into the laboratory, the Environmental, Health and Safety Manual contains requirements for visitors and vendors. There are specific safety forms that must be reviewed and signed. Visitors (with the exception of company employees) are escorted by laboratory personnel at all times, or the location of the visitor is noted in the visitor's logbook. Signs are posted in the laboratory designating employee only areas - "Authorized employees beyond this point".

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 sampling, handling, transport, storage and preparation of samples, and, where appropriate, an estimation of the measurement of uncertainty as well as statistical techniques for analysis of environmental data.

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

19.2 Standard Operating Procedures (SOPs)

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 method SOPs are derived from the most recently promulgated/approved, published methods and are specifically adapted to the

laboratory facility. Modifications or clarifications to published methods are clearly noted in the SOPs. All SOPs are controlled in the laboratory.

- 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 TestAmerica's Corporate SOP entitled 'Writing a Standard Operating Procedure', No. CW-Q-S-002.
- SOPs are reviewed at a minimum of every 2 years (annually for Drinking Water SOPs), 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 analytical SOP.

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.

19.4 Selection of Methods

Since numerous methods and analytical techniques are available, continued communication between the client and laboratory is imperative to assure the correct methods are utilized. Once client methodology requirements are established, this and other pertinent information is summarized by the Project Manager. These mechanisms ensure that the proper analytical methods are applied when the samples arrive for log-in. For non-routine analytical services (e.g., special matrices, non-routine compound lists), 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 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 U. S. 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; Analysis and Sampling Procedures; 40CFR Part 136 as amended by Method Update Rule; May 18, 2012.
- 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
- Statement of Work for Inorganics & Organics Analysis, SOM and ISM, current versions, USEPA Contract Laboratory Program Multi-media, Multi-concentration.
- Standard Methods for the Examination of Water and Wastewater, 18th/19th /20th/ on-line edition; Eaton, A.D. Clesceri, L.S. Greenberg, A.E. Eds; American Water Works Association, Water Pollution Control Federation, American Public Health Association: Washington, D.C.
- Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW846), Third Edition, September 1986, Final Update I, July 1992, Final Update IIA, August 1993, Final Update II, September 1994; Final Update IIB, January 1995; Final Update III, December 1996; Final Update IV, January 2008; Final Update V, August 2015.
- 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, demonstration of capability may be performed on quality control samples.

A demonstration of capability (DOC) is performed whenever there is a change in instrument type (e.g., new instrumentation), matrix, method or personnel (e.g., analyst hasn't performed the test within the last 12 months). Additional information on training and documentation can be found in the Laboratory SOP No. IR-QA-TRAIN.

Note: The laboratory shall have a DOC for all analytes included in the methods that the laboratory performs, and proficiency DOCs for each analyst shall include all analytes that the laboratory routinely performs. Addition of non-routine analytes does not require new DOCs for all analysts if those analysts are already qualified for routine analytes tested using identical chemistry and instrument conditions.

The initial demonstration of capability must be thoroughly documented and approved by the Technical Manager and QA Manager prior to independently analyzing client samples. All associated documentation must be retained in accordance with the laboratories archiving procedures.

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

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

- The instrument is calibrated for the analyte to be reported using the criteria for the method and ICV/CCV criteria are met (unless an ICV/CCV is not required by the method or criteria are per project DQOs).
- The laboratory's nominal or default reporting limit (RL) is equal to the quantitation limit (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, Relationship of Limit of Detection (LOD) to Quantitation Limit (QL).

- The client request is documented and the lab informs the client of its procedure for working with unusual compounds. The final report must be footnoted: *Reporting Limit based on the low standard of the calibration curve.*

19.4.3 Initial Demonstration of Capability (IDOC) 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 the concentration specified by a method or the laboratory SOP.
- 19.4.3.3** At least four aliquots shall be prepared (including any applicable clean-up procedures) and analyzed according to the test method (either concurrently or over a period of 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 Method 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 in laboratory generated acceptance criteria (LCS or interim criteria) if there is no mandatory criteria established. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.
- 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 19.4.3.3 above.
 - Beginning with 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 19.4.3.1 above.

Note: Results of successive LCS analyses can be used to fulfill the DOC requirement.

A certification statement (refer to Figure 19-1 as an example) shall be used to document the completion of each initial demonstration of capability. A copy of the certification is archived in the analyst's training folder.

Methods on line prior to the effective date of this Section shall be updated to the procedures outlined above as new analysts perform their demonstration of capability. A copy of the new record will replace that which was used for documentation in the past. At a minimum, the

precision and accuracy of four mid-level laboratory control samples must have been compared to the laboratory's quality control acceptance limits.

19.5 Laboratory Developed Methods and Non-Standard Methods

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 (LOD) to the Quantitation Limit (QL) – An important characteristic of expression of sensitivity is the difference in the LOD and the QL. The LOD is the minimum level at which the presence of an analyte can be reliably concluded. The QL is the minimum concentration of analyte that can be 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 quantitation limit is defined by highest acceptable calibration concentration. The lower quantitation limit or 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 LCS, method blanks or PT samples.
- 19.7 Method Detection Limits (MDL) / Limits of Detection (LOD)**

Method detection limits (MDL) are initially determined in accordance with 40 CFR Part 136, Appendix B or alternatively by other technically acceptable practices that have been accepted by regulators. MDL is also sometimes referred to as Limit of Detection (LOD). The MDL theoretically represents the concentration level for each analyte within a method at which the analyst is 99% confident that the true value can be differentiated from blanks. 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 seven replicates of solution spiked at one to five times the estimated method detection limit (most often at the lowest standard in the calibration curve) into the applicable matrix with all the analytes of interest. Each of these aliquots is extracted (including any applicable clean-up procedures) and analyzed in the same manner as the samples. Where possible, the seven replicates should be analyzed over 2-4 days to provide a more realistic MDL. To allow for some flexibility, this low level standard may be analyzed every batch or every week or some other frequency rather than

doing the study all at once. In addition, a larger number of data points may be used if the appropriate t-value multiplier is used.

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

19.8 Instrument Detection Limits (IDL)

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

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

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

19.9 Verification of Detection and Reporting Limits

Once an MDL is established, it must be verified, on each instrument, by analyzing a quality control sample (prepared as a sample) at no more than 3 times the calculated MDL for single analyte analyses (e.g. most wet chemistry methods, Atomic Absorption, etc.) and no more than 4 times the calculated MDL for multiple analyte methods (e.g. GC, GCMS, ICP, etc.). 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 does not verify, then the lab will not report to the MDL, or redevelop their MDL or use the level where qualitative identification is established. MDLs must be verified at least annually.

When the laboratory establishes a quantitation limit, it must be initially verified by the analysis of a low level standard or QC sample at 1-2 times the reporting limit and annually thereafter. The annual requirement is waived for methods that have an annually verified MDL. The laboratory will comply with any regulatory requirements.

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 specific 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 retention time. The variance in the expected time of elution is defined as the retention time window. As the key to analyte identification in chromatography, retention time windows must be established on every column for every analyte used for that method. These records are kept with the files associated with an instrument for later quantitation of the analytes. Complete details are available 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 retention time 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 92-67-10175-1). Knowledge of the uncertainty of a measurement provides additional confidence in a result’s validity. Its value accounts for all the factors which could possibly affect the result, such as adequacy of analyte definition, sampling, matrix effects and interferences, climatic conditions, variances in weights, volumes, and standards, analytical procedure, and random variation. Some national accreditation organizations require the use of an “expanded uncertainty”: the range within which the value of the measurand is believed to lie within at least a 95% confidence level with the coverage factor $k=2$.
- 19.12.2** Uncertainty is not error. Error is a single value, the difference between the true result and the measured result. On environmental samples, the true result is never known. The measurement is the sum of the unknown true value and the unknown error. Unknown error is a combination of systematic error, or bias, and random error. Bias varies predictably, constantly, and independently from the number of measurements. Random error is unpredictable, assumed to be Gaussian in distribution, and reducible by increasing the number of measurements.
- 19.12.3** The minimum uncertainty associated with results generated by the laboratory can be determined by using the Laboratory Control Sample (LCS) accuracy range for a given analyte. The LCS limits are used to assess the performance of the measurement system since they take into consideration all of the laboratory variables associated with a given test over time (except for variability associated with the sampling 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., 524.2, 525, etc.) and specifies

the form of presentation of calculated results, no further discussion of uncertainty is required.

19.13 Sample Reanalysis 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 'reanalysis') may result in either a higher or lower value from an initial sample analysis. There are also variables that may be present (e.g., sample homogeneity, analyte precipitation over time, etc.) that may affect the results of a reanalysis. Based on the above comments, the laboratory will reanalyze samples at a client's request with the following caveats. Client specific Contractual Terms & Conditions for reanalysis protocols may supersede the following items.

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

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. More detail is outlined in the laboratory SOP No. IR-IT-COMPSEC. The laboratory is currently running the TALS which is a proprietary in-house developed LIMS system that has been highly customized to meet the needs of the laboratory. It is referred to as LIMS for the remainder of this section. The LIMS utilizes 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. 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 back-ups, stable file server network architecture, secure storage of media, line filter, Uninterruptible Power Supply (UPS), 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 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, e.g., Wet Chemistry, the data is reduced by the analyst and then verified by the Department Manager or alternate analyst prior to updating the data in LIMS. The spreadsheets, or any other type of applicable documents, are signed by both the analyst and alternate reviewer to confirm the accuracy of the manual entry(s).

Manual integration of peaks will be documented and reviewed and the raw data will be flagged in accordance with the TestAmerica Corporate SOP No. CA-Q-S-002, *Acceptable Manual Integration Practices*.

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 manufacturer's indication; otherwise, it should not be performed. Calculations are independently verified by appropriate laboratory staff. Calculations and data reduction steps for various methods are summarized in the respective analytical SOPs or program requirements.

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

19.14.2.2 In general, concentration results are reported in milligrams per liter (mg/L) or micrograms per liter ($\mu\text{g/L}$) for liquids and milligrams per kilogram (mg/kg) or micrograms per kilogram ($\mu\text{g/kg}$) for solids. For values greater than 10,000 mg/L, results can be reported in percent, i.e., 10,000 mg/L = 1%. Units are defined in each laboratory SOP.

- 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 in LIMS with at least three significant figures. In general, results are reported to 2 significant figures on 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 System, the raw results and dilution factors are entered directly into LIMS by the analyst, and the software calculates the final result for the analytical report. LIMS has a defined significant figure criterion for each analyte.
- 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 instrumental output compatible with the LIMS, the raw results and dilution factors are transferred into LIMS electronically after reviewing the quantitation report, and removing unrequested or poor spectrally-matched compounds. The analyst may print a copy of what has been entered to check for errors. This printout and the instrument's printout of calibrations, concentrations, retention times, chromatograms, and mass spectra, if applicable, are retained with the data file. The data file is stored in a monthly folder on the instrument computer; periodically, this file is transferred to the server and, eventually, to a tape file.

19.14.3 Logbook / Worksheet Use Guidelines

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

- Corrections are made following the procedures outlined in Section 12.
- Logbooks are controlled by the QA department. A record is maintained of all logbooks in the lab.
- Unused portions of pages must be "Z"ed out, signed and dated.
- Worksheets are created with the approval of the Technical Manager/QA Manager at the facility. The QA Department controls all worksheets following the procedures in Section 6.

19.14.4 Review / Verification Procedures

Review procedures are outlined in several laboratory SOPs to ensure that reported data are free from calculation and transcription errors, that QC parameters have been reviewed and evaluated before data is reported. The laboratory applies the corporate SOP No. CA-Q-S-002 on 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.

- 19.14.4.1 Log-In Review** – The data review process starts at the sample receipt stage. Sample control personnel review chain-of-custody forms and project instructions from the project management group. This is the basis of the sample information and analytical instructions entered into the LIMS. The log-in instructions are reviewed by

the personnel entering the information, and a second level review is conducted by the project management staff.

19.14.4.2 First Level Data Review – The next level of data review occurs with the analysts. As data are generated, analysts review their work to ensure that the results meet project and SOP requirements. First level reviews include inspection of all raw data (e.g., instrument output for continuous analyzers, chromatograms, spectra, and manual integrations), evaluation of calibration/calibration verification data in the day's analytical run, evaluation of QC data, and reliability of sample results. The analyst transfers data into LIMS, data qualifiers are added as needed. All first level reviews are documented.

19.14.4.3 Second Level Data Review – All analytical data are subject to review by a second qualified analyst or supervisor. Second level reviews include inspection of all raw data (e.g., instrument output, chromatograms, and spectra) including 100% of data associated with any changes made by the primary analyst, such as manual integrations or reassignment of peaks to different analytes, or elimination of false negative analytes. The second review also includes evaluation of initial calibration/calibration verification data in the day's analytical run, evaluation of QC data, reliability of sample results, qualifiers and NCM narratives. Manual calculations are checked in second level review. All second level reviews are documented.

Issues that deem further review include the following:

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

19.14.4.4 Unacceptable analytical results may require reanalysis of the samples. Any problems are brought to the attention of the Laboratory Director, Project Manager, Quality Director/Manager, Technical Manager, or Supervisor for further investigation. Corrective action is initiated whenever necessary.

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

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

completed. The process includes, but is not limited to, verifying that the COC is followed, cover letters / narratives are present, flags are appropriate, and project specific requirements are met. The Project Manager may also evaluate the validity of results for different test methods given expected chemical relationships.

- 19.14.4.7** Any project that requires a data package is subject to a tertiary data review for transcription errors and acceptable quality control requirements. The Project Manager then signs the final report. The accounting personnel also check the report for any clerical or invoicing errors. When complete, the report is sent out to the client.
- 19.14.4.8** 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

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

- 19.14.6** The analyst must adjust baseline or the area of a peak in some situations, for example when two compounds are not adequately resolved or when a peak shoulder needs to be separated from the peak of interest. The analyst must use professional judgment and common sense to determine when manual integrating is required. Analysts are encouraged to ask for assistance from a senior analyst or manager when in doubt.
- 19.14.7** 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 grounds for immediate termination.
- 19.14.8** Client samples, performance evaluation samples, and quality control samples are all treated equally when determining whether or not a peak area or baseline should be manually adjusted.
- 19.14.9** All manual integrations receive a second level review. Manual integrations must be indicated on an expanded scale "after" chromatograms such that the integration performed can be easily evaluated during data review. Expanded scale "before" chromatograms are also required for all manual integrations on QC parameters (calibrations, calibration verifications, laboratory control samples, internal standards,

surrogates, etc.) unless the laboratory has another documented corporate approved procedure in place that can demonstrate an active process for detection and deterrence of improper integration practices.

Figure 19-1. Example – Demonstration of Capability Documentation

**DEMONSTRATION OF CAPABILITY
CERTIFICATION STATEMENT**

Page 1 of 1

Date:
Laboratory Name:
Laboratory Address:
Analyst(s) Name(s):

Matrix:
SOP# and Rev#:
Parameter:

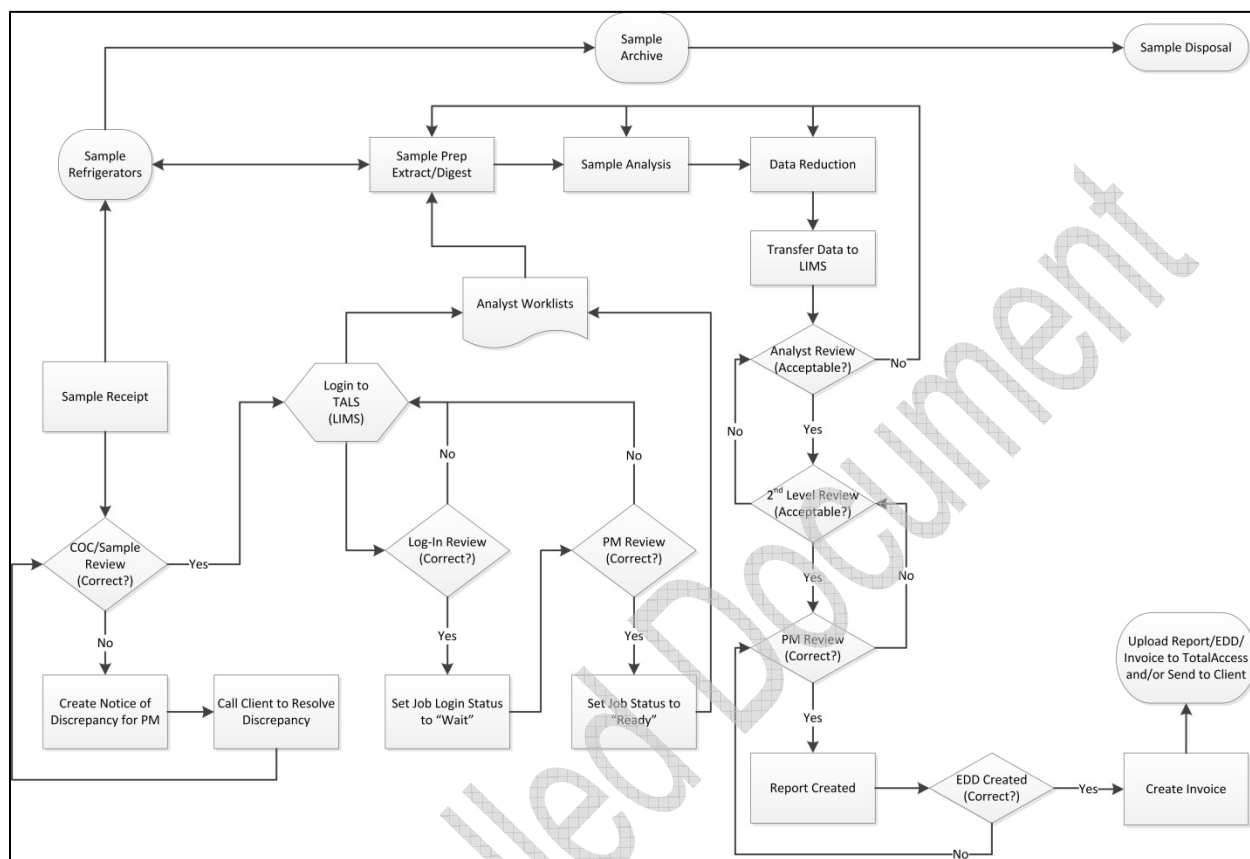
We, the undersigned, CERTIFY that:

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: Data properly labeled and stored so that the results are clear and require no additional explanation.

Figure 19-2. Example – Work Flow



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 the laboratory SOPs. A list of laboratory 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

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.

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 quality control criteria.

Table 20-2 lists examples of scheduled routine maintenance. It is the responsibility of each Technical Manager to ensure that instrument maintenance logs are kept for all equipment in his/her department. Preventative maintenance procedures may be / are also outlined in analytical SOPs or instrument manuals. (Note: For some equipment, the log used to monitor performance is also the maintenance log. Multiple pieces of equipment may share the same log as long as it is clear as to which instrument is associated with an entry.)

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

- Documentation must include all major maintenance activities such as contracted preventive maintenance and service and in-house activities such as the replacement of electrical components, lamps, tubing, valves, columns, detectors, cleaning and adjustments.
- Each entry in the instrument log includes the Analyst's initials, the date, a detailed description of the problem (or maintenance needed/scheduled), a detailed explanation of the solution or maintenance performed, and a verification that the equipment is functioning properly (state what was used to determine a return to control; e.g., CCV run on 'date' was acceptable, or instrument recalibrated on 'date' with acceptable verification, etc.) must also be documented in the instrument records.
- 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. This stapled in page must be signed across the page entered and the logbook so that it is clear that a page is missing if only half a signature is found in the logbook.

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

In the event of equipment malfunction that cannot be resolved, service shall be obtained from the instrument vendor manufacturer, or qualified service technician, if such a service can be tendered. If on-site service is unavailable, arrangements shall be made to have the instrument shipped back to the manufacturer for repair. Back up instruments, which have been approved,

for the analysis shall perform the analysis normally carried out by the malfunctioning instrument. If the back-up is not available and the analysis cannot be carried out within the needed timeframe, the samples shall be subcontracted.

At a minimum, if an instrument is sent out for service or transferred to another facility, it must be recalibrated and the laboratory MDL verified (using an MDLV) prior to return to lab 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 dispensing or 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 logs, and the recalibration/recertification certificates are kept on file. Refer to the laboratory SOP No. IR-QA-BAL for procedures.

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 umhos/cm.

Turbidity meters are also calibrated before each use.

All of this information is documented in logs. Consult pH and Conductivity, and Turbidity SOPs for further information.

20.3.3 Thermometers

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

- If the temperature measuring device is used over a range of 10°C or less, then a single point verification within the range of use is acceptable;
- If the temperature measuring device is used over a range of greater than 10°C, then the verification must bracket 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°C 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 thermometer(s) have increments of 1 degree (0.5 degree or less increments are required 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 documented in logbooks. Monitoring method-specific temperatures, including incubators, heating blocks, water baths, and ovens, is documented in method-specific logbooks. More information on this subject can be found in the laboratory SOP No. IR-QA-THERMA.

20.3.4 Refrigerators/Freezer Units, Waterbaths, Ovens and Incubators

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

Ovens, waterbaths and incubators are monitored on days of use (twice for microbiology).

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

Sample storage refrigerator temperatures are kept between $> 0^{\circ}\text{C}$ and $\leq 6^{\circ}\text{C}$.

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

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

20.3.5 Autopipettors, Dilutors, and Syringes

Mechanical volumetric dispensing devices including burettes (except Class A Glassware and Glass microliter syringes) are given unique identification numbers and the delivery volumes are verified gravimetrically, at a minimum, on a quarterly basis or monthly per project specific requirements.

For those dispensers that are not used for analytical measurements, a label is applied to the device stating that it is not calibrated. Any device not regularly verified cannot be used for any quantitative measurements. More information on this subject can be found in the laboratory SOP No. IR-QA-PIPET.

Micro-syringes are purchased from Hamilton Company. Each syringe is traceable to NIST. The laboratory keeps on file an "Accuracy and Precision Statement of Conformance" from Hamilton attesting established accuracy.

Glass micro-syringes with volumes of $> 20 \mu\text{L}$ are checked for accuracy every six months. Glass micro-syringes with volumes $< 20 \mu\text{L}$ are certified by the manufacturer (e.g., Hamilton Company). Certificate of accuracy and precision must be obtained and kept on file in the laboratory.

20.3.6 Autoclaves

Refer to the laboratory SOP No. IR-MICRO-AUTOCLAVE and 2009 TNI Standard V1M5 Section 1.7.3.7.b.ii. for performance evaluation and maintenance.

20.3.7 Field Sampling Devices (Isco Auto Samplers)

Each Auto Sampler (ISCO) is assigned a unique identification number in order to keep track of the calibration. This number is also recorded on the sampling documentation.

Refer to the laboratory SOP No. IR-SC-FIELD for calibration and maintenance.

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 method detection limits, the working range of the analytical instrumentation and any fluctuations that may occur from day to day.

Sufficient raw data records are retained to allow an outside party to reconstruct all facets of the initial calibration. Records contain, but are not limited to, the following: calibration date, method, instrument, analyst(s) initials or signatures, analysis date, analytes, concentration, response, type of calibration (Avg RF, curve, or other calculations that may be used to reduce instrument responses to concentration).

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

If the initial calibration results are outside of the acceptance criteria, corrective action is performed and any affected samples are reanalyzed if possible. If the reanalysis is not possible, any data associated with an unacceptable initial calibration will be reported with appropriate data qualifiers (refer to Section 12).

Note: Instruments are calibrated initially and as needed after that and at least annually (the annual requirement does not apply to Isotope dilution). 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 method SOP. If a reference method does not specify the number of calibration standards, a minimum of 3 calibration points 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 initial calibration must be at or below the stated reporting limit 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 initial instrument calibration 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., defined qualifiers or flags (additional information may be included in the case narrative). The exceptions to these rules are ICP and ICPMS methods which define the working range with periodic linear dynamic range studies, rather than through the range of concentrations of daily calibration standards.

All initial calibrations are verified with a standard obtained from a second source and traceable to a national standard, when available (or vendor certified different lot if a second source is not available). For unique situations, such as air analysis where no other source or lot is available, a standard made by a different analyst at a different time or a different preparation would be considered a second source. This verification occurs immediately after the calibration curve has been analyzed, and before the analysis of any samples.

20.4.1.1 Calibration Verification

The calibration relationship established during the initial calibration must be verified initially and at least daily as specified in the laboratory method SOPs in accordance with the referenced analytical methods and in the 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. Initial calibration verification is with a standard source secondary (second source standard) to the calibration standards, but continuing calibration verifications may use the same source standards as the calibration curve.

Note: The process of calibration verification referred to here is fundamentally different from the approach called "calibration" in some methods. As described in those methods, the calibration factors or response factors calculated during calibration are used to update the calibration factors or response factors used for sample quantitation. This approach, while employed in other EPA programs, amounts to a daily single-point calibration.

All target analytes and surrogates, including those reported as non-detects, must be included in periodic calibration verifications for purposes of retention time confirmation and to demonstrate that calibration verification criteria are being met, i.e., RPD, 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 retention time). The frequency is found in the determinative methods or SOPs.

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

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

A continuing instrument calibration verification (CCV) must be repeated at the beginning and, for methods that have quantitation by external calibration models, at the end of each analytical batch. Some methods have more frequent CCV requirements see specific SOPs. Most Inorganic methods require the CCV to be analyzed after every 10 samples 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 & 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 an unacceptable calibration verification may be fully useable under the following special conditions and reported based upon discussion and approval of the client:

- 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 regulatory limit/decision level. 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 by the 2 conditions identified above will be appropriately flagged.

20.4.1.2 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 initial calibration and each subsequent analysis of the verification standard. (These calculations are available in the laboratory method SOPs. Verification standards are evaluated based on the % Difference from the average CF or RF of the initial calibration or based on % Drift or % Recovery if a linear or quadratic curve is used.

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

- When the acceptance criteria for the calibration verification are exceeded high, i.e., high bias, and there are associated samples that are non-detects, then those non-detects may be reported. Otherwise, the samples affected by the unacceptable calibration verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.
- When the acceptance criteria for the calibration verification are exceeded low, i.e., low bias, those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise, the samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted. Alternatively, a reporting limit standard may be analyzed to demonstrate that the laboratory can still support non-detects at their reporting limit.

20.5 Tentatively Identified Compounds (TICs) – GC/MS Analysis

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

Note: If the TIC compound is not part of the client target analyte list, but is calibrated by the laboratory and is both qualitatively and/or quantitatively identifiable, it 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 GCMS analytical sequence, including calibration, the instrument parameters for the tune and subsequent sample analyses within that sequence must be set.

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

Table 20-1. Example – Instrumentation List ¹

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
Gas Chromatograph (FID/PID)	Hewlett Packard	5890A	S/N2750A15898	1997-01-01	EPA 8015B Gas
Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3033A33301	1998-01-01	EPA 8015B Gas
Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3223A2733	1993-01-01	EPA 8015B Gas
Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3336A60064	1993-01-01	EPA 8015B Gas
Gas Chromatograph (FID/TCD)	Varian	CP-3800	11827	2013-05-20	EPA 25C
Gas Chromatograph (FID/TCD)	Varian	CP-3800	5262	2013-05-20	RSK-175
NanoPure Diamond (UV/UF)	Barnstead	D11931	1193040693134		
Flashpoint Tester	Koehler	K-162	10A/Y-2	1992-01-01	EPA 1010
Flashpoint Tester	Erdco	RT-0001-600	151436	2015-03-30	EPA 1020A
Microwave	CEM	MARS5	MD3165	2010-01-01	EPA 3546
Microwave	CEM	MARS XPRESS	MD8441	2010-01-01	EPA 3546
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	5890Ser.II/5971	3140A39653	1993-01-01	Screening
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	5890Ser.II/5971	3033A30488/ 3133A37717	1993-01-01	1,4-Dioxane

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973 Inert	CN10349032/ US33220240	2008-01-30	EPA 625, EPA 8270C
Gas Chromatograph/ Mass Spectrometer	Agilent	6890/5973	US10226108/ US21843299	2010-01-01	EPA 625, EPA 8270C
Gas Chromatograph/ Mass Spectrometer	Agilent	7890/5975	CN10752039/ US80148288	2010-01-01	EPA 625 LL, EPA 8270C LL
Gas Chromatograph/ Mass Spectrometer	Agilent	7890/5975	CN10824037/ US83140433	2010-01-01	EPA 1625(M)
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	5890/5970	3336A60053/ 3307A00396	2011-01-01	EPA 8270C Screening
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973N	US10232062/ US21863660	2009-01-01	EPA 525.2
Gas Chromatograph/ Mass Spectrometer	Agilent	6890/G1530N	US10243060	2010-01-01	EPA 548.1
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N / 5973	CN10521030/ US40620627	2009-01-01	EPA 524.2 SIM
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N / 5973	CN10503040/ US10461983	2009-01-01	EPA 524.2, EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N / 5973	US00002015/ US10440578	2009-01-01	EPA 524.2
Moisture Analysis Balance	Ohaus	MB90	B605073296	2016-08-12	Moisture
NanoPure Diamond (UV/UF)	Barnstead	D11931	119020964094		
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	6890/5973A	US00020097/ US72810389	1999-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	6890/5973A	US00007750/ US70810354	2000-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	6890/5973A	US00022931/ US82311546	2000-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973N	US00001207/ US01140222	2001-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973	US00001206/ US01140215	2001-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973N	US0001947/ US10340261	2002-01-01	EPA 8260B SIM
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973N	US00002140/ US10440793	2002-01-01	EPA 8260B

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973N	US00002860/ US21843317	2003-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890/5973	US00034262/ US01112246	2004-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973	CN10318006/ US30945515	2004-01-01	EPA 8260B Screening
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973	CN10318007/ US30945517	2004-01-01	EPA 8260B SIM
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973	CN01521014/ US44647184	2005-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973	US00001682/ US92522712	2001-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973N	US10222064/ US10462085	2006-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973 Inert	CN10339005/ US35120285	2007-01-01	EPA 524.2, EPA 524.2 LL
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973 Inert	CN10345035/ US33220184	2009-01-01	EPA 8260B SIM
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	6890/5973	US00029799	2011-01-01	EPA 8260B
Gas Chromatograph (Dual ECD)	Agilent	6890N	US10215019	2002-01-01	EPA 608, EPA 8082
Gas Chromatograph (Dual ECD)	Agilent	6890N/G1530N	US10250081	2005-01-01	EPA 608, EPA 8081
Gas Chromatograph (Dual ECD)	Agilent	6890N/G1540N	US10423015	2008-01-01	EPA 608, EPA 8081
Gas Chromatograph (Dual ECD)	Agilent	6890N/G1540N	US10423014	2008-01-01	EPA 608, EPA 8082
Gas Chromatograph (Dual ECD)	Agilent	6890N/1530N	CN10551059	2007-01-01	EPA 608 LL, EPA 8081 LL
Gas Chromatograph (Dual ECD)	Agilent	6890N/G1530N	US10322076	2007-01-01	EPA 608, EPA 8082
Gas Chromatograph (Dual ECD)	Agilent	7890A/G3440A	CN10741034	2007-01-01	EPA 608, EPA 8082, EPA 8082 LL
Gas Chromatograph (Dual FID)	Agilent	6890N/G1540N	US10546009	2007-01-01	EPA 8015B Diesel
Gas Chromatograph (Dual FID)	Agilent	6890N/G1540N	US10546010	2007-01-01	EPA 8015B Diesel

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
Gas Chromatograph (FID/PID)	Agilent	5890 Series II	S/N3133A37568	2008-01-01	EPA 8015(M) Methanol/Ethanol
Gas Chromatograph (FID)	Agilent	6890N	CN10505005	2013-01-18	EPA 8015B Diesel
Gas Chromatograph (Dual ECD)	Agilent	6890N	US10212094	2009-01-01	EPA 505
Gas Chromatograph (Dual ECD)	Agilent	6890N	US10244152	2009-01-01	EPA 552.2
Gas Chromatograph (Dual ECD)	Agilent	6890N	US10402034	2009-01-01	EPA 552.2, EPA 504.1
Gas Chromatograph (Dual ECD)	Agilent	6890N	US10244151	2010-01-01	EPA 515.4
HPLC (FLD)	Agilent	1100	DE14903835	2009-01-01	EPA 547
HPLC (DAD)	Agilent	1100	DE14914766	2009-01-01	EPA 549.2
HPLC (FLD)	Agilent	1100	DE14903629	2009-01-01	EPA 531.1
HPLC (DAD)	Hewlett Packard	G1316A	US54000547	2009-01-01	EPA 8315A
pH Meter	Mettler Toledo	SevenEasy	1227116127	2006-01-01	Redox
pH Meter	Thermo	OrionStarA111	J00943	2006-01-01	pH for TCLP
pH meter	Hach	HQ40d	150800013699	2017-02-07	EPA 150.1, SM 4500-H+ B
pH meter	Thermo Scientific	STARA1110	J15139	2017-02-09	EPA 150.1, SM 4500-H+ B
Turbidity Meter	Orbeco-Hellige	965-10A	5187	2009-01-01	EPA 180.1, SM 2130 B
pH meter	Thermo Scientific	Orion 3 Star pH Portable	A12744	2017-01-01	EPA 150.1, SM 4500-H+ B
Flow Injection Mercury Analyzer	Perkin Elmer	FIMS 400	4167	1995-01-01	EPA 245.1, EPA 7470, EPA 7471
Flow Injection Mercury Analyzer	Perkin Elmer	FIMS 400	401510021001	2010-01-01	EPA 245.1, EPA 7470, EPA 7471
Inductively Coupled Plasma Optical Emission Spectrometer	Perkin Elmer	Optima 5300DV	077N5112802	2006-01-01	EPA 200.7, EPA 6010B
Inductively Coupled Plasma Optical Emission Spectrometer	Perkin Elmer	Optima 8300	078N1051001	2011-01-01	EPA 200.7, EPA 6010B

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
Inductively Coupled Plasma Mass Spectrometer	Agilent	7700 series G3281A	JP09480189	2010-01-01	EPA 200.8 DW
Inductively Coupled Plasma Mass Spectrometer	Agilent	7700 series G3281A	JP12091608	2012-01-01	EPA 200.8, EPA 6020, EPA 6020 LL
Inductively Coupled Plasma Mass Spectrometer	Agilent	7900	JP16211410	2016-06-27	EPA 200.8, EPA 6020, EPA 6020 LL
Turbidity Meter	Orbeco-Hellige	965-10A	4389	2007-01-01	EPA 180.1, SM 2130 B
Stereo Microscope with Fluorescence Source	VWR	HF-745	V167693	2009-01-01	
Compound Microscope (10x100)	VWR	BB-P/TB-P	V167531	2009-01-01	
UV Lamp (small)	UVP	CC-10	95007201	2009-01-01	
UV Lamp (big)	UVP	C-65	95025701	2009-01-01	
UV Viewing Cabinet (big)	UVP	UVLMS	95025201	2009-01-01	
Autoclave	Tuttnaur/ Brinkman	3870E	2903420	2009-01-01	
Autoclave	Market Forge	STM-E Type C	3Y0521	2009-01-01	
Incubator for Micro (35C)	VWR	1915	800902	2009-01-01	MTF and QC
Incubator for Micro (35C)	VWR	1915	1102003	2009-01-01	P/A, HOC-SIM, HPC-PP, Q-Tray
Incubator for Micro	Fisher Scientific	Fisher-Isotemp	501N0018	2009-01-01	
Incubator for Micro (55C)	Fisher Scientific	516D	502N0034	2009-01-01	
pH Meter	Fisher Scientific	Accumet AB15 Plus	AB92334024	2010-01-01	Microbiology pH
pH Meter	Thermo Scientific	Orion Star AIII	J0791	2014-04-07	Microbiology pH
Quanti Tray Sealer	Idexx	89-10894-04	6345	2009-01-01	
UV Lamp with Black Box	UVLMS	38EL-Series UV	030510-001	2009-01-01	

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
Colorimeter for Chlorine	Hach	Pocket ColrimeterII	13050E222500		SM 4500-CI G
Colorimeter for Chlorine	Hach	Pocket ColrimeterII	08120E115054		SM 4500-CI G
pH Meter	Oaktron	EcoTestr pH2	2491005	2016-06-08	Field pH
pH Meter	Oaktron	EcoTestr pH2	2490996	2016-06-08	Field pH
pH Meter	Oaktron	EcoTestr pH2	2491010	2016-06-08	Field pH
pH Meter	Oaktron	EcoTestr pH2	554915		Field pH
ISCO GLP Sampler	Teledyne ISCO	60-2954-00	210F01206	2006-01-01	Field Sampling
ISCO GLP Sampler	Teledyne ISCO	60-2954-00	202F00477	2006-01-01	Field Sampling
ISCO GLP Sampler	Teledyne ISCO	60-2954-00	210F01211	2006-01-01	Field Sampling
ISCO GLP Sampler	Teledyne ISCO	60-2954-00	210C01100	2006-01-01	Field Sampling
ISCO 3710 Sampler	Teledyne ISCO	603714001	198H00868	2006-01-01	Field Sampling
Colorimeter for Chlorine	Hach	Pocket ColrimeterII	09110E138552		SM 4500-CI G
Colorimeter for Chlorine	Hach	Pocket ColrimeterII	08030E089795		SM 4500-CI G
pH Meter	Thermo Scientific	Orion 3Star 1219000	A11235	2010-07-01	Field Sampling
pH Meter	Hach	Sens10N™+pH1	321113	2013-07-15	Field Sampling
Fluoride Probe	Orion	96-09	9609BN	2006-01-01	SM 4500-F C, EPA 9214
BOD probe	Jenco			2006-01-01	BOD
Colorimeter for Chlorine	Hach	Pocket ColrimeterII	06060D51326	2006-01-01	SM 4500-CI G
Conductivity Meter	VWR	21800-012	Q022545	2009-01-01	SM 2510 B
Conductivity/TDS Probe	Acument	AP75	943318	2013-01-01	SM 2510 B
NanoPure Diamond (UV/UF)	Barnstead	D4641	582910257268		
Furnace, Thermolyne 48000	Thermolyne	F48015	1205001206827	2015-01-01	TVS

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
UV/VS Spectrometer	Thermo Spectronic	Genesys20	3SGQ068003	2012-01-01	SM 3500-Cr D, EPA 365.3, SM 5220 D, EPA 410.4, EPA 7196A, EPA 9014, SM 4500-CN E/I, SM 4500-S2- D, SM 5540 C, SM 4500-KMnO4, LACSD 253B/258
UV/VS Spectrometer	Thermo Spectronic	Genesys20	3SGS260009	2014-10-06	SM 3500-Cr D, EPA 365.3, SM 5220 D, EPA 410.4, EPA 7196A, EPA 9014, SM 4500-CN E/I, SM 4500-S2- D, SM 5540 C, SM 4500-KMnO4, LACSD 253B/258
Ion Chromatograph	Dionex	LC25	2050420	2005-01-01	EPA 300.1
Ion Chromatograph	Dionex	ICS-1000	3110585	2002-01-01	EPA 300.0, EPA 9056, EPA 300.1
Ion Chromatograph	Dionex	LC 30	97040546	2002-01-01	EPA 300.0, EPA 9056
Ion Chromatograph	Dionex	LC20	94010215	2006-09-01	EPA 300.0, EPA 9056, EPA 300.1
Ion Chromatograph	Metrohm	861/838	1861004003159/ 1838001009124	2010-03-29	EPA 300.0, EPA 9056
Ion Chromatograph (with UV/VIS Detector)	Metrohm	881	1881000007119	2010-03-29	EPA 218.6, EPA 7199
Ion Chromatograph (with UV/VIS Detector)	Metrohm	881/887	15105/03140	2011-05-02	EPA 218.7
Ion Chromatograph	Metrohm	881	1881000123101	2012-11-05	EPA 218.6, EPA 7199
Ion Chromatograph	Metrohm	861	1861002008105	2013-10-03	EPA 300.0, EPA 9056
Ion Chromatograph (with UV/VIS Detector)	Dionex	ICS-2000-TC	8010736	2013-10-03	EPA 218.6, EPA 7199
Ion Chromatograph	Dionex	ICS-2000	4100753	2013-10-28	EPA 314.0
Ion Chromatograph	Dionex	ICS-2100	11021089	2014-01-24	EPA 314.0
Ion Chromatograph	Dionex	ICS-2100	13071408	2015-01-01	EPA 314.0
Ion Chromatograph	Dionex	ICS-1600	14028658	2016-04-06	EPA 300.0, EPA 9056
Ion Chromatograph	Dionex	ICS-1600	11071115	2016-04-06	EPA 300.0, EPA 9056
Ion Chromatograph/ Mass Spectrometer	Metrohm (IC)/ Agilent (MS)	Metrohm 820 IC/ Agilent LC/MSD SL	1820023004102/ US34800214	2005-01-01	EPA 332.0, EPA 6860

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
Ammonia Probe	Orion	96-12		2005-01-01	SM 4500-NH3 D
Lachat Flow Injection Analyzer	Lachat	QuickChem 8500 Series 2	140100001626	2014-01-28	EPA 350.1
Auto-titrator	ManTech	PC-Titrate PC1000-102	MS-9K8-210	2009-01-01	SM2320B, 150.1, SM4500H-B, SM 4500-NH3 D
mV Meter	Denver Instrument	Basic	13036	2006-01-01	pH for BOD
pH Meter	Denver Instrument	UB-10	UB10107126	2008-01-02	pH for alkalinity
mV Meter	Accumet	Model 25	C0021582	2006-01-01	BOD
pH Meter	Accumet	AB15	AB92338994	2006-01-01	Fluoride
pH Meter	Sartorius	Basic Meter PB-11	31350114	2014-10-14	pH
TOC Analyzer	Tekmar-Dohrmann	Phoenix 8000	US02106006	2002-01-01	SM 5310 C
TOC Analyzer	Shimadzu	TOV-V CSH	HS1104535257CS	2011-01-01	SM 5310 B, EPA 9060
TOC Analyzer	Tekmar-Dohrmann	Phoenix 8000	99099014	2016-01-31	EPA 9060 (Soil Only)
Kone Aquakem 250	Thermo Scientific	Aquakem 250	E2319629		EPA 351.2

Note:

¹ The Instrumentation List is subject to change. Refer to the Equipment database for the updated list.

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

Instrument	Procedure	Frequency
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
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	0.01 M 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

Instrument	Procedure	Frequency
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
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

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, temperature, Deionized (DI) and Reverse Osmosis (RO) 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, quarterly (or monthly) accuracy checks are performed for all mechanical volumetric devices. Microsyringes are verified at least semi-annually or disposed of 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 (National Voluntary Laboratory Accreditation Program), or another accreditation organization that is a signatory to a MRA (Mutual Recognition Arrangement) of one or more of the following cooperations – ILAC (International Laboratory Accreditation Cooperation) or APLAC (Asia-Pacific Laboratory Accreditation Cooperation). A calibration certificate and scope of accreditation is kept on file at the laboratory.

21.3 Reference Standards / Materials

Reference standards/materials, where commercially available, are traceable to certified reference materials. Commercially prepared reference standards, to the extent available, are purchased from vendors that are accredited to ISO Guide 34 and ISO/IEC Guide 17025. All reference standards from commercial vendors shall be accompanied with a certificate that includes at least the following information:

- Manufacturer
- Analytes or parameters calibrated
- Identification or lot number
- Calibration method
- Concentration with associated uncertainties
- 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.

All reference, primary and working standards/materials, whether commercially purchased or laboratory prepared, must be checked regularly to ensure that the variability of the standard or material from the 'true' value does not exceed method requirements. The accuracy of calibration standards is checked by comparison with a standard from a second source. In cases where a second standard manufacturer is not available, a vendor certified different lot is acceptable for use as a second source. For unique situations, such as air analysis where no other source or lot is available, a standard made by a different analyst would be considered a second source. The appropriate Quality Control (QC) criteria for specific standards are defined in laboratory SOPs. In most cases, the analysis of an Initial Calibration Verification (ICV) or

LCS (where there is no sample preparation) is used as the second source confirmation. These checks are generally performed as an integral part of the analysis method (e.g. calibration checks, laboratory control samples).

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

Standards and reference materials shall not be used after their expiration dates unless their reliability is verified by the laboratory and their use is approved by the Quality Assurance Manager. The laboratory must have documented contingency procedures for re-verifying expired standards.

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 TestAmerica's Corporate SOP (CA-Q-S-001), Solvent and Acid Lot Testing and Approval.]

All manufacturer or vendor supplied Certificate of Analysis or Purity must be retained, stored appropriately, and readily available for use and inspection. These records are maintained in the TALS Reagent program or 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 method specific SOPs and the 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. Blended gas standard cylinders use a nominal concentration if the certified value is within +/-15%, otherwise the certified values is used for the canister concentration.

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

- Standard ID
- Description of Standard
- Department
- Preparer's name

- Final volume and number of vials prepared
- Solvent type and lot number
- Preparation Date
- Expiration Date
- Standard source type (stock or daughter)
- Standard type (spike, surrogate, other)
- Parent standard ID (if applicable)
- Parent Standard Analyte Concentration (if applicable)
- Parent Standard Amount used (if applicable)
- Component Analytes
- Final concentration of each analyte
- Comment box (text field)

Records are maintained electronically for standard and reference material preparation. These records show the traceability to purchased stocks or neat compounds. These records also include method of preparation, date of preparation, expiration date and preparer's name or initials. Preparation procedures are provided in the Method SOPs.

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

- Expiration Date (include prep date for reagents)
- Standard ID (Specify from TALS or logbook)
- Special Health/Safety warnings if applicable

Records must also be maintained of the date of receipt for commercially purchased items or date of preparation for laboratory prepared items. Special Health/Safety warnings must also be available to the analyst. This information is maintained in the TALS Reagent program.

21.4.3 In addition, the following information may be helpful:

- Date opened (for multi-use containers, if applicable)
- Description of standard (if different from manufacturer's label or if standard was prepared in the laboratory)
- Recommended storage conditions
- Concentration (if applicable)
- Initials of analyst preparing standard or opening container

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

Procedures for preparation of reagents can be found in the Method SOPs.

Standard ID numbers must be traceable through associated logbooks, worksheets and preparation/analytical batch records.

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.

SECTION 22. SAMPLING

22.1 Overview

The laboratory provides sampling services. Sampling procedures are described in the laboratory SOP No. IR-SC-FIELD.

22.2 Sampling Containers

The laboratory offers clean sampling containers for use by clients. These containers are obtained from reputable container manufacturers and meet EPA specifications as required. Certificates of cleanliness for bottles and preservatives are provided by the supplier and are maintained at the laboratory. Alternatively, the certificates may be maintained by the supplier and available to the laboratory on-line.

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 day and time zero. As a general rule, when the maximum allowable holding time is expressed in "days" (e.g., 14 days, 28 days), the holding time is based on calendar day measured. Holding times expressed in "hours" (e.g., 6 hours, 24 hours, etc.) are measured from date and time zero. Holding times for analysis include any necessary reanalysis. However, there are some programs that

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

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 times or preservation requirements are not met, the reports will be qualified using a flag, footnote or case narrative. As soon as possible or "ASAP" is an EPA designation for tests for which rapid analysis is advised, but for which neither EPA nor the laboratory have a basis for a holding time.

22.5 Sample Aliquots / Subsampling

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

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

Guidelines on taking sample aliquots & subsampling are located in the laboratory SOP No. IR-QA-SUBSAMP.

SECTION 23. HANDLING OF SAMPLES

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

23.1 Chain of Custody (COC)

The COC form is the written documented history of any sample and is initiated when bottles are sent to the field, or at the time of sampling. This form is completed by the sampling personnel and accompanies the samples to the laboratory where it is received and stored under the laboratory's custody. The purpose of the COC form is to provide a legal written record of the handling of samples from the time of collection until they are received at the laboratory. It also serves as the primary written request for analyses from the client to the laboratory. The COC form acts as a purchase order for analytical services when no other contractual agreement is in effect. An example of a COC form may be found in Figure 23-1.

23.1.1 Field Documentation

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

- Sample identification
- Date and time
- Preservative

During the sampling process, the COC form is completed and must be legible (see Figure 23-1). This form includes information such as:

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

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

Note: Independent couriers are not required to sign the COC form. The COC is usually kept in the sealed sample cooler. The receipt from the courier is stored in log-in by date; it lists all receipts each date.

23.1.2 Legal / Evidentiary Chain-of-Custody

If samples are identified for legal/evidentiary purposes on the COC, sample receiving personnel 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 during login.

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.

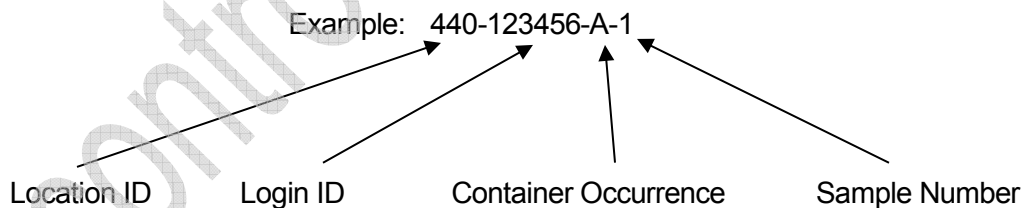
23.2.1 Laboratory Receipt

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

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. This system includes identification for all samples, subsamples and subsequent extracts and/or digestates.

The laboratory assigns a unique identification (e.g., Sample ID) code to each sample container received at the laboratory. This Primary ID is made up of the following information (consisting of 4 components):



Note: Sample ID is generated by TALS.

The above example states that TestAmerica Irvine Laboratory (Location 440). Login ID is 123456 (unique to a particular client/job occurrence). The container code indicates it is the first container (“A”) of Sample #1.

If the primary container goes through a prep step that creates a “new” container, then the new container is considered secondary and gets another ID. An example of this being a client sample in a 1-Liter amber bottle is sent through a Liquid/Liquid Extraction and an extraction vial is created from this step. The vial would be a SECONDARY container. The secondary ID has 5 components.

Example: 440-123456-A-1-A

Secondary Container Occurrence

Example: 440-123456-A-1-A would indicate the PRIMARY container listed above that went through a step that created the 1st occurrence of a Secondary container.

With this system, a client sample can literally 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:

- A COC filled out completely;
- Samples must be properly labeled;
- Proper sample containers with adequate volume for the analysis (Sampling Guide) and necessary QC;
- Samples must be preserved according to the requirements of the requested analytical method (Sampling Guide);
- sample holding times must be adhered to (Sampling Guide);

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

Data from samples which do not meet these criteria are flagged and the nature of the variation from policy is defined.

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

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

- Retain all correspondence and/or records of communications with the client regarding the disposition of rejected samples, or
- Fully document any decision to proceed with sample analysis that does not meet sample acceptance criteria.

Once sample acceptance is verified, the samples are logged into the LIMS according to the 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 refrigerators, freezers or protected locations suitable for the sample matrix (for analyses requiring thermal preservation) or in protected locations like secured shelvings 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 and place them on carts, 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 secure 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 four weeks before they are disposed of. This 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 or, if after completion of analysis the result exceeds the acceptable regulatory levels, a Hazardous Sample Notice must be completed by the analyst. This form may be completed by Sample Control, Project Managers, or analysts and must be attached to the report. The sample itself is clearly marked with a red stamp, stamped on the sample label reading "HAZARDOUS" or "FOREIGN SOIL" and placed in a colored and/or marked bag to easily identify the sample. The date, log number, lab sample number, and the result or brief description of the hazard are all written on the Hazardous & Foreign Soil Sample Notice. A copy of the form must be included with the original COC and Work Order and the original must be given to the Sample Control Custodian. Analysts will notify Sample Control of any sample determined to be hazardous after completion of analysis by completing a Hazardous Sample Notice. All hazardous samples are either returned to the client or disposed of 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 a cooler with enough ice to ensure the samples remain just above freezing and at or below 6.0°C during transit. The samples are carefully surrounded by packing material to avoid breakage (yet maintain appropriate temperature). A trip blank is enclosed for those samples requiring water/solid volatile organic analyses (see Note). The chain-of-custody form is signed by the sample control technician and attached to the shipping paperwork. Samples are generally shipped overnight express or hand-delivered by a TestAmerica courier to maintain sample integrity. All personnel involved with shipping and receiving samples must be trained to maintain the proper chain-of-custody documentation and to keep the samples intact and on ice. The Environmental, Health and Safety Manual contains additional shipping requirements.

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 consumed completely during analysis, the sample may be returned to the customer or location of sampling for disposal, or the sample may be disposed of in accordance with the laboratory's waste disposal procedures (SOP No. IR-EHS-WASTE). All procedures in the laboratory Environmental, Health and Safety Manual are followed during disposal. Samples are normally maintained in the laboratory no longer than two months from receipt unless otherwise requested. Unused portions of samples found or suspected to be hazardous according to state or federal guidelines may be returned to the client upon completion of the analytical work.

If a sample is part of a known litigation, the affected legal authority, sample data user, and/or submitter of the sample must participate in the decision about the sample's disposal. All documentation and correspondence concerning the disposal decision process must be kept on file. Pertinent information includes the date of disposal, nature of disposal (such as sample depletion, hazardous waste facility disposal, return to client, etc.), 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.



Irvine 17461 Derian Ave Suite 100 Irvine, CA 92614 phone 949.261.1022 fax 949.260.3299		Chain of Custody Record					 <small>THE LEADER IN ENVIRONMENTAL TESTING</small>				
Client Contact Your Company Name here Address City/State/Zip (xxx) xxx-xxxx Phone (xxx) xxx-xxxx FAX Project Name Site P O #		Project Manager: Tel/Fax: Analysis Turnaround Time Calendar (C) or Work Days (W) <input type="checkbox"/> AT if different from Below <input type="checkbox"/> 2 weeks <input type="checkbox"/> 1 week <input type="checkbox"/> 2 days <input type="checkbox"/> 1 day		Site Contact: Lab Contact: Date: Carrier:		TestAmerica Laboratories, Inc. COC No. _____ of _____ COCs Job No. _____ SDG No. _____					
Sample Identification		Sample Date	Sample Time	Sample Type	Matrix	# of Cont.	Enter sample ID's	Sample Specific Notes:			
Preservation Used: 1=Ice, 2=HCl; 3=H2SO4; 4=HNO3; 5=NaOH; 6=Other _____											
Possible Hazard Identification <input type="checkbox"/> Non-Hazard <input type="checkbox"/> Flammable <input type="checkbox"/> Skin Irritant <input type="checkbox"/> Poison B <input type="checkbox"/> Unknown <input type="checkbox"/>				Sample Disposal (A fee may be assessed if samples are retained longer than 1 month) <input type="checkbox"/> Return To Client <input type="checkbox"/> Disposal By Lab <input type="checkbox"/> Archive For _____ Months							
Special Instructions/QC Requirements & Comments:											
Relinquished by:		Company:		Date/Time:		Received by:		Company:		Date/Time:	
Relinquished by:		Company:		Date/Time:		Received by:		Company:		Date/Time:	
Relinquished by:		Company:		Date/Time:		Received by:		Company:		Date/Time:	

Figure 23-1. Example – Chain of Custody (COC)

Figure 23-2. Example – Sample Acceptance Policy (Page 1 of 2)



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.

Per State and/or Federal Regulation, the client is responsible to ensure that samples are shipped in accordance with DOT/IATA requirements, and that radioactive materials may only be delivered to licensed facilities. Any samples containing (or suspected to contain) Source, Byproduct, or Special Nuclear Material as defined by 10 CFR should be delivered directly to facilities licensed to handle such radioactive material. Natural material or ores containing naturally occurring radionuclides may be delivered to any TestAmerica facility or courier as long as the activity concentration of the material does not exceed 270 pCi/g alpha or 2700 pCi/g beta (49 CFR Part 173).

- 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

Continued on other side.

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Figure 23-2. Example – Sample Acceptance Policy (Page 2 of 2)

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 $\leq 10^{\circ}\text{C}$), the samples must arrive within $\pm 2^{\circ}\text{C}$ 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).

- 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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Updated June 20, 2014

Figure 23-3. Example – Hazardous & Quarantine/Foreign Soil - Drum for Incineration Sample Notice

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

Date: _____

CLIENT: _____ LOG NO: _____

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 quality control measurements (e.g. Blanks, Laboratory Control Samples (LCS), Matrix Spikes (MS), duplicates (DUP), surrogates, Internal Standards (IS)). These quality control checks are performed as required by the method or regulations to assess precision and accuracy. Quality control samples are to be treated in the exact same manner as the associated field samples being tested. In addition to the routine process quality control samples, Proficiency Testing (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. Negative Controls

Control Type	Details
Method Blank (MB)	<p>Are used to assess preparation and analysis for possible contamination during the preparation and processing steps.</p> <p>The specific frequency of use for method blanks during the analytical sequence is defined in the specific standard operating procedure for each analysis. Generally, it is 1 for each batch of samples; not to exceed 20 environmental samples.</p> <p>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.</p> <p>The method blank goes through all of the steps of the process (including as necessary: filtration, clean-ups, etc.).</p> <p>Reanalyze or qualify associated sample results when the concentration of a targeted analyte in the blank is at or above the reporting limit (or at or above ½ the reporting limit) as established by the method or by regulation, AND is greater than 1/10 of the amount measured in the sample.</p>
Calibration Blanks	<p>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.</p>
Instrument Blanks	<p>Are blank reagents or reagent water that may be processed during an analytical sequence in order to assess contamination in the analytical system. In general, instrument blanks are used to differentiate between contamination caused by the analytical system and that caused by the sample handling or sample prep process. Instrument blanks may also be inserted throughout the analytical sequence to minimize the effect of carryover from samples with high analyte content.</p>

Control Type	Details
Trip Blank ¹	Are required to be submitted by the client with each shipment of samples requiring aqueous and solid volatiles analyses (or as specified in the client's project plan). Additionally, trip blanks may be prepared and analyzed for volatile analysis of air samples, when required by the client. 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	Are sometimes used for specific projects by the field samplers. A field blank prepared in the field by filling a clean container with pure reagent water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA OSWER)
Equipment Blanks ¹	Are also sometimes created in the field for specific projects. An equipment blank is a sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures. (TNI)
Holding Blanks	Also referred to as refrigerator or freezer blanks, are used to monitor the sample storage units for volatile organic compounds during the storage of VOA samples in the laboratory.

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 with labels such as "FB", "EB", or "TB."

Evaluation criteria and corrective action for these controls are defined in the specific standard operating procedure 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)	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	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)	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)	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.
Sterility Checks (Filters)	Are also performed on at least one filter from each new lot of membrane filters using non-selective growth media.

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 (Laboratory Control Sample (LCS) or Blank Spike (BS)), which entails both the preparation and measurement steps; and (2) Matrix Effects (Matrix Spike (MS) or Sample Duplicate (MD, DUP), which evaluates field sampling accuracy, precision, representativeness, interferences, and the effect of the matrix on the method performed. Each regulatory program and each method within those programs specify the control samples that are prepared and/or analyzed with a specific batch.

Note that frequency of control samples vary with specific regulatory, methodology and project specific criteria. Complete details on method control samples are as listed in each analytical SOP.

24.4.1 Method Performance Control - Laboratory Control Sample (LCS)

The LCS measures the accuracy of the method in a blank matrix and assesses method performance independent of potential field sample matrix affects in a laboratory batch.

The LCS is prepared from a clean matrix similar to that of the associated samples that is free from target analytes (for example: Reagent water, Ottawa sand, glass beads, etc.) and is processed along with and under the same conditions as the associated samples. The LCS is spiked with verified known amounts of analytes or is made of a material containing known and verified amounts of analytes, taken through all preparation and analysis steps along with the field samples. Where there is no preparation taken for an analysis (such as in aqueous volatiles), or when all samples and standards undergo the same preparation and analysis process (such as Phosphorus), a calibration verification standard is reported as the LCS. In some instances where there is no practical clean solid matrix available, aqueous LCS's may be processed for solid matrices; final results may be calculated as mg/kg or µg/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.).

The specific frequency of use for LCS during the analytical sequence is defined in the specific standard operating procedure for each analysis. It is generally 1 for each batch of samples; not to exceed 20 environmental samples.

If the mandated or requested test method, or project requirements, do not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample (and Matrix Spike) where applicable (e.g., no spike of pH). However, in cases where the components interfere with accurate assessment (such as simultaneously spiking chlordane, toxaphene and PCBs in Method 608), the test method has an extremely long list of components or components are incompatible, at a minimum, a

representative number of the listed components (see below) shall be used to control the test method. The selected components of each spiking mix shall represent all chemistries, elution patterns and masses, permit specified analytes and other client requested components. However, the laboratory shall ensure that all reported components are used in the spike mixture within a two-year time period.

- 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

Control Type	Details	
Matrix Spikes (MS)	Use	Used to assess the effect sample matrix of the spiked sample has on the precision and accuracy of the results generated by the method used.
	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 Laboratory Control Sample and Matrix Spike. Refer to the method 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	Are added to all samples, standards, and blanks, for all organic chromatography methods except when the matrix precludes its use or when a surrogate is not available. The recovery of the surrogates is compared to the acceptance limits for the specific method. 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.

Control Type	Details	
Surrogate	Description	Are similar to matrix spikes except the analytes are compounds with properties that mimic the analyte of interest and are unlikely to be found in environment samples.
Duplicates ²	Use	For a measure of analytical precision, with each matrix-specific batch of samples processed, a matrix duplicate (MD or DUP) sample, matrix spike duplicate (MSD), or LCS duplicate (LCSD) is carried through the complete analytical procedure.
	Typical Frequency ¹	Duplicate samples are usually analyzed with methods that do not require matrix spike analysis.
	Description	Performed by analyzing two aliquots of the same field sample independently or an additional LCS.
Internal Standards	Use	Are spiked into all environmental and quality control samples (including the initial calibration standards) to monitor the qualitative aspect of organic and some inorganic analytical measurements.
	Typical Frequency ¹	All organic and ICP methods as required by the analytical method.
	Description	Used to correct for matrix effects and to help troubleshoot variability in analytical response and are assessed after data acquisition. Possible sources of poor internal standard response are sample matrix, poor analytical technique or instrument performance.

¹ See the specific analytical SOP for type and frequency of sample matrix control samples.

² LCSD's are normally not performed except when regulatory agencies or client specifications require them. The recoveries for the spiked duplicate samples must meet the same laboratory established recovery limits as the accuracy QC samples. If an LCSD is analyzed both the LCS and LCSD must meet the same recovery criteria and be included in the final report. The precision measurement is reported as "Relative Percent Difference" (RPD). Poor precision between duplicates (except LCS/LCSD) may indicate non-homogeneous matrix or sampling.

24.6 Acceptance Criteria (Control Limits)

As mandated by the test method and regulation, each 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. When this occurs, the regulatory or project limits will supersede the laboratory's in-house limits.

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

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.

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

- Regardless of the calculated limit, the limit should be no tighter than the Calibration Verification (ICV/CCV), unless the analytical method specifies a tighter limit.
- 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 data quality objectives (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 is 10%.
- If either the high or low end of the control limit changes by $\leq 5\%$ from previous, the control chart is visually inspected and, using professional judgment, they may be left unchanged if there is no effect on laboratory ability to meet the existing limits.

24.6.1 The lab must be able to generate a current listing of their control limits and track when the updates are performed. In addition, the laboratory must be able to recreate historical control limits. Refer to laboratory SOP No. IR-QA-CNTRLLIM.

One example: The QA department generates a Quality Control Limit Summary that contains tables that summarize the precision and accuracy acceptability limits for analyses performed at TestAmerica Irvine. This summary includes an effective date, is updated each time new limits are generated and is located in the TestAmerica LIMS (TALS). An archive of all limits used within the laboratory is also maintained in TALS.

24.6.2 A LCS that is within the acceptance criteria establishes that the analytical system is in control and is used to validate the process. Samples that are analyzed with an LCS with recoveries outside of the acceptance limits may be determined as out of control and should be reanalyzed if possible. If reanalysis is not possible, then the results for all affected analytes for samples within the same batch must be qualified when reported. The internal corrective action process (see Section 12) is also initiated if an LCS exceeds the acceptance limits. Sample results may be qualified and reported without reanalysis if:

- The analyte results are below the reporting limit and the LCS is above the upper control limit.
- If the analytical results are above the relevant regulatory limit and the LCS is below the lower control limit.

For TNI work, there is an allowable number of Marginal Exceedances (ME):

< 11 analytes	0 marginal exceedances are allowed
11 – 30 Analytes	1 marginal exceedance is allowed

31 – 50 Analytes	2 marginal exceedances are allowed
51 – 70 Analytes	3 marginal exceedances are allowed
71 – 90 Analytes	4 marginal exceedances are allowed
> 90 Analytes	5 marginal exceedances are allowed

- Marginal exceedances are recovery exceedances between 3 SD and 4 SD from the mean recovery limit (TNI).
- Marginal exceedances must be random. If the same analyte exceeds the LCS control limit repeatedly, it is an indication of a systematic problem. The source of the error must be located and corrective action taken. The laboratory has a system to monitor marginal exceedances to ensure that they are random.

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

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 limits. If obvious preparation errors are suspected, or if requested by the client, unacceptable MS/MSDs are reprocessed and reanalyzed to prove matrix interference. A more detailed discussion of acceptance criteria and corrective action can be found in the lab's method 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, reanalyze the sample to confirm a possible matrix effect. If the recoveries confirm or there was obvious chromatographic interference, results are reported from the original analysis and a qualifier is added. If the reanalysis meets surrogate recovery criteria, the second run is reported (or both are reported if requested by the client). Under certain circumstances, where all of the samples are from the same location and share similar chromatography, the reanalysis may be performed on a single sample rather than all of the samples and if the surrogate meets the recovery criteria in the reanalysis, all of the affected samples would require reanalysis.

24.7 Additional Procedures to Assure Quality Control

The laboratory has written and approved method 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 MDLs, Limit of Detection (LOD) and Limit of Quantitation (LOQ) can be found in Section 19.

- Use of formulae to reduce data is discussed in the method SOPs and in Section 20.
- Selection of appropriate reagents and standards is included in Section 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 laboratories sample acceptance policy is included in Section 23.

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 set up 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. There still must be enough information that would show any analyses that were out of conformance (QC out of limits) and there should be a reference to a full report that is made available to the client. Review of reported data is included in Section 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 project manager. At a minimum, the standard laboratory report shall contain the following information:

- 25.2.1** A report title (e.g., Analytical Report For Samples) with a "sample results" column header.
- 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., work order number) and on each page an identification in order to ensure the page is recognized as part of the report and a clear identification of the end.

Note: Page numbers of report are represented as page # of ##. Where the first number is the page number and the second is the total number of pages.

- 25.2.4** A copy of the chain of custody (COC).

Any COCs involved with Subcontracting are included.

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

- 25.2.6 Client project manager 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, Standard Methods, etc.).
- 25.2.11 Practical quantitation limits or reporting limit.
- 25.2.12 Method detection limits (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, LCS, and MS/MSD recoveries and control limits.
- 25.2.16 Condition of samples at receipt including temperature. This may be accomplished in a narrative or by attaching sample login sheets (Refer to Sec. 25.2.4 – Item 3 regarding additional addenda).
- 25.2.17 A statement expressing the validity of the results, that the source methodology was followed and 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.
- 25.2.20 A signature and title of the person(s) accepting responsibility for the content of the report and date of issue. Authorized signatories are qualified Project Managers appointed by the Manager of Project Managers.
- 25.2.21 When TNI accreditation is required, the lab shall certify that the test results meet all requirements of TNI or provide reasons and/or justification if they do not.
- 25.2.22 The laboratory includes a cover letter.
- 25.2.23 Where applicable, a narrative to the report that explains the issue(s) and corrective action(s) taken in the event that a specific accreditation or certification requirement was not met.

- 25.2.24** When soil samples are analyzed, a specific identification as to whether soils are reported on a “wet weight” or “dry weight” basis.
- 25.2.25** Appropriate laboratory certification number for the state of origin of the sample, if applicable.
- 25.2.26** If only part of the report is provided to the client (client requests some results before all of it is complete), it must be clearly indicated on the report (e.g., partial report). A complete report must be sent once all of the work has been completed.
- 25.2.27** 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.
- 25.2.28** A Certification Summary Report, where required, will document that, unless otherwise noted, all analytes tested and reported by the laboratory were covered by the noted certifications.

Note: Refer to the Corporate SOP on Electronic Reporting and Signature Policy (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 quality control reporting. Each level, in addition to its own specific requirements, contains all the information provided in the preceding level. The packages provide the following information in addition to the information described above:

- Level 1 is a report with all of the elements outlined in Section 25.2 above, excluding 25.2.15 (QC data).
- Level II is a Level I report plus summary information, including results for the method blank reported to the laboratory MDL, percent recovery for laboratory control samples and matrix spike samples, and the RPD values for all MSD and sample duplicate analyses.
- Level III contains all the information supplied in Level II, but presented on the CLP-like summary forms, and relevant calibration information. A Level II report is not included, unless specifically requested. No raw data is provided.
- Level IV is the same as Level III with the addition of all raw supporting data.

In addition to the various levels of QC packaging, the laboratory also provides reports in CD deliverable form. Initial reports may be provided to clients by facsimile or e-mail, or uploaded to TestAmerica’s Total Access database. Procedures used to ensure client confidentiality are outlined in Section 25.6.

25.3.1 Electronic Data Deliverables (EDDs)

EDDs are routinely offered as part of TestAmerica’s services in addition to the test report as described in Section 25.2. When NELAP accreditation is required and both a test report and EDD are provided to the client, the official version of the test report will be the combined information of the report and the EDD. TestAmerica Irvine offers a variety of EDD formats

including, but is not limited to, NAS, ADR, COELT EDF, EQUIS, GISKEY, Microsoft Excel, Locus EIM, Standard TestAmerica Format, FoxPro, and Terrabase.

EDD specifications are submitted to the IT department by the PM for review and undergo the contract review process. 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 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 lab identifies any unacceptable QC analyses or any other unusual circumstances or observations such as environmental conditions and any non-standard conditions that may have affected the quality of a result. This is typically in the form of a footnote or a qualifier and/or a narrative explaining the discrepancy in the front of the report.

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

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

When opinions or interpretations are included in the report, the laboratory provides an explanation as to the basis upon which the opinions and interpretations have been made.

Opinions and interpretations are clearly noted as such and where applicable, a comment should be added suggesting that the client verify the opinion or interpretation with their regulator.

25.5 Environmental Testing Obtained From Subcontractors

If the laboratory is not able to provide the client the requested analysis, the samples would be subcontracted following the procedures outlined in the Corporate SOP on Subcontracting (SOP 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 stationary 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 accrediting authority are permitted to make copies of any analyses or records relevant to the accreditation process, and copies may be removed from the laboratory for purposes of assessment.

25.6.1 Report deliverable formats are discussed with each new client. If a client requests that reports be faxed or e-mailed, the reports are faxed with a cover sheet or e-mailed with the following note that includes a confidentiality statement similar to the following:

This material is intended only for the use of the individual(s) or entity to which it is addressed, and may contain information that is privileged and confidential. If you are not the intended recipient, or the employee or agent responsible for delivering this material to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone at the 1-800-765-0980 (or for e-mails: please notify us immediately by e-mail or by phone (1-800-765-0980) and delete this material from any computer).

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

When the report is re-issued, a notation of "report re-issue" is placed on the cover/signature page of the report or at the top of the narrative page with a brief explanation of reason for the re-issue 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 Reporting Limit Increases

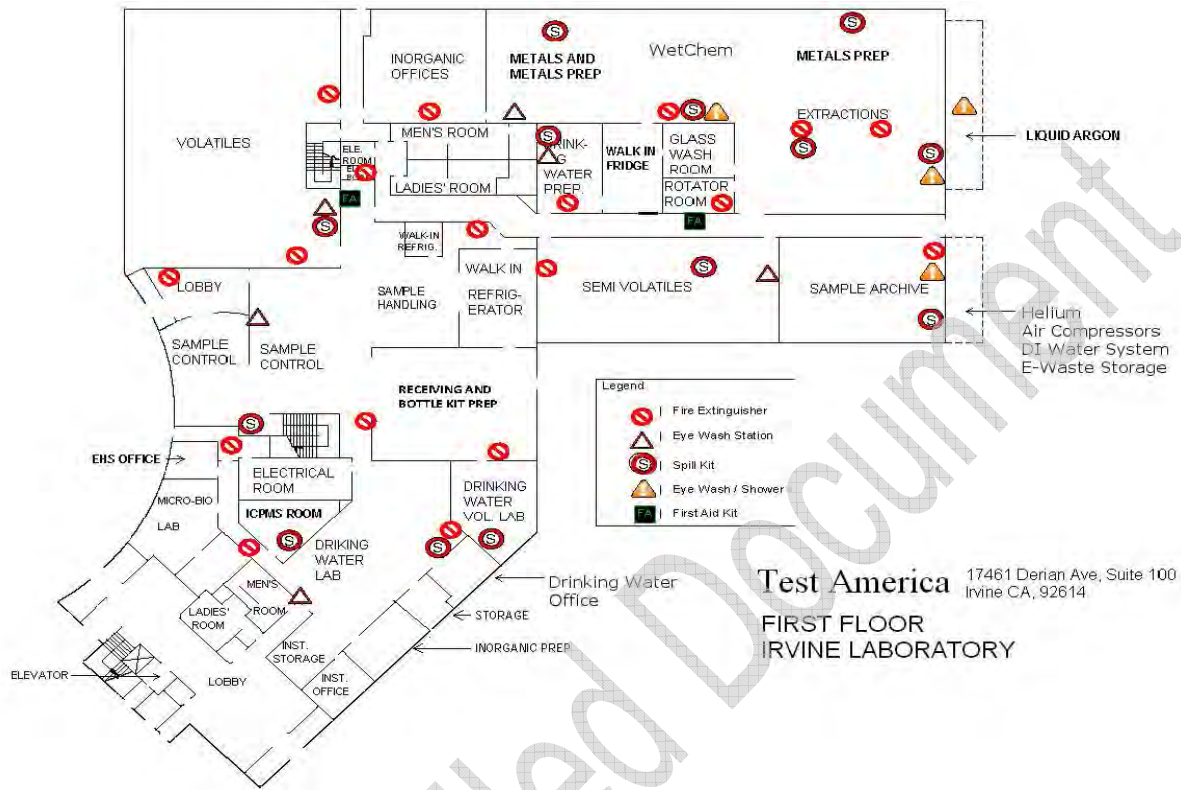
Fundamentally, our policy is simply to not omit previously reported results (including data qualifiers) or to not raise reporting limits and report sample results as ND. This policy has few exceptions. Exceptions are:

- Laboratory error.
- Sample identification is indeterminate (confusion between COC and sample labels).
- An incorrect analysis (not analyte) was requested (e.g., COC lists 8315 but client wanted 8310). A written request for the change is required.
- Incorrect limits reported based on regulatory requirements.
- The requested change has absolutely no possible impact on the interpretation of the analytical results and there is no possibility of the change being interpreted as misrepresentation by anyone inside or outside of our company.

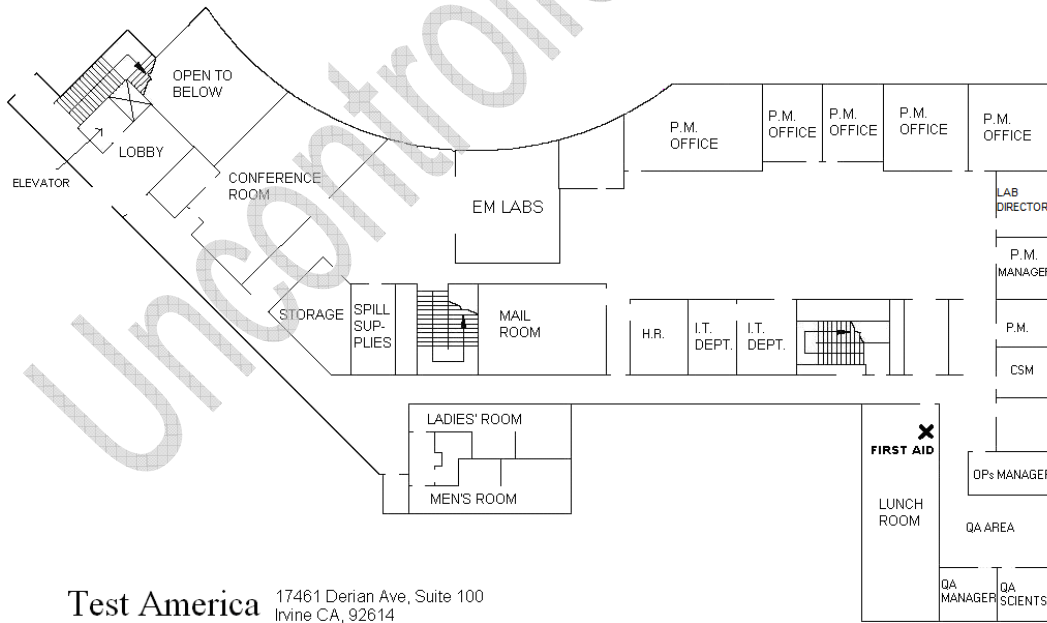
25.9.2 Multiple Reports

TestAmerica does not issue multiple reports for the same work order where there is different information on each report (this does not refer to copies of the same report) unless required to meet regulatory needs and approved by QA.

Appendix 1. Laboratory Floor Plan



Test America
FIRST FLOOR
IRVINE LABORATORY



Test America
SECOND FLOOR
IRVINE LABORATORY

Appendix 2. Glossary/Acronyms (EL-V1M2 Sec. 3.1)

Glossary:

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

Accreditation: The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory.

Accuracy: The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. (QAMS)

Analyst: The designated individual who performs the “hands-on” analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

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

Anomaly: A condition or event, other than a deficiency, that may affect the quality of the data, whether in the laboratory’s control or not.

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: Environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one (1) to twenty (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 twenty-four (24) hours. An **analytical batch** is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various quality system matrices and can exceed twenty (20) samples. (TNI)

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. (ASQC)

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 (SI).

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. (QAMS)

Certified Reference Material (CRM): 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 (COC) Form: Record that documents the possession of the samples from the time of collection to receipt in 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 (chain of custody and other sample records and/or labels), improperly preserved, collected in improper containers, or exceeding holding times when delivered to a laboratory. Under normal conditions, compromised samples are not analyzed. If emergency situation require analysis, the results must be appropriately qualified.

Confidential Business Information (CBI): Information that an organization designates as having the potential of providing a competitor with inappropriate insight into its management, operation or products. 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 Cleanup 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/ASQC E4-1994)

Correction: Actions necessary to correct or repair analysis specific non-conformances. The acceptance criteria for method specific QC and protocols as well as the associated corrective actions. 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 re of acceptable quality (i.e., that they meet specified acceptance criteria).

Data Reduction: The process of transforming the number of data items 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 (ASQC), whether in the laboratory's control or not.

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. (ASQC)

Duplicate Analyses: The analyses or measurements of the variable of interest performed identically on two subsamples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation or storage internal to the laboratory. (EPA-QAD)

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: 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 de-ionized 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 time 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 (IDL): 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 $\pm 100\%$. The IDL represents a range where qualitative detection occurs on a specific instrument. Quantitative results are not produced in this range.

Laboratory Control Sample (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 organics and 0.995 for inorganics.

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 LOD for single analyte tests and 4X the LOD 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)

(QS) Matrix: The component or substrate that contains the analyte of interest. For purposes of batch and QC requirement determinations, the following matrix distinctions shall be used:

Aqueous: Any aqueous sample excluded from the definition of Drinking Water 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 sorbent tube, impinger solution, filter, or other device. (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. Matrix spikes are 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): A replicate matrix spike prepared 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.

Observation: A record of phenomena that (1) may assist in evaluation of the sample data; (2) may be of importance to the project manager and/or the client, and yet not at the time of the observation have any known effect on quality.

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)

Preservation: Any conditions 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 Test Sample (PT): A sample, the composition of which is unknown to the laboratory and is provided to test whether the 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 (QAPP): A formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EAP-QAD)

Quality Control: The overall system of technical activities 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 and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users. (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)

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, print outs 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 2nd order curves are a mathematical calculation of a slightly curved line over two axis. The y axis represents the instrument response (or Response ratio) of a standard or sample and the x axis represents the concentration. The 2nd order regression will generate a coefficient of determination (COD or r^2) that is a measure of the "goodness of fit" of the quadratic curvature the data. A value of 1.00 indicates a perfect fit. In order to be used for quantitative purposes, r^2 must be greater than or equal to 0.99.

Selectivity: 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 quality control 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 (SOPs): 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 environment samples and is added to them for quality control purposes.

Surrogate compounds must be added to all samples, standards, and blanks, for all organic chromatography methods except when the matrix precludes its use or when a surrogate is not available. Poor surrogate recovery may indicate a problem with sample composition and shall be reported to the client whose sample produced poor recovery. (QAMS)

Systems Audit (also Technical Systems Audit): A thorough, systematic, qualitative on-site assessment of the facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system. (EPA-QAD)

Technical Manager: 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 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:

CAR – Corrective Action Report

CCV – Continuing Calibration Verification
CF – Calibration Factor
CFR – Code of Federal Regulations
COC – Chain of Custody
DOC – Demonstration of Capability
DQO – Data Quality Objectives
DUP - Duplicate
EHS – Environment, Health and Safety
EPA – Environmental Protection Agency
GC - Gas Chromatography
GC/MS - Gas Chromatography/Mass Spectrometry
HPLC - High Performance Liquid Chromatography
ICP - Inductively Coupled Plasma Atomic Emission Spectroscopy
ICP/MS – ICP/Mass Spectrometry
ICV – Initial Calibration Verification
IDL – Instrument Detection Limit
IH – Industrial Hygiene
IS – Internal Standard
LCS – Laboratory Control Sample
LCSD – Laboratory Control Sample Duplicate
LIMS – Laboratory Information Management System
LOD – Limit of Detection
LOQ – Limit of Quantitation
MDL – Method Detection Limit
MDLCK – MDL Check Standard
MDLV – MDL Verification Check Standard
MRL – Method Reporting Limit Check Standard
MS – Matrix Spike
MSD – Matrix Spike Duplicate
SDS - Safety Data Sheet
NELAP - National Environmental Laboratory Accreditation Program
PT – Performance Testing
TNI – The NELAC Institute
QAM – Quality Assurance Manual
QA/QC – Quality Assurance / Quality Control
QAPP – Quality Assurance Project Plan
RF – Response Factor
RPD – Relative Percent Difference
RSD – Relative Standard Deviation
SD – Standard Deviation
SOP – Standard Operating Procedure
TAT – Turn-Around-Time
VOA – Volatiles
VOC – Volatile Organic Compound

Appendix 3. Laboratory Certifications, Accreditations, Validations

TestAmerica Irvine maintains accreditations, certifications, 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 QA Manual, Standard Operating Procedures, Method Detection Limits, training records, etc. At the time of this QA Manual revision, the laboratory has accreditation/ certification/licensing with the following organizations:

TestAmerica Certifications

Laboratory	Program	Authority	Identification	Expiration Date
TestAmerica Irvine	Federal	USDA	P330-15-00184	07/08/2018
TestAmerica Irvine	LA Cty Sanitation Districts	California	10256	08/30/2018
TestAmerica Irvine	NELAP	Oregon	4028	01/29/2017 *
TestAmerica Irvine	NELAP Secondary AB	Kansas	E-10420	07/31/2017
TestAmerica Irvine	State Program	Alaska	CA01531	08/30/2017
TestAmerica Irvine	State Program	Arizona	AZ0671	10/14/2017
TestAmerica Irvine	State Program	California	CA ELAP 2706	08/30/2018
TestAmerica Irvine	State Program	Guam	Cert. No. 16-001r	01/23/2017 *
TestAmerica Irvine	State Program	Hawaii	N/A	01/29/2017 *
TestAmerica Irvine	State Program	Nevada	CA01531 2016-2	07/31/2017
TestAmerica Irvine	State Program	New Mexico	N/A	01/29/2017 *
TestAmerica Irvine	State Program	Northern Mariana Islands	MP0002	01/29/2017 *
TestAmerica Irvine	State Program	Washington	C900	09/03/2017

* Certification Valid - Laboratory is Pending Renewal with the Program Authority

For more information, or to contact a local TestAmerica representative nearest you, please visit our website at www.testamericainc.com

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The certificates and accredited parameter lists are available for each State/Program at www.testamericainc.com under Analytical Services Search – Certifications.

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EQUS Formats

Overview

The project will utilize EQUS Chemistry (version 5) from EarthSoft, Inc. as its internal data repository standard.

The 4-file format, including the refinements noted below, is the required format. The generic documentation for these specifications is available directly from EarthSoft at <http://www.earthsoft.com/support/edd.asp> and will not be repeated in this document.

EQUS 4-File Record Structures

1.0 Sample File

The sample file should contain the required information for all samples, regardless of their source (e.g., field, lab). Information that is not marked required should be provided in all cases where the information is available.

Shaded columns denote fields that are included in the default EQUS sample loader file, but contain information that is generally not provided to the laboratory. For consistency with the import utility, these fields must remain in the EDD; however, population of these fields is not expected.

Pos#	Field Name	Data Type	Required	Comments
1	sys_sample_code	Text(40)	Y	Unique sample identifier. Each sample must have a unique value, including spikes and duplicates. Laboratory QC samples must also have unique identifiers. As noted in Section 1.6 above, for field samples, this should match the value which appears on the chain of custody.
2	Sample_name	Text(30)	Y	Standardized sample name across all permutations. It is not required to be unique (i.e., duplicates are OK). As noted above, for field samples, this should match the value which appears on the chain of custody.
3	Sample_matrix_code	Text (10)	Y	Code which distinguishes between different types of sample matrix. For example, blank samples must be distinguished from ground water samples, etc.
4	Sample_type_code	Text (20)	Y	Code which distinguishes between different types of samples. For example, normal field samples must be distinguished from laboratory method blank samples, etc.
5	Sample_source	Text (10)	Y	Field identifies where the sample came from ie. field or lab.

Pos#	Field Name	Data Type	Required	Comments
6	parent_sample_code	Text(40)	N	The value of "sys_sample_code" that uniquely identifies the sample that was the source of this sample. For example, the value of this field for a duplicate sample would identify the normal sample of which this sample is a duplicate. Required in the laboratory EDD for all laboratory "clone" samples (e.g., spikes and duplicates). Field duplicates may be submitted blind to the laboratory, so this field is not required in the laboratory EDD for field "clones". Must be blank for samples which have no parent (e.g., normal field samples, LCS samples, method blanks, etc.).
7	sample_delivery_group	Text(10)	Y	The lab job identifier, consistent with the labeling on the final report.
8	sample_date	Date	Y	Date sample was collected (in MM/DD/YYYY format for EDD)
9	sample_time	Time	N	Time of sample collection in 24-hr (military) HH:MM format.
10	sys_Joe_code	Text(20)	N	Sample collection location.
11	start_depth	Double	N	Beginning depth (top) of soil sample.
12	end_depth	Double	N	Ending depth (bottom) of soil sample.
13	depth_unit	Text(15)	N	Unit of measurement for the sample begin and end depths.
14	chain_of_custody	Text(15)	N	Chain of custody identifier. A single sample may be assigned to only one chain of custody. If the chains are not serialized, please use the collection date of the samples, formatted as

Pos#	Field Name	Data Type	Required	Comments
15	sent_to_lab_date	Date	N	Date sample was sent to lab (in MM/DD/YYYY format for EDD).
16	sample_receipt_date	Date	N	Date that sample was received at laboratory (in MM/DD/YYYY format for EDD).
17	sampler	Text(30)	N	Name or initials of sampler.
18	sampling_company_code	Text(10)	N	Name or initials of sampling company (no controlled vocabulary).
19	sampling_reason	Text(30)	N	Optional reason for: sampling.
20	sampling_technique	Text(40)	N	Sampling technique.
21	Task code	Text 10	N	Code used to identify the task under which the field sample was retrieved.
22	collection_quarter	Text(5)	N	Quarter of the year sample was collected (e.g., "1Q96").
23	Composite_yn	Text (1)	N	Boolean field used to indicate whether a sample is a composite sample.
24	composite_desc	Text(255)	N	Description of composite sample.
25	sample_class	Text(10)	N	Navy sample class code.
26	custom field 1	Text(255)	N	Custom sample field.
27	custom_field_2	Text(255)	N	Custom sample field.
28	custom field 3	Text(255)	N	Custom sample field.
29	comment	Text(255)	N	Sample comments as necessary (e.g., broken jar, cooler issues).
30	sample_receipt_time	Text(5)	N	Time of lab receipt sample in 24-hr (military) HH:MM format.

2.0 Test File

The test file should contain the required information for all samples, regardless of their source (e.g., field, lab). Information that is not marked required should be provided in all cases where the information is available.

Pos#	Field Name	Data	Required	Comments
1	sys_sample_code	Text(40)	Y	Unique sample identifier. Each sample must have a unique value, including spikes and duplicates. Laboratory QC samples must also have unique identifiers. As noted in Section 1.6 above, for field samples, this should match the value which appears on the chain of custody.
2	lab_anl_method_name	Text(35)	Y	Laboratory analytic method name or description.
3	analysis_date	Date	Y	Date of sample analysis in MM/DD/YYYY format.
4	analysis_time	Text(5)	Y	Time of sample analysis in 24-hr (military) HH:MM format.
5	total or dissolved	Text(1)	Y	Type of analysis. Valid values include: "T"=Total analysis; "D"=Dissolved or Filtered analysis; "N" – Constitutes where neither total nor dissolved is warranted. This differs from the default EQUIS specification which constrains the use of T and D to metals analyses.
6	column number	Text(2)	N	Column identifier for dual column analyses.
7	test_type	Text(10)	Y	Type of test. Valid values include: "INITIAL"; "DILUTION"; "REEXTRACT"; "REANALYSIS". Contact DBA if other values are needed.
8	lab_matrix_code	Text(10)	N	The matrix of the sample as analyzed may be different from the matrix of the sample as retrieved (e.g. leachates).

Pos#	Field Name	Data Type	Required	Comments
9	analysis_location	Text(2)	Y	Valid values include: "F" for field instrument or probe; "FL" for mobile field laboratory analysis; "LB" for fixed-based laboratory analysis. Contact DBA if other values are needed.
10	basis	Text(10)	Y	Valid values include: "WET" for wet-weight basis reporting; "DRY" for dry-weight basis reporting; "NA" where this distinction is not applicable. Contact DBA if other values are needed.
11	container_id	Text(30)	N	Sample container identifier.
12	dilution factor	Single	N	Effective test dilution factor.
13	prep_method	Text(35)	N	Laboratory sample preparation method name or description.
14	prep_date	Date	N	Date of sample preparation in MM/DD/YYYY. This field, in conjunction with extraction time, is used to determine whether holding times for field samples have been exceeded.
15	prep_time	Text(5)	N	Time of sample preparation in 24-hr (military) HH:MM format. This field, in conjunction with extraction date, is used to determine whether holding times for field samples have been exceeded.
16	leachate_method	Text(15)	N	Laboratory leachate generation method name or description.
17	leachate date	Date	N	Date of leachate preparation in : MM/DD/YYYY format.
18	leachate time	Text(5)	N	Time of leachate preparation in 24-hr (military) HH:MM format.
19	lab name code _	Text(10)	N	Unique identifier of the laboratory. Must be consistent across all projects.
20	qcJewel	Text(10)	N	Laboratory QC level associated with the analysis.
21	lab_sample_id	Text(20)	Y	Unique sample ID internally assigned by the laboratory.

Pos#	Field Name	Data Type	Required	Comments
22	percent_noisture	Text(5)	N	Percent moisture of the sample portion used in this test; this value may vary from test to test for any sample. Numeric format is ¹¹ NN.MM.", i.e., 70.1% should be reported as
23	subsample_amount	Text(14)	N	Amount of sample used for test. This is an optional field for the laboratory EDD unless otherwise specified by the EQUIS Chemistry project
24	subsample_amount_unit	Text(15)	N	Unit of measurement for subsample amount.
25	analyst_name	Text(30)	N	Name or initials of laboratory analyst.
26	instrument id	Text(50)	N	Instrument identifier.
27	Comment	Text (255)	N	Sample comments as necessary (e.g. broken jar, cooler issues).
28	Preservative	Text(50)	N	Sample preservative used.
29	Final_volume	Text(15)	N	The final amount of the sample after sample preparation.
30	Final_volume_unit	Text(15)	N	The unit of measure that corresponds to the final amount

3.0 Batch File

The batch file should contain the required information for all samples, regardless of their source (e.g., field, Jab). Information that is not marked required should be provided in all cases where the information is available.

Pos#	Field Name	Data Type	Required	Comments
1	sys_sample_code	Text(40)	Y	Unique sample identifier. Each sample must have a unique value, including spikes and duplicates. Laboratory QC samples must also have unique identifiers. As noted in Section 1.6 above, for field samples, this should match the value which appears on the chain of custody.
2	lab_anl_method_name	Text(35)	Y	Laboratory analytical method name or description.
3	analysis_date	Date	Y	Date of sample analysis in MM/DD/YYYY format.
4	analysis_time	Text(5)	Y	Time of sample analysis in 24-hr (military) HH:MM format.

Pos#	Field Name	Data Type	Required	Comments
5	Total_or_dissolved	Text (1)	Y	Type of analysis. Valid values include: "T"=total analysis, "D"=dissolved or filtered analysis, "N"=constituents for which neither total nor dissolved is applicable. This differs from the default EQuIS specification, which constrains the use of T and D to metals analyses.
6	Column_number	Text (2)	N	Column identifier for dual column analyses.
7	Test_type	Text (10)	Y	Type of test, valid values include "INITIAL"; "DILUTION"; "REEXTRACT"; "REANALYSIS". Contact DBA if other values are needed.
8	Test_batch_type	Text (10)	Y	Type of test. Valid values include: "Prep"; "Analysis"; "Leach"
9	Test_batch_id	Text (20)	Y	Unique identifier for all lab batches. Must be unique within EQuIS chemistry database. Fore xample, the same identifier cannot be used for prep batch and an analysis batch.

4.0 Result File

The result file should contain the required information for all samples, regardless of their source (e.g., field, lab). Information that is not marked required should be provided in all cases where the information is available.

Pos#	Field Name	Data Type	Required	Comments
1	sys_sample_code	Text(40)	Y	Unique sample identifier. Each sample must have a unique value, including spikes and duplicates. Laboratory QC samples must also have unique identifiers. As noted above, for field samples, this should match the value which appears on the chain of custody.
2	lab_anl_method name	Text(35)	Y	Name of the analytical method (eg. US EPA Method 300.0)
3	analysis_date	Date	Y	Date of sample analysis in MM/IDD/YYYY format.
4	analysis_time	Text(5)	Y	Time of sample analysis in 24-hr (military) HH:MM format.

Pos#	Field Name	Data Type	Required	Comments
5	Total_or_dissolved	Text(1)	Y	Type of analysis. Valid values include: "T"=Total analysis; "D"=Dissolved or Filtered analysis; "N"=constituents for which neither "total" nor "dissolved" is applicable. This differs from the default EQuIS specification, which constrains the use of T and D to metals analyses.
6	Column_number	Text (2)	N	Column identifier for dual column analyses.
7	test_type	Text(10)	Y	Type of test. Valid values include: 'INITIAL"; "DILUTION\ "REEXTRACT"; "REANALYSIS". Contact DBA if other values are needed.
8	cas_num	Text(15)	Y	Unique analyte identifier. Use assigned CAS number when one is identified for an analyte. Tentatively Identified Compounds (TICs) are not assigned a standard CAS number. The laboratory is required to assign a UNIQUE identifier for each TIC. The unique identifier must be placed in this field. Since retention time for TICs are unique per sample and sample analysis method, this information is the recommended value to use as the unique identifier.
9	Chemical_name	Text (60)	Y	Chemical name as it appears in the lab pack.
10	Result_value	Text (20)	N	Must only be a numeric value. It is stored as a string of characters so that significant digits can be retained. Must be identical with values presented in the hard copy. It must be blank for non-detects.
11	Result_error_delta_value	Text (20)	N	Error range applicable to the result value; typically used only for radiochemistry results.
12	Result_type_code	Text (10)	Y	Type of result. Valid values include: ""TRG" for a target or regular result; "TIC" for tentatively identified compounds; "SUR" for surrogates; "IS" for internal standards; "SC" for spiked compounds.

Pos#	Field Name	Data Type	Required	Comments
13	Reportable_result	Text (10)	Y	Valid values include "Yes" for a reportable result and "No" for an unreportable result. For a given sample/method/analyte combination there should only be ONE result record with YES in the reportable_result field.
14	Detect_flag	Text (2)	Y	Valid values include "Y" for detected analytes and "N" for non-detected analytes.
15	Lab_qualifiers	Text (7)	Y	Qualifier flags assigned by the laboratory in accordance with CLP SOW documents (U = non-detect, not ND or <)
16	Organic_yn	Text(1)	Y	Valid values include: "Y" for organic constituents; "N" for inorganic constituents.
17	Method_detection_limit	Text(20)	Y	Method Detection Limit (MDL). The MDL is the minimum amount of an analyte that can be routinely identified using a specific method.
18	reporting_detection_limit	Text(20)	Y	Practical Quantitation Limit (PQL). The PQL, defined in SW846 methods, is the lowest level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory
19	quantitation_limit	Text(20)	Y	Sample quantitation limit (SQL). Per USEPA guidance, the SQL is the MDL adjusted to reflect sample-specific action such as dilution or use of a smaller sample aliquot for analysis due to matrix effects or the high concentration of some analytes.
20	result unit	Text(15)	Y	Units of measurement for the result.
21	detection_limit_unit	Text(15)	N	Units of measurement for the detection limit(s).
22	TIC_retention_time	Text(8)	N	For tentatively identified compounds. May be used in the CAS number field to identify individual TICs as long as each retention time per sample per method of analysis is unique.
23	result_comment	Text(255)	N	Any comments related to the analysis.
24	qc_original_conc	Text(14)	N	The concentration of the analyte in the original (unspiked) sample.
25	qc_spike_added	Text(14)	N	The concentration of the analyte added to the original sample.

Pos#	Field Name	Data Type	Required	Comments
26	qc_spike_rmeasured	Text(14)	N	The measured concentration of the analyte. Use zero for spiked compounds that were not detected in the sample.
27	qc_spike_recovery	Text(14)	N	The percent recovery calculated as specified by the laboratory QC program. Report as percentage value (e.g., report "120%" as "120", not 1.2).
28	qc_dup_original_conc	Text(14)	N	The concentration of the analyte in the original (unspiked) sample.
29	qc_dup_spike_added	Text(14)	N	The concentration of the analyte added to the original sample.
30	qc_dup_spike_measured	Text(14)	N	The measured concentration of the analyte in the duplicate.
31	qc_dup_spike_recovery	Text(14)	N	The duplicate percent recovery calculated as specified by the laboratory QC program. Report as percentage value (e.g., report "120%")
32	qc_rpd	Text(8)	N	The relative percent difference calculated as specified by the laboratory QC program. Report as percentage value (e.g., report "120%" as "120", not 1.2).
33	qc_spike_lcl	Text(8)	N	Lower control limit for spike recovery. Report as percentage value (e.g., report "120%" as "120" not 1.2).
34	qc_spike_ucl	Text(8)	N	Upper control limit for spike recovery. Report as percentage value (e.g., report "120%" as "120", not 1.2).
35	qc_rpd_cl	Text(8)	N	Relative percent difference control limit. Required for any duplicated sample. Report as percentage multiplied by 100 (e.g., report "120%" as "120").
36	qc_spike_status	Text(10)	N	Used to indicate whether the spike recovery was within control limits. Use the "*" character to indicate failure, otherwise leave blank. Required for spikes, spike duplicates, surrogate compounds, LCS and any spiked sample.
37	qc_dup_spike_status	Text(10)	N	Used to indicate whether the duplicate spike recovery was within control limits. Use the "*" character to indicate failure otherwise leave blank.

Pos#	Field Name	Data Type	Required	Comments
38	qc_rpd_status	Text(10)	N	Used to indicate whether the relative percent difference was within control limits. Use the "*" character to indicate failure, otherwise leave blank. Required for any duplicated sample.

Appendix C

Example Chain-of-Custody Forms

