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Quality Assurance Project Plan

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





Quality Assurance Project Plan Final

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Quality Assurance Project Plan

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.

Sally W. Biludean

4-7-2016

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%RSDpercent relative standard deviationBMIBlack Mountain IndustrialDIdeionizedDOdissolved oxygenDQIdata quality indicatorsDQOdata quality objectiveDVSRData Validation Summary ReportEDDElectronic Data DeliverableEPAU.S. Environmental Protection AgencyFSAPField Sampling and Analysis PlanGSPGroundwater Sampling PlanHASPHealth and Safety PlanICPinductively coupled plasmaIDidentificationLCSlaboratory control sampleLCSDlaboratory control sample duplicateLVWLas Vegas WashMDLmethod detection limitMSmatrix spikeMSDmatrix spike duplicateNDEPNevada Division of Environmental ProtectionNELACNational Environmental Laboratory Accreditation ConferenceNELAPNational Environmental Response TrustORPOxygen Reduction PotectionPIDphotoinization detectorPMProject ManagerPQLPractical Quantitation LimitQAquality assuranceQAPPQuality Assurance Project PlanQCquality assuranceQAPPrelative percent differenceRPMRemedial Investigation and Feasibility StudyRPDrelative percent differenceRPMRemedial Project ManagerSDGSample Delivery Group	%R	percent recovery
DIdeionizedDOdissolved oxygenDQIdata quality indicatorsDQOdata quality objectiveDVSRData Validation Summary ReportEDDElectronic Data DeliverableEPAU.S. Environmental Protection AgencyFSAPField Sampling and Analysis PlanGSPGroundwater Sampling PlanHASPHealth and Safety PlanICPinductively coupled plasmaIDidentificationLCSlaboratory control sampleLCSDlaboratory control sample duplicateLWWLas Vegas WashMDLmethod detection limitMSmatrix spikeMSDmatrix spike duplicateNEPPNevada Division of Environmental ProtectionNELACNational Environmental Laboratory Accreditation ConferenceNELAPNational Environmental Laboratory Accreditation ProgramNERTNevada Division detectorPMProject ManagerPQLPractical Quantitation LimitQAquality assuranceQAPPQuality Assurance Project PlanQCquality controlRIFSRemedial Investigation and Feasibility StudyRPDrelative percent differenceRPMRemedial Project ManagerSDGSample Delivery Group	%RSD	• •
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DVSRData Validation Summary ReportEDDElectronic Data DeliverableEPAU.S. Environmental Protection AgencyFSAPField Sampling and Analysis PlanGSPGroundwater Sampling PlanHASPHealth and Safety PlanICPinductively coupled plasmaIDidentificationLCSlaboratory control sampleLCSDlaboratory control sample duplicateLVWLas Vegas WashMDLmethod detection limitMSmatrix spikeMSDmatrix spike duplicateNEEPNevada Division of Environmental ProtectionNELACNational Environmental Laboratory Accreditation ConferenceNELAPNational Environmental Response TrustORPOxygen Reduction PotentialOSHAOccupational Safety and Health AdministrationPIDphotoinization detectorPMProject ManagerPQLQuality AssuranceQAPPQuality Assurance Project PlanQCquality controlRI/FSRemedial Investigation and Feasibility StudyRPDrelative percent differenceRPMRemedial Project ManagerSDGSample Delivery Group	DQI	data quality indicators
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FSAPField Sampling and Analysis PlanGSPGroundwater Sampling PlanHASPHealth and Safety PlanICPinductively coupled plasmaIDidentificationLCSlaboratory control sampleLCSDlaboratory control sample duplicateLVWLas Vegas WashMDLmethod detection limitMSmatrix spikeMSDmatrix spike duplicateNDEPNevada Division of Environmental ProtectionNELACNational Environmental Laboratory Accreditation ConferenceNELAPNational Environmental Response TrustORPOxygen Reduction PotentialOSHAOccupational Safety and Health AdministrationPIDphotoionization detectorPMProject ManagerPQLQuality AssuranceQAPPQuality Assurance Project PlanQCquality controlRI/FSRemedial Investigation and Feasibility StudyRPDrelative percent differenceRPMRemedial Project ManagerSDGSample Delivery Group	EDD	Electronic Data Deliverable
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NERTNevada Environmental Response TrustORPOxygen Reduction PotentialOSHAOccupational Safety and Health AdministrationPIDphotoionization detectorPMProject ManagerPQLPractical Quantitation LimitQAquality assuranceQAPPQuality Assurance Project PlanQCquality controlRI/FSRemedial Investigation and Feasibility StudyRPDrelative percent differenceRPMSDGSDGSample Delivery Group	NELAC	National Environmental Laboratory Accreditation Conference
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PQLPractical Quantitation LimitQAquality assuranceQAPPQuality Assurance Project PlanQCquality controlRI/FSRemedial Investigation and Feasibility StudyRPDrelative percent differenceRPMRemedial Project ManagerSDGSample Delivery Group	PID	photoionization detector
QAquality assuranceQAPPQuality Assurance Project PlanQCquality controlRI/FSRemedial Investigation and Feasibility StudyRPDrelative percent differenceRPMRemedial Project ManagerSDGSample Delivery Group	PM	Project Manager
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RI/FSRemedial Investigation and Feasibility StudyRPDrelative percent differenceRPMRemedial Project ManagerSDGSample Delivery Group		
RPDrelative percent differenceRPMRemedial Project ManagerSDGSample Delivery Group		
RPMRemedial Project ManagerSDGSample Delivery Group	RI/FS	Remedial Investigation and Feasibility Study
SDG Sample Delivery Group		•
	RPM	Remedial Project Manager
	SOP	standard operating procedure
SWSP Initial Surface Water Sampling Plan	SWSP	Initial Surface Water Sampling Plan

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.

Weiquan Dong Nevada Department of Environmental Protection (NDEP) 2030 East Flamingo Road, Suite 230 Las Vegas, Nevada 89119 wdong@ndep.nv.gov

Nevada Environmental Response Trust 35 East Wacker Drive, Suite 1550 Chicago, Illinois 60601 andrew.steinberg@lepetomaneinctrustee.com

NDEP c/o Broadbent and Associates 8 West Pacific Avenue Henderson, Nevada 89015 kstowers@broadbentinc.com

Steve Clough Nevada Environmental Response Trust 510 S. Fourth Street Henderson, NV 89015 <u>steve.clough@nert-trust.com</u> Tanya O'Neill Foley & Lardner LLP 777 East Wisconsin Avenue Milwaukee, Wisconsin 53202 toneill@foley.com

Patty Mata TestAmerica Laboratories, Inc. 17461 Derian Avenue, Suite 100 Irvine, California 92614 patty.mata@testamericainc.com

David Frohnen Silver State Laboratories 3626 E. Sunset Road, Suite 100 Las Vegas, Nevada 89120 dfrohnen@ssalabs.com

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 prepared this Quality Assurance Project Plan (QAPP) to describe the quality assurance/quality control (QA/QC) procedures to be used during investigation activities conducted in the Remedial Investigation of the Nevada Environmental Response Trust (NERT) Remedial Investigation – Downgradient Study Area (Downgradient Study Area) located in Clark County, Nevada as shown on **Figure 1**. Currently planned work in the Downgradient Study Area is described in two work plans prepared by AECOM: the Groundwater Sampling Plan (GSP) and the Initial Surface Water Sampling Plan (SWSP). This QAPP is generally consistent in approach with the NDEP-approved QAPP prepared by Ramboll Environ (formerly known as ENVIRON) (Ramboll 2014).

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 GSP and SWSP which 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).

A Field Sampling and Analysis Plan (FSAP) is planned to support future geophysics pilot testing and full-scale test plans as well as the installation, sampling, pump testing, and tracer testing of new wells within the Downgradient Study Area. A Surface Water Investigation Plan (SWIP) is also planned for future surface water sampling and analysis. Both of these plans will be incorporated into this QAPP by reference. The program-specific work plans (GSP, SWSP, FSAP, and SWIP) 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 and 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. QA can be defined as the integrated system of activities that ensures that a project meets defined standards.

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 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 GSP and SWSPs and that data quality is consistently assessed and documented with respect to its precision, accuracy, sensitivity, and completeness. 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 GSP and SWSP. 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 GSP/SWSP Work Plans 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 (NDEP 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 Quality Assurance/Quality Control 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 the approved work plan, 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 the approved work plan, 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.
- Daniel Frohnen, Laboratory Manager at Silver State Analytical Laboratories, Inc. (Silver State): Silver State's Las Vegas, Nevada laboratory is responsible for hexavalent chromium analysis for surface water and groundwater for this project.

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 COPCs) in groundwater, to support the Remedial Action Objectives as part of NERT's Remedial Investigation and Feasibility Study. 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 Complex companies. The Scope of Work includes planning for and implementation of RI-activities within the Downgradient Study Area that covers the section of 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 NERT RI Study Area (NERT RI Study Area) has been the location of industrial operations since 1942 when it was developed by the United States 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 from 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 action Completion Report (ENVIRON 2012). On-site groundwater removal actions include the installation of the 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 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 GSP and SWSP. 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.

Following the DQO Process has driven the development of the GSP and SWSP, 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 for precision, accuracy, completeness, representativeness, comparability, and sensitivity. 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 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 (RLs), 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 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

Performance and acceptance criteria are often expressed in terms of data quality indicators (DQIs). The principal DQIs are sensitivity, accuracy, precision, completeness, representativeness, and comparability. These DQIs are discussed below.

Sensitivity refers to the amount of analyte necessary to produce a detector response that can be reliably detected (MDL) or quantified (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 contaminant of concern should be lower than 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 from 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**.

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; the results of this is used to calculate percent recovery. Accuracy of laboratory analyses will be assessed by comparing results for a surrogate standard, matrix spike (MS) or laboratory control sample (LCS), and initial and continuing calibration of instruments to control limits. Laboratory accuracy is expressed as the percent recovery (%R). If the %R is determined to be outside of acceptance criteria, 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 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.

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 PQL. The most commonly used estimates of precision are percent relative standard deviation (%RSD) and the relative percent difference (RPD) when only two samples are used. RPDs for LCS are listed in **Table 2** under MS RPD and blank spike/LCS RPD. %RSD 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 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 analysis of duplicate samples, which measure variability introduced by the laboratory and field operations. Field duplicate 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.

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 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.

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.

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.

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 the 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. The reliability and credibility of analytical laboratory results can be corroborated by the inclusion of a program of scheduled replicate analyses, analyses of standard or spiked samples, and analysis of split samples with QA laboratories for some projects. 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 Principal in Charge and 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 shall 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 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 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 identification (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 consistence 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 (SDG). 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,
- CAS#,
- 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
- SDG.

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 IV equivalent. The Level IV 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;
- Raw data for samples, tunes, calibrations, internal standards, etc.;
- Summaries for initial calibration, calibration verification, internal standards, interference check standards (metals only), serial dilutions (metals only), and post digestion spikes (metals only);
- Dilution factors;
- Initial sample aliquots (weights or volumes) and final sample volumes;
- · Sample preparation logs, sample run logs and injection logs; and
- 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 shall 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 sample quantitation limit, 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:

- <u>Method Blank Analyses</u> 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.
- <u>MS/MSD</u> 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.
- <u>LCS/LCSD</u> For LCS/LCSD analyses the spiked sample results, percent recovery, 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.
- <u>Laboratory Duplicates</u> 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 GSP and SWSP, 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 GSP and SWSP. 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 GSP and SWSP.

2.2.1 Sampling Procedures

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

2.2.2 QC Sample Collection

QC samples may include equipment field blanks, field duplicates, 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 – Equipment blanks 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. Equipment blanks will be collected at a frequency of one equipment blank for every 20 primary samples for all aqueous primary 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.

<u>Field Blanks -</u> Field blank samples are obtained by filling a clean sampling container with reagentgrade deionized (DI) water, in the field at a sample location. The sample is then analyzed in the same manner as the primary sample. Field blank 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.

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

MS/MSDs –MS/MSD (inorganics) 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 laboratory. 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 Identification

To maintain consistency, a sample identification convention has been developed and will be followed throughout the GSP and SWSP. 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 but is not required since it is not expected in the current scope of work.

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.

An equipment blank should be named for the sample collected immediately prior to the collection of the equipment blank.

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

The field duplicate represents the primary sample that is being duplicated, thus the field duplicate 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 equipment blank 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 (equipment blank)
- MW-1-20140701-FB (field blank)
- MW-1-20140701-FD (field duplicate)

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 identifier;
- 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 identifications 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 laboratory. The laboratories will maintain certification documentation in their files. All preserved samples will be clearly identified on the sample label and chain-of-custody form. 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:

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 take care 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 degrees Celsius or lower for transport to the laboratory.
- All sample lids will stay with the original containers, and will not be mixed.
- Sample bottles or canisters 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 laboratory, or by the 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 laboratory 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 laboratory. 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 identifier 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 upon arrival. Once the sample has arrived at the stationary 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 laboratory.

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

Samplers may conduct in-field measurement for 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 project-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 may 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 laboratory 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 GSP and SWSP.

2.5.1 Field

Field QA/QC samples that will be collected during the proposed investigation include field duplicate samples, field blanks, and equipment blanks. 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 measurements 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 field duplicates, MS/MSDs, field blanks, and equipment blanks 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 field duplicate 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. Field duplicate samples will be labeled and packaged in the same manner as primary samples but with "FD" appended to the sample ID. Field duplicates 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 field duplicate 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

Field blanks samples are used to assess the presence of contaminants arising from field sampling procedures. Field blank 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. Field blank 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

Equipment blank samples are used to assess the effectiveness of decontamination procedures. Equipment blank samples are obtained by filling decontaminated sampling equipment with reagentgrade 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. Equipment blanks 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 GSP and SWSP include method blanks, LCS, MS, LCSD, 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**. The 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 Silver State Laboratories David Frohnen 3626 E. Sunset Road, Suite 100 Las Vegas, Nevada 89120

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
- 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 method blank sample 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

A 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, a LCS will be analyzed once 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 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 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 1 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 the precision. There are three types of duplicates - sample duplicates, LCSDs and MSs. For applicable analytical methods, duplicates will be collected and analyzed in accordance the laboratory QA Manuals at a frequency of at least 1 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. 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 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 the 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 laboratory. 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. Maintenance will be 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 predetermined QC criteria.

2.7.1 Field Calibration Procedures

Instruments requiring calibration include air monitoring equipment (e.g., PIDs, gas multimeters, and dust monitoring 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 verification. 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.

The 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.

The 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.

The 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 μ m filters), calibration standards, disposable bladders for pumping, sample tubing, and 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 such 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 the laboratory QA Manual. A list of primary supplies and consumables necessary for each laboratory analysis are provided in the individual SOPs.

The 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. This data was evaluated during development of the GSP and SWSP and will be used to inform the FSAP.

The sampling and analysis as described in the GSP and SWSP 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 this data is 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. The 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 EQuIS® 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 EQuIS 4-File EDD format as defined by the AECOM Laboratory EDD Format Specification, EQuIS Edition. EDDs provided by the laboratories will be in the EQuIS 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 EQuIS 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.

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 GSP and SWSP 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 GSP and SWSP 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

The 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 GSP and SWSP 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, and 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 Project Manager. 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, 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 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 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 IV will be required to support the DQOs. Approximately 90 percent of the data will be validated to NDEP Stage-2b and approximately 10 percent of data will be validated to NDEP Stage-4, as further discussed below (NDEP 2006).

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. 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 laboratory QA Manuals (**Appendix A**). 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.

The laboratory will perform in-house analytical data validation under the direction of their own QA personnel and the Laboratory PM. The 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 2014a and 2014b) 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 at least to Stage 2B, which includes:

- Completeness Check;
- Chain-of-Custody Review;
- Review of Holding Times;
- Initial and Continuing Calibration;
- Review of QC Summaries, including negative controls (blanks), positive controls (LCS), and Sample Specific Controls (replicates, MS, tracers/yields);
- Review of Internal Standards;
- Interference Check Sample, ICP Serial Dilution and PQLs;
- Project or sampling specific items that have been identified for review; and

At least 10 percent of the analytical results will be validated to Stage 4, which includes:

- All parameters reviewed for Stage 2B, and
- Random recalculation (10 to 20 percent) of reported results versus raw data.

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 the 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 the 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:

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

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

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

An additional measure of accuracy is blank contamination. The blanks associated with these sampling events include laboratory method blanks and field blanks (e.g., equipment rinsate blanks, trip blanks). The results of the laboratory and field blanks 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, or sample and sample duplicate in the case of some of the inorganic parameters, and field duplicate 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.

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

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:

Completene ss = $\frac{(number of valid measuremen ts)}{(number of measuremen ts planned)} x 100$

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 EQuIS 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 GSP and SWSP. 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 quality control objectives the AECOM Analytical Task Leader will take appropriate action to obtain acceptable data as determined necessary. This may include reanalyzing 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 will typically will not be necessary.

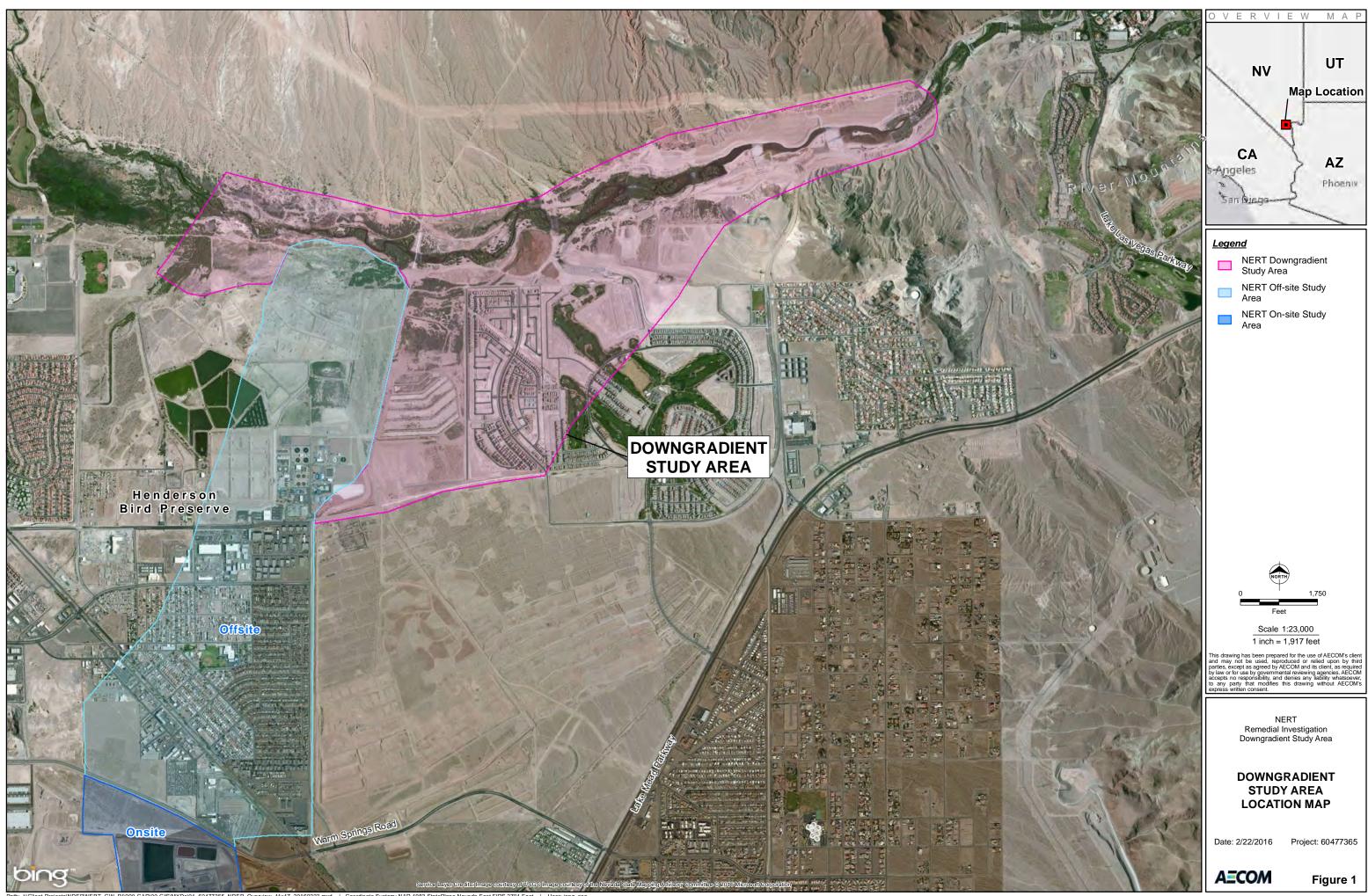
Other corrective actions may include more intensive training, equipment repair followed by a more intensive preventive maintenance program, or removal of the source of systemic problems. Any and all corrective actions will be reviewed by the AECOM Task Leader(s) for certainty that resolution was achieved.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

5.0 References

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- NDEP. 2009c. NDEP Supplemental Guidance on Data Validation for the BMI Plant Sites and Common Areas Projects, Henderson, Nevada. April 13.
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- NDEP. 2013. Guidance on Unified Chemical Electronic Data Deliverable Format, BMI Plant Sites and Common Areas Projects, Henderson, Nevada. June 5.
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Figures



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Tables

TABLE 1. ANALYTICAL METHODS AND LABORATORIESQUALITY ASSURANCE PROJECT PLANNevada 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	
otal 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 ANALTICAL QUALITY CONTROL CRITERIAQUALITY ASSURANCE PROJECT PLANNevada Environmental Response Trust Site - Downgradient Study Area; Henderson, Nevada

				Practical	Method	QUALITY CONTROL LIMITS ⁽²⁾								
		Screening	Screening Level	Quantitation Limit	Detection Limit	Surr	ogate	Duplicate		Matrix S	pike	BI	ank Spi	ike/LCS
ANALYTES	CAS Number	Level	Source ⁽¹⁾	(PQL)	(MDL)	%	۶R	RPD		%R	RPD		%R	RPD
Metals (µg/L)														
EPA Method 200.7														
Chromium (dissolved)	7440-47-3	100	MCL	5	2			30	75	- 125	20	80	- 120	20
EPA Method 200.8														
Chromium (dissolved)	7440-47-3	100	MCL	5	2			30	75	- 125	20	80	- 120	20
EPA Method 218.7														
Chromium (hexavalent)	18540-29-9	100	BCL	1	0.25			30	90	- 110	10	90	- 110	10
Others (µg/L)														
EPA Method 300.0														
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
EPA Method 300.1														
Chlorate	7790-93-4			20	8			30	75	- 125	25	75	- 125	25
EPA Method 314.0														
Perchlorate	14797-73-0	18	BCL	4	0.95			30	80	- 120	20	85	- 115	15
SM 2540C														
Total Dissolved Solids	10-33-3	500,000	2nd MCL	10000	5000			30				90	- 110	10

TABLE 2. GROUNDWATER AND SURFACE WATER ANALYTES AND ANALTICAL QUALITY CONTROL CRITERIAQUALITY ASSURANCE PROJECT PLANNevada Environmental Response Trust Site - Downgradient Study Area; Henderson, Nevada

				Practical	Method						
			Screening	Quantitation	Detection						
		Screening	Level	Limit	Limit	Surrogate	Duplicate	Matrix S	pike	Blank Sp	ike/LCS
ANALYTES	CAS Number	Level	Source ⁽¹⁾	(PQL)	(MDL)	%R	RPD	%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.

(2)

TABLE 3. FREQUENCY OF QA/QC SAMPLESQUALITY ASSURANCE PROJECT PLANNevada 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 TIMESQUALITY ASSURANCE PROJECT PLANNevada Environmental Response Trust Site - Downgradient Study Area; Henderson, Nevada

MATRIX	ANALYTES	ANALYTICAL METHOD	PRESERVATION	CONTAINER ⁽¹⁾⁽²⁾	ТАТ	HOLD TIME ⁽³ Prior to pH After adjustment adjust	r pH
Water	Metals (dissolved chromium)	EPA Method 200.7	HNO₃ to pH <2; 4 °C	500 mL HDPE	10d	180d	
Water	Metals (dissolved chromium)	EPA Method 200.8	HNO ₃ to pH <2; 4 $^{\circ}$ C	500 mL HDPE	10d	180d	
Water	Hexavalent chromium	EPA Method 218.7	Cool to <4 °C	500 mL HDPE	10d	24h 7c	d
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:							

Notes:

EPA = United States Environmental Protection Agency TAT = Turnaround Time

HDPE = high-density polyethylene

 $HNO_3 = Nitric Acid$ d = day(s) h = hoursmL = 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 FREQUENCIESQUALITY ASSURANCE PROJECT PLANNevada Environmental Response Trust Site - Downgradient Study Area; Henderson, Nevada

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				

QUALITY CONTROL CHECK⁽¹⁾

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.

Appendix A

Laboratory Quality Manuals and EDD Format





QUALITY ASSURANCE PLAN

Laboratory Director/Quality Assurance Officer: John Sloan (702) 873-4478

Organizations covered by this Manual:

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1 QUALITY POLICY SUMMARY

1.1 Purpose

Silver State Analytical Laboratories is a private environmental, analytical laboratory certified by the State of Nevada. The objective of Silver State Analytical Laboratories (SSAL) is to provide its clients with quality analytical data which meets all regulatory requirements. The objective of this QAP is to provide a procedural basis that establishes laboratory requirements that enable and ensure the production of reliable and accurate analytical data by Silver State Analytical Laboratories.

- 1.1.1 To meet this goal, the staff of Silver State Analytical Laboratories commits to
 - 1. Promote client discussions to establish the scope and objective of a project, along with the suitability of analytical procedures and methods.
 - 2. Require application of analytical procedures and methods previously determined suitable for a project.
 - 3. Appoint a regime of laboratory QA procedures that maintain the precision and accuracy of data produced by SSAL personnel.
 - 4. Use of a rigorous quality control program to further verify the performance of the laboratory on a whole.
- 1.1.2 These commitments are implemented through the laboratory's quality system. This quality system is designed to meet the standards set forth by Nevada Department of Environmental Protection (NDEP). These protocols are included within this Quality Assurance Plan (QAP) and associated Standard Operating Procedures (SOPs).
- 1.1.3 The purpose of this QAP is to establish protocols to ensure that the analytical data provided to SSAL clients is accurate and reliable. Such protocols include:
 - A. QA procedure requirements for laboratory practices and procedures including sample collection, handling and analysis.
 - B. A description of the methods used to implement the QA procedures and requirements.
 - C. Client contact and communication
- 1.1.4 It is SSAL policy that all laboratory personnel follow all aspects of this Quality Assurance Plan (QAP). It is the responsibility of the Quality Assurance Officer (QAO) to ensure that all personnel of SSAL follow its QAP. The QAO is responsible for the supervision and policing of the laboratory personnel to assure the proper implementation this plan. The QAO reports directly to the President on all matters concerning laboratory quality assurance and control.

1.2 Goals

The goal of SSAL is to ensure that all measured data generated is scientifically and legally defensible. Additionally, the data must be of known and acceptable quality per the data quality objectives. This data must be documented to provide sound support for environmental decisions and comply with contractual requirements and environmental regulations established by local, state, and federal authorities.

Our specific goals are:

- 1.2.1 To provide a uniform framework for physical and chemical data generation.
- 1.2.2 To operate under a comprehensive, effective, and ongoing quality assurance program.
- 1.2.3 To instill a commitment to quality and excellence at all levels of operation and staffing.
- 1.2.4 To detect anomalies and nonconformance that would adversely affect data quality and integrity.
- 1.2.5 To monitor the QA/QC system for data accuracy, representativeness, comparability, completeness, and detectability through proven methodologies.
- 1.2.6 To enable personnel responsible for the production of data to identify and implement corrective actions necessary to ensure data integrity.
- 1.2.7 To establish a stringent system of QA/QC that is applied to all analytical procedures and data handling procedures as well as sample login and runs.
- 1.2.8 To have adequate document control.
- 1.2.9 To have good laboratory and measurement practices
- 1.2.10 To have good automated laboratory practices, and good standard operating procedures.
- 1.2.11 To have sufficient flexibility for customized QA procedures to meet customers' specific requirements for data quality.

In order to reflect better technologies and ever-changing regulatory requirements, this QAP will be reviewed and revised semi-annually or at the discretion of the QAO and Laboratory Director.

This QAP contains information that is considered confidential and proprietary in nature. It is intended for use only by the clients and staff of SSAL. Unauthorized reproduction or distribution of this document is strictly prohibited.

2.0 ORGANIZATION AND MANAGEMENT STRUCTURE

- 2.1. Business Organization
 - 2.1.1. Legal Organization: Silver State Analytical Laboratories, Inc. is a Nevada C-corporation. The stock shares are privately owned.
 - 2.1.2. The current organizational chart of the laboratory is included in Appendix 1.

- 2.1.3. The laboratory may assign the duties of more than one position described below to a single individual.
- 2.2. Management Responsibilities
 - 2.2.1. It is the responsibility of Laboratory Director to ensure that laboratory personnel carry out environmental sampling and analysis activities to meet the requirements of the Nevada Department of Environmental Protection (NDEP) and to satisfy the needs of the laboratory's clients.
 - 2.2.2. To meet these responsibilities, Laboratory Director will
 - ensure that sufficient resources are provided to the laboratory to meet the requirements of the applicable quality standards.
 - be responsible for the quality of data produced by the laboratory, including the implementation of data integrity procedures, and for documenting all analytical and operational activities of the laboratory.
 - ensure the proper supervision of all personnel employed by the laboratory.
 - nominate deputies in the absence of the Laboratory Director.
 - be responsible for establishing the minimum level of personnel qualifications and experience.
 - be responsible for keeping training of personnel up to date on laboratory quality documents, procedures, techniques, and operation of instrumentation.
 - be responsible for training personnel in ethical and legal responsibilities.
 - be responsible for documenting personnel training and performance.
 - ensure that laboratory personnel are free of undue commercial, financial or other pressures and influences that may adversely affect the quality of their work.
 - ensure that acceptable document control procedures are in place and are followed.
 - implement procedures to protect client confidentiality
 - support implementation of the quality system.
 - develop and implement policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity.
 - ensure participation by the laboratory in a proficiency testing program.

2.3. Job Descriptions and Personnel Qualifications

- 2.3.1. Laboratory Director
 - 2.3.1.1. Responsibilities- The person holding this position is responsible for administrative oversight and overall operation of the laboratory as defined by NELAC (Chapter 5). The Laboratory Director is responsible for the technical supervision of personnel, including coordination of work assignments. The Laboratory Director will define minimum qualifications, experience, and skills necessary for all technical employees. The Laboratory Director will ensure through an annual competency check that each technical employee demonstrates initial and ongoing proficiency for the tests the technical employee performs. The Laboratory Director will supervise and be responsible for the production and quality of all results reported by the certified laboratory. The Laboratory Director will assume responsibility for compliant sample handling, analysis, reporting, and chemical hygiene.

2.3.1.2. Qualifications

2.3.1.2.1. Laboratory Director: The educational and work history requirements and responsibilities of this position are listed in the NELAC (chapter 4). In general, the Laboratory Director must have a bachelor's degree in the biological, chemical, or physical science, with at least 24 college semester hours in chemistry, 4 college semester hours in General Microbiology, plus four years experience in a certified laboratory or a laboratory with equivalent requirements. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

2.3.2. Quality Assurance Officer (QAO)

- 2.3.2.1. Responsibilities. The QAO will
 - 2.3.2.1.1. serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data;
 - 2.3.2.1.2. be responsible for the laboratory's quality assurance program and its implementation;

- 2.3.2.1.3. maintain the laboratory's quality documents, including this Quality Assurance Plan;
- 2.3.2.1.4. review laboratory quality control data;
- 2.3.2.1.5. conduct or arrange for annual internal laboratory audits;
- 2.3.2.1.6. notify laboratory management of deficiencies in the quality system;
- 2.3.2.1.7. ensure any corrective actions arising from internal audits are implemented in a timely manner.

2.3.2.2. Qualifications

- 2.3.2.2.1. The QAO must be free from internal and external influences when evaluating data and conducting audits.
- 2.3.2.2.2. The QAO must have documented training and experience in QA/QC procedures and must be knowledgeable of the approved analytical methods and quality assurance program requirements.
- 2.3.2.2.3. The QAO must have functions independent from the operations for which they have quality assurance oversight and be able to evaluate data without outside influence.
- 2.3.3. Chemist/Technician

The chemists and technicians are responsible for routine analysis of all microbiology and wet chemical analyses following the laboratory SOP for each analysis. They follow all quality control procedures. They record analytical and Quality Control results as defined in the Standard Operating Procedures and this QAP. They operate and maintain analytical equipment. If there is a problem with precision or accuracy of an analysis, they will immediately investigate, troubleshoot and correct it. When appropriate, they will review these procedures with the Laboratory Director and corrective action will be taken. The chemists and technicians report to the Laboratory Director.

2.3.4. Branch Manager

The Branch Manager is responsible for customer service and overall operations of a Company Branch facility. Typically, this includes customer service scheduling, commercial terms, and allocation of resources to meet requirements for services (testing and environmental supplies) to clients of Silver State Analytical Laboratories, Inc. Unless the Branch Manager has specific analytical chemistry education and training; technical management and testing procedures are supervised and directed by the Laboratory Director, Quality Assurance Officer and Chemist/Technicians on site at the Branch Location in coordination and under the supervision of the main Las Vegas Laboratory Director and President. Laboratory Reports from Branch facilities are reviewed and signed and issued from the Main Laboratory following QC procedures contained in this manual. Reference Appendix 1- Organizational Structure.

- 2.4. Assignment of Deputies
 - 2.4.1. In the event of brief (<15 calendar days) expected or unexpected absences of the Laboratory Director, the senior person holding the highest level position in the lab will fill in for them as required.
 - 2.4.2. In the event of an absence from the laboratory of 15 calendar days or longer, the Laboratory Director will assign a deputy who meets all of the qualification requirements for the position.
- 2.5. Identification of Approved Signatories

The following individuals are authorized to sign laboratory reports:

- The Laboratory Director
- The Quality Assurance Officer
- Laboratory Chemists
- President

3.0 PROCEDURES FOR DOCUMENT CONTROL

This section describes procedures for document management, which includes controlling, distributing, and accepting modifications for all documents that make up the quality system. These include this Quality Assurance Plan (QAP) and related Standard Operating Procedures (SOPs), Laboratory Method SOPs, instrument manuals and any other documents that provide instruction to analytical personnel. All documents that affect the quality of laboratory data are managed appropriate to the scope and depth required.

- 3.1 Document Issue and Approval
 - 3.1.1 The laboratory will keep a master list of documents written by the laboratory that are part of its quality system. This list will include the title of the document, the revision, effective date, and distribution locations.

The Quality Assurance Plan, as well as all administrative and method SOPs will be included on this master list. The Laboratory Director is responsible to maintain the master list. The list must be revised each time a document is added or revised, as well as each time the distribution of a document changes.

- 3.1.2 Documents not written by the laboratory, such as instrument manuals prepared by the instrument manufacturer, will not be included on the master list. These documents will be kept on shelves that are accessible to laboratory personnel.
- 3.1.3 Distribution of quality system documents will be performed in a manner that ensures that only approved documents are in use in the laboratory and so that a historical record of instructions is maintained.
 - 3.1.3.1 The Laboratory Director/QA Officer prior to implementation must approve new documents and major revisions of older documents. The LD/QAO will carefully review the document prior to implementation, making any necessary changes before implementation of the document.
 - 3.1.3.1.1 When the new document is ready for implementation, the document will be saved to the appropriate drive on the computer network and a hardcopy will be placed in the SOP Binder.
 - 3.1.3.1.2 The author of the document and the Laboratory Director or designee must sign and date the document. If an additional reviewer is used, they may also sign the document but it is not required.
 - 3.1.3.2 Authorized editions of the QAP and related administrative SOPs will be kept on the laboratory's computer server. These are the master copies.
 - 3.1.3.3 Authorized editions of Laboratory Method SOPs will be kept on the laboratory's computer server. These are the master copies.
 - 3.1.3.4 Any other copies of these documents must be labeled as being "uncontrolled" or "draft" or some similar label so that it is clear that they are not to be relied on for current instruction.
 - 3.1.3.5 Whenever a new revision of a document is approved, the old version of the document will be removed from the "Current SOPs"

Binder, the cover sheet of the old document will be edited to include the retirement date, and the old version will be filed in an archive folder.

- 3.1.3.6 When a document is retired without a replacement, it will be edited to include the retirement date and will be filed in an archive folder.
- 3.1.3.7 All quality system documents prepared by the laboratory must be reviewed at least once per year. If no changes are required, the reviewer will date and initial the master list to indicate that the review has been performed and no changes are required. If changes are required, the document will be checked out, labeled as "Draft" or some similar label, and the revision process will be performed starting with that copy.
- 3.2 Document Identification

All documents will be uniquely identified in the header in the upper right hand corner of each page of the document. The identifier consists of an abbreviated version of the title of the document (*e.g.*, "QA Plan", "pH", etc.) combined with the revision number, which will be incremented for each new revision. The header must also include the effective date of the revision and the number of pages in the format of "Page X of Y" where Y is the total number of pages in the document.

3.3 Changes to Documents

- 3.3.1 Changes to documents must be made in a deliberate and controlled manner.
- 3.3.2 Minor changes to a document may be made to make editorial corrections, add clarification or correct minor errors in text. Make a minor change by checking the document out, making the correction, and checking the document back in.
 - 3.3.2.1 Changes to correct minor typographical errors that have no impact to the performance of the procedure (e.g. 'smaple' instead of 'sample') and insignificant modifications (e.g. a reagent vendor reference) may be made without Laboratory Director approval in the master copy. These changes are documented to ensure that they can be tracked throughout the life of the document.
 - 3.3.2.2 Changes to correct typographical errors (e.g. 0.5 g instead of 0.05 g) that may potentially impact performance of the procedure shall be considered major revisions and require Laboratory Director

approval and a new revision number (see major changes below).

- 3.3.3 Major changes to a document require that the document receive a new revision number and go through the full review process.
- 3.4 Standard Operating Procedures

STANDARD OPERATING PROCEDURES (SOPs) are used to ensure consistency of application of common procedures, are written procedures that describe in detail how to accurately reproduce laboratory processes, and are of two types, 1) test method SOPs, which have specifically required details, and 2) general use SOPs which document the more general organizational procedures. Copies of all SOPs are accessible to all personnel. Each SOP indicates the effective date, the revision number, and contains the signature(s) of the Laboratory Director/QAO.

- 3.4.1 Analytical Method SOPs
 - 3.4.1.1 The laboratory has SOPs for all test methods within its scope, and for procedures that are part of the Quality System that accurately reflect how the process is performed.
 - 3.4.1.2 All analytical method SOPs must contain all of the information required by NDEP. The SOPs must be definitive in their procedural descriptions, defining the specific procedures and equipment the laboratory has chosen to use to implement the analytical method.
 - 3.4.1.3 The laboratory maintains a standard format for analytical method SOPs as follows. Each heading listed below is a required primary heading in an analytical method SOP. Any required section may reference another laboratory SOP or the Quality Assurance Plan. The headings are listed as they should appear in the SOP.
 - 3.4.1.4 Format for Analytical Method SOPs
 - 1. TITLE

This Section includes the EPA or Standard Methods numbers and the analyte name (*e.g.*, BOD, Chloride, etc.). It is listed on the title page. The title is listed on the title page. See Section 3.5 for stylistic considerations for more information.

2. SCOPE AND APPLICATION

This section includes the basic objective of the method, the matrices that can be analyzed (*e.g.*, surface waters, drinking waters, sludges, etc.), and the practical range of the method, where applicable.

3. SUMMARY

This section is a brief outline of the method, written in paragraph form, excluding technical information.

4. DEVIATIONS FROM THE METHOD

This section lists all changes that have been made by the laboratory to an approved method. Examples of changes that could be made include chemicals, general supplies, or technical refinements.

- Any change in the chemistry of the method is not allowed. In some cases, changes of sample sizes may be allowed as long as all reagent amounts are changed proportionally.
- For each deviation or modification, list the specific requirement in the method, the deviation or modification implemented by the laboratory, and the justification for the deviation.
- For each choice made, the SOP will state the general area in which the choice is made and the particular choice selected by the laboratory.

5. **DEFINITIONS**

This section references a listing of definitions that will explain terminology used in SOPs and throughout the Laboratory.

6. INTERFERENCES

This section includes a list of known interferences extracted from Standard Methods, EPA Methods for Chemical Analysis of Water and Wastes, 40 CFR, or Method for Microbiological Analyses of Sewage Sludges, as well as any interferences noted during the laboratory's history.

7. SAFETY

This section includes a list of protective equipment analysts should wear when performing the procedure and specific warnings about any particularly hazardous materials used in the procedure.

8. EQUIPMENT AND SUPPLIES

This section includes a list of all apparatus used, from instruments to beakers and pipettes, and all supplies used, such as filters and disposable items.

9. REAGENTS AND STANDARDS

This section includes a list of all reagents and standards used, purchased or prepared for use in the method. For each prepared reagent, the listing will include preparation instructions unless the reagent is a common stock reagent such as water or a standard concentration acid.

10. SAMPLE COLLECTION, PRESERVATION AND STORAGE

This section includes temperature and chemical preservation requirements, container requirements, storage and holding time requirements.

11. QUALITY CONTROL

This section lists all of the batch and instrument quality control that must be performed with this method, including but not limited to standardization, interference checks, instrument performance checks, spiked samples and blanks. Preparation instructions for each QC type are included.

12. INITIAL DEMONSTRATION OF PERFORMANCE

This section references the current rules governing the performance of an initial demonstration or method required parameters. When the method is not amenable to spiking and requires a unique demonstration of capability, it must be described in this section

13. METHOD DETECTION LIMIT

This section includes a reference to the method used to determine the method detection limit, the approximate MDL expected, and the location of documentation of the laboratory MDL

14. CALIBRATION AND STANDARDIZATION

This section describes the standardization procedures of the method, including any required instrument performance checks. Limits used to evaluate the calibration may be included in this section or in section 16, or both at the analyst's discretion.

15. PROCEDURE

This section describes the procedure of the analysis in a step-by-step fashion. It is important for this section to be written describing how the analysts in the laboratory perform this method, as opposed to simply copying the method text into the SOP. Include descriptions of techniques and helpful hints for performing the analysis, determining proper performance, and for streamlining implementation of the procedure. It is extremely helpful to capture the analyst's knowledge of the procedure in this section.

16. DATA ANALYSIS AND CALCULATIONS

This section describes how results are calculated. All of the information and equations required will be listed or referenced here, unless they are already listed in a master QA document.

17. METHOD PERFORMANCE, DATA REVIEW AND ACCEPTANCE CRITERIA

This section lists the quality control limits that must be used to evaluate the batch quality control samples and instrument calibration standards. The section will also contain additional information on corrective actions and contingencies for handling out of control or unacceptable data.

18. REFERENCES

This section includes a list of all documentation reviewed to derive the method/procedure, including the primary published method.

19. TABLES

This section includes any tables or diagrams that may be helpful in understanding the procedure. This section may be left blank.

20. WORKSHEETS

This section contains an example of any laboratory work sheets. The examples are not controlled so that modifications may be made to the worksheets to aid the analysts without generating a revision to the SOP. The example should be updated during the annual SOP review.

3.4.3 Administrative SOPs

3.4.3.1 Administrative SOPs are formatted as is convenient for the procedure being described. Certain elements are required in all of the SOPs, but the document is formatted at the discretion of the writer. Each SOP will be clearly organized and written so that any member of the laboratory staff may use and understand it. Required sections include the following items.

TITLE

The title is listed on the title page.

PURPOSE

A brief paragraph stating the purpose of the SOP is included here.

APPLICABILITY

This section will list the procedures, systems, and personnel that are governed by the document.

SUMMARY

This section is a brief outline of the procedure or system, written in paragraph form, excluding technical information.

PROCEDURE

This section may be labeled in any logical fashion and is developed to guide the reader through the procedure in a logical fashion

Any other necessary sections.

These may include definitions, QA/QC considerations, logbook descriptions, special safety or waste handling procedures, flow charts, tables, diagrams, etc. Forms included in the SOP shall be regarded as examples unless the SOP states that the form must be controlled with the SOP. Forms may be modified without formal revision of the SOP. Forms with required formats must be modified only with formal revision of the SOP.

3.5. Stylistic Considerations

Standard Operating Procedures will be written in a consistent document style and font.

- 3.5.1.1. SOPs shall be written using fonts approved by the Laboratory Director, typically Arial or Times New Roman. Documents must be easily readable by all personnel.
- 3.5.1.2. Paragraphs will be numbered with an additional number after the digit of the main heading, as in this section.
- 3.5.1.3. Secondary headings will be indented one tab for each additional digit in the numbering system.
- 3.5.1.4. There are no required footers. Footnotes may be used for references to copyrighted materials.
- 3.5.1.5. A title and signature page will be placed on top of every SOP.
 - 3.5.1.5.1. The title page will include the name of the laboratory, the words "Standard Operating Procedure", and the title of the SOP.
 - 3.5.1.5.2. The title page will include the approval signature of the Laboratory Director and date approved. These signatures will document the approval by these

individuals of the document for use in the laboratory.

4.0 Procurement, Supplies and Equipment

The Laboratory Director is responsible for purchasing all laboratory supplies, equipment and subcontract services. The Laboratory Director is responsible for approving technical and quality requirements of each item and service purchased.

4.1 General Supplies

All supplies are purchased through "known quality" chemical suppliers i.e. VWR, Restek, Fisher, etc. Each item is purchased using a laboratory PO number.

4.2 Chemicals & Solvents

All chemicals used at Silver State Analytical Laboratories are ACS Reagent Grade, Spectrophotometric Grade, or HPLC Grade depending on method requirements. All chemicals are NIST traceable and/or traceable to the manufacturer. When chemicals are received, each one logged with the receiving date, source, lot number, expiration date, unique laboratory ID number and person whom received the compound into the corresponding logbook. Each chemical is marked with the date it is opened to ensure freshness. Certificate of analysis for chemicals are bound into a book for permanent storage. Whenever possible the each standard is validated against the previous standard. A solvent blank is run on each lot number of a new solvent to ensure quality. The solvent can only be used after it has been shown to have no contamination higher than the method detection limit for that analysis. Material Safety Data Sheets (MSDS) for each compound are kept in a separate loose-leaf notebook.

4.3 Glassware

All glassware is ACS Class A. All glassware is washed individually with brushes in phosphate-free 2% Liquinox detergent. Soap is removed by rinsing the glassware in tap water ten times followed by rinsing in reagent water ten times. Glass ware is then allowed to air dry on the dish rack. When appropriate glassware is washed in an acid bath before the final rinsing.

4.4 Water Type

a) Las Vegas Laboratory:

Tap water is provided by the Las Vegas Valley Water district and is used during the preparation of glassware cleaning solutions and during the initial rinsing of glassware. Reagent Water is provided through the use of a Nanopure ultrapure water system model 4741. The Nanopure water system is designed to produce Type I Reagent Grade Water equal to or exceeding standards established by ASTM, CAP, and NCCLS with bacterial endotoxin levels below 0.005 EU/ml. This reagent grade water is used for all analytical methods as well as the final rinse of all glassware cleansing. Reagent water is tested monthly to ensure that it possess conductivity levels less than 2.0 micromhos/cm at 25°C, Total Chlorine Residual <0.1 mg/L and Heterotrophic Plate Count <500 CFU/ml. Reagent water is annually tested to ensure the metals Pb, Cd, Cr, Cu, Ni, Zn are not greater than 0.05 mg/L per contaminant or collectively at 0.1 mg/L. b) Reno Laboratory:

Tap water is provided by the Truckee Meadows Water Authority through the City of Reno and is used during the preparation of glassware cleaning solutions and during the initial rinsing of glassware. Reagent Water is provided through the use of purchased distilled water from a major brand manufacturer. Purchased distilled water is designed to provide Type I Reagent Grade Water equal to or exceeding standards established by ASTM, CAP, and NCCLS with bacterial endotoxin levels below 0.005 EU/ml. This reagent grade water is used for all analytical methods as well as the final rinse of all glassware cleansing. Reagent water is tested monthly to ensure that it possess conductivity levels less than 2.0 micromhos/cm at 25°C, Total Chlorine Residual <0.1 mg/L and Heterotrophic Plate Count <500 CFU/ml. Reagent water is annually tested to ensure the metals Pb, Cd, Cr, Cu, Ni, Zn are not greater than 0.05 mg/L per contaminant or collectively at 0.1 mg/L.

4.5 Balances

Balances are calibrated annually by the National Calibration Inc. Calibration records are maintained in a loose-leaf binder maintained by the QA Officer. Balance calibration is verified daily through the use of ASTM Class I certified weights purchased through Mettler Toledo. These are certified every year through an accredited source. Documentation of this daily verification is maintained in a loose-leaf binder maintained by the QA Officer. Balances are recalibrated when this calibration verification fails protocol set forth in the SOP.

4.6 Thermometers

Thermometers are calibrated once a year through comparison to a NIST certified reference thermometer used only for thermometer calibration. The All thermometers used in refrigerators, freezers, incubators, and drying ovens are checked annually by the comparison to the reference thermometer. Any variance is recorded on the thermometer and discrepancies greater than 1°C results in the thermometer being discarded and replaced.

4.7 High Pressure Gases

High pressure gas cylinders used in the laboratory are purchased through Airgas. The cylinders are securely chained to the wall at all times. The following gases and corresponding instruments are in use in the laboratory.

Argon-ICP

Helium- IC, GC-MS, GC-FID

Nitrogen- Cold Vapor Mercury Analyzer, GC-FID, Oil & Grease Extraction system. Hydrogen- GC-FID

Air- GC-FID

4.8 Refrigerators and Freezers.

Refrigerators and Freezers are designated for either samples only or for standards and chemicals only. Refrigerators are kept at a constant temperature of $4^{\circ}C \pm 2$ using a calibrated thermometer and recorded each working day in a loose-leaf notebook maintained by the QA Officer. Freezers are kept at a constant temperature of $25^{\circ}C \pm 2$ using a calibrated thermometer and recorded each working day in a loose-leaf notebook maintained by the QA Officer.

4.9 Incubators

The coliform incubator is kept at $35^{\circ} \pm 0.5$ and is verified twice a day at least four hours apart using a calibrated thermometer and recorded each working day in a loose-leaf notebook maintained by the QA Officer. The BOD incubator is kept at $20^{\circ} \pm 1.0$ and is verified each day of use using a calibrated thermometer and recorded each working day in a loose-leaf notebook maintained by the QA Officer

4.10 Disposal

Chemicals are disposed of in accordance with state and federal regulations when either its expiration date is exceeded or it is determined that analytical results and performance is deemed inadequate using that reagent.

5.0 SERVICES TO CLIENTS

5.1 General

- 5.1.1 This laboratory primarily serves Nevada and adjoining states based clients both public and private.
- 5.1.2 Many of the procedures described in this section require some sort of documentation. Documentation of client information will be contained in e-mails or a telephone log.
- 5.2 Review of Requests, Tenders, and Contracts
 - 5.2.1 In general, the laboratory's workload is routine and static but unique unscheduled projects do occur occasionally. If the laboratory decides to change its scope significantly, the following items will be taken into consideration.
 - 5.2.1.1 The laboratory will verify that the proper accreditations are in place to perform the methods requested. If new methods are required, they will be implemented as a planned activity in accordance with this QAP.
 - 5.2.1.2 The laboratory will verify that the volume of work will not negatively impact the laboratory's ability to perform the new work and work previously contracted.

5.3 Subcontracting

5.3.1 In the event that Silver State Analytical Laboratories is unable to meet a client's requirements the sample may be subcontracted upon client approval. The subcontracted lab must be approved to meet the client's requirements. Instructions will be sent with a COC to the subcontracted

lab. The final report will clearly state that the work was completed by the subcontractor and not Silver State Analytical Laboratories.

5.4 Client Complaints

- 5.4.1 Complaints and/or input may be received from clients. Complaints will be documented using the e-mail system. The person receiving the complaint records the name of complainant, the date, contact number, problem, analysis involved, and who received the complaint.
- 5.4.2 The Laboratory Director or designee will evaluate all complaints. If it is determined that the complaint is without merit, it will be documented, the client will be contacted and the process will end.
- 5.4.3 If it is determined that the complaint has merit, the complaint will be documented (whether or not it is considered a quality system failure) using the Corrective Action Report and following the steps of the corrective action system. See the Corrective Action section of this QAP (Section 6.1) for more information.
- 5.5 Control of Nonconforming Work
 - 5.5.1 Non-conforming work is defined as work in which quality control outliers or quality system failures are identified. When discovered, the laboratory will investigate the situation and take action appropriate to the significance of the non-conformance using the corrective action system.
 - 5.5.1.1 The Laboratory Director (LD), Quality Assurance Officer (QAO), or designee will make an evaluation of the significance of the non-conformance.
 - 5.5.1.2 The laboratory will ensure that any corrective actions are taken immediately and documented appropriately using the laboratory's corrective action system.
 - 5.5.1.3 If necessary, the LD or QAO will direct the laboratory to stop work until the non-conformance is corrected.
 - 5.5.1.4 If it is determined that reported data was affected, the client will be notified in writing.
 - 5.5.1.5 If work has been halted, the LD or QAO will determine and document when work may be resumed.

5.5.1.6 The laboratory will follow its corrective action procedures to ensure that the problem will not recur and that the laboratory is operating in compliance with its policies and procedures.

5.6 Client Confidentiality

It is the laboratory's policy to protect client confidentiality. Information regarding these analyses shall not be disclosed to any other outside entity without specific permission from the client.

6.0 CORRECTIVE AND PREVENTATIVE ACTION

6.0 Corrective Action

- 6.1.1 The laboratory must have a process for performing a root cause analysis and taking corrective action when departures from policies, procedures, and QC requirements or when other types of exceptions occur.
- 6.1.1 The laboratory has defined processes to address two types of exceptions: quality control sample outliers and quality system failures.
- 6.1.2 A quality control sample outlier is the type of exception that occurs during an analysis or procedure where a quality control sample result, such as a QC spike recovery, does not conform to requirements. Procedures for required actions are included in the associated technical SOP. Note that a consistent pattern of quality control sample outliers is indicative of a quality system failure and shall be addressed as described below.
- 6.1.3 A quality system failure is the type of exception where an event within the overall quality system is not compliant with the NDEP standard or internal quality policies or procedures. Examples include, but are not limited to: findings from internal audits or NDEP assessments, Proficiency Testing sample failures, and deviations from the SOP. Quality system failures are remedied through the corrective action process and are documented using a Corrective Action Form.
- 6.1.4 The corrective action process must include the following elements:
 - 6.1.4.1 Definition of the problem, concern or failure
 - 6.1.4.1.1 The Laboratory Director, Quality Assurance Officer or Analytical Personnel may initiate the Corrective Action Process whenever quality system failures occur. The Laboratory Director or Quality Assurance Officer will

make the assignments or appoint responsibilities described in this section.

- 6.1.4.1.2 The issue shall be defined with adequate detail to allow further investigation. Typically, the important elements to include are:
 - what event(s) occurred
 - in what process did the event(s) occur
 - who witnessed the event(s) or performed the process
 - when (date/time) did the event(s) occur
 - where did the event(s) occur
 - what other processes were or may be impacted.
- 6.1.4.2 Investigation of the cause(s), including Root Cause Analysis
 - 6.1.4.2.1 Root Cause Analysis seeks to identify the origin of a problem. It assumes that systems and events are interrelated. One event leads to another, which leads to another. By tracing back these actions, you can discover the original source of the problem.¹
 - 6.1.4.2.2 Root causes are specific underlying causes that can be reasonably identified management has control to fix and effective recommendations for preventing occurrences can be generated.²
 - 6.1.4.2.3 Adequate data must be collected to allow effective Root Cause Analysis.
- 6.1.4.3 Identification of possible solutions
 - 6.1.4.3.1 If possible, generate several potential solutions to the root cause of the problem.
- 6.1.4.4 Selection of one or more of the proposed solutions appropriate to

¹"Root Cause Analysis: Tracing a Problem to Its Origins" http://www.mindtools.com/pages/article/newTMC_80.htm

² "Root Cause Analysis for Beginners", Rooney and Vanden Heuvel, <u>Quality Progress</u>, July, 2004

the magnitude and risk of the failure

- 6.1.4.4.1 Rank the potential solutions according to their likelihood of eliminating the problem, preventing its recurrence, the cost vs. benefit, and the risk of unintended negative impacts.
- 6.1.4.4.2 Select one or more actions appropriate to the magnitude of the problem and the risk of recurrence.
- 6.1.4.4.3 Assign personnel responsible for implementation.
- 6.1.4.4.4 Assign a completion date for implementation.
- 6.1.4.5 Implementation of the solution(s) within the specified time-frame
 - 6.1.4.5.1 Date of the implementation must be documented.
 - 6.1.4.5.2 Solutions that require major modifications to equipment, procedures or methods may require formal revisions to laboratory policies or procedures, formal validation processes and/or notification of the accrediting authority.
- 6.1.4.6 Follow up to verify the effectiveness of the change.
 - 6.1.4.6.1 The QAO will define what will be checked, assign a party responsible for following up, and ensure follow up occurred within a timely manner.
- 6.1.5 It is often beneficial to include as many laboratory personnel as possible in the corrective action process to facilitate generation of ideas.
- 6.1.6 The corrective action process shall be documented on the Corrective Action form and shall be filed in the Corrective Action Binder. Occasionally, during the investigation, Root Cause Analysis, implementation and/or follow up, supplemental data will be generated which will be maintained in an appropriate format for five years.
- 6.2 Preventive Action
 - 6.2.1 The laboratory will be aware of possible preventive actions that may be taken. Preventive actions are proactive actions taken to eliminate possible quality control sample failures or quality system failures before they

occur.

- 6.2.2 Performing appropriate preventive action requires a mindset of looking at laboratory operations with an eye toward seeing what could go wrong. Often, this will be based on what types of problems have been solved in the past. Preventive actions may come as a result of the management review process.
- 6.2.3 The preventive action process is as follows
 - Identify the needed preventive action
 - Develop an action plan to implement the action
 - Implement the action, with changes as necessary
 - Monitor to the results of the action to verify that the action taken is achieving the desired results and has not caused unanticipated negative impacts

Preventive actions should be documented. The corrective action system may be used to document the preventive action or another means may be used.

7.0 CONTROL OF RECORDS

7.1 General Considerations

The laboratory must retain all records required to demonstrate compliance to the NDEP standard and any other applicable regulations. The laboratory will retain all original observations, calculations and derived data, calibration records and a copy of the bench sheet for a minimum of five years from the date of the last entry into the record.

- 7.1.1 The procedures that follow in this section describe how the laboratory will maintain all necessary quality and technical records.
- 7.1.2 In general, working records are stored on shelves or in filing cabinets in the laboratory area or an offsite storage facility. Reasonable efforts are made to protect records from fire, theft, loss, environmental deterioration, and vermin. Only authorized personnel have access to this area.
- 7.1.3 Analytical data is stored as written documents and/or electronically in the laboratory area or an offsite storage facility. Data entered into electronic systems is stored on computer drives that are routinely backed up or the records may be printed and filed with paper documents. Data entered into paper systems is stored in folders or binders in the laboratory. Alternately,

paper data may be scanned into the computer system and then stored as electronic data.

- 7.1.4 A signature log is required. This log will include the name of each temporary or permanent employee, their signature and their initials. This is designed to allow the signatures and initials in the documentation to be easily traced to the personnel of the laboratory.
- 7.2 The Record Keeping System
 - 7.2.1 The record keeping system is designed to allow historical reconstruction of all laboratory activities that produced the analytical data. The history of the sample is to be understood solely through the documentation. To meet this goal, the following procedures are implemented.
 - 7.2.2 Each record includes the identity of personnel involved in the process recorded. All bench sheets, log books, and notebooks are designed to include the signature or initials of the personnel performing steps.
 - 7.2.3 Each step has a documentation process designed for it, including activities such as sampling, sample receiving, analysis, data review and reporting as well as information relating to the laboratory facilities and equipment.
 - 7.2.4 The record-keeping system is designed to contain sufficient information to facilitate identification of factors affecting the uncertainty and to enable the environmental test to be repeated under conditions as close as possible to the original.
 - 7.2.5 Records are kept in a logical manner to facilitate retrieval.
 - 7.2.6 Access to electronic records is controlled by username and password requirements for the computer drive(s) on which the files are stored.
 - 7.2.7 All data recorded by hand must be recorded directly, promptly, and legibly in permanent ink on the permanent record for that data.
 - 7.2.8 Entries made in records must not be obliterated by methods such as erasures, overwriting or markings. All corrections must be made using a single line strike out of the error. The individual making the correction must sign (or initial) and date the correction. If the reason for the correction is not readily apparent, a reason for the change shall be included. Other than typographical errors, corrections made to comment fields in electronic records will be appended to the existing record and the inaccurate portion of the record will be clearly identified.

- 7.2.9 Analysts must keep records of unusual occurrences in analysis or departures, intentional of inadvertent, from written procedures. When such events occur, the analyst must document on the appropriate bench sheet or log a description of the unusual situation or departure all actions taken to address it, and the results of those actions.
- 7.2.10 The laboratory will retain records of all 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.

7.3 Analytical Records

- 7.3.1 Each manual analysis performed in the laboratory has a bench sheet that is designed to track critical information required by the standard. Each bench sheet contains the following information.
 - 7.3.1.1 The following information must be recorded in a traceable manner. It is typically part of the bench sheet template, but some items may be recorded in logbooks in such a way that the analysis can be accurately reconstructed.
 - Identification of any instruments used.
 - The date of analysis, and when required, the time of analysis. The time is required if the holding time is 72 hours or less or when time critical steps are included in the analysis such as color development or incubations.
 - All manually calculated results (may be on a separate calculation sheet)
 - The initials or signature of the analyst
 - Sample preparation information including, as applicable, ID codes, volumes, weights, meter readings, calculations, reagents, temperatures, etc.
 - Sample analysis information
 - Standard and reagent identifications
 - Calibration information
 - Quality control sample information and results
 - The initials or signature of the data reviewer
- 7.3.2 Additional required information is contained in the reports generated by the laboratory, including the following items.
 - Data interpretation, assessment and reporting conventions

- Quality control assessment
- 7.4 Records Management and Storage
 - 7.4.1 All records (including those pertaining to laboratory instruments and support equipment) and reports are to be safely stored, held secure and in confidence to the client. Additionally, all records required to demonstrate compliance with the NDEP standard and any other applicable regulations must be made available to the accrediting authority during routine business hours of the laboratory.
 - 7.4.2 The laboratory has a system for managing all notebooks, logbooks, and records of data including data reduction, validation, storage and reporting.
 - 7.4.2.1 Standard and reagent logbooks are maintained in the laboratory area. Reagent Certificates of Analysis (C of A) may be maintained in hardcopy form in files in the laboratory area, or in electronic form either as a scanned document, downloaded document or a web link within a manufacturer's website.
 - 7.4.2.2 All records of sample preparation, analysis, calibration, raw data, data reduction and validation are collected on bench sheets or in logbooks customized for each analysis. Bench sheets are maintained in folders and filed with the completed reports in the laboratory area. At approximately the end of each year these data are placed in files in the laboratory area or boxed and placed in the archive.
 - 7.4.2.2.1 Analytical data for wet chemistry and microbiological methods are stored on bench sheets sorted by method/analyte and filed chronologically.
 - 7.4.2.2.2 Supporting data for wet chemistry and microbiological methods (*e.g.*, balance checks, temperature records, etc.) are stored separately from the analytical data in notebooks or files in the laboratory areas.
 - 7.4.2.2.3 Chain of Custody records are stored with the completed report in the designated area.
 - 7.4.2.3 The long-term storage area considered an archive area. Data stored here is protected from fire, theft, loss, environmental deterioration, vermin and magnetic sources. All data removed from this area, even for a short time, must be logged in the archive

access log.

- 7.4.2.4 After five years, records may be destroyed or, returned to the client.
- 7.4.3 In the event that the laboratory ceases to do business, Silver State Analytical Laboratories will maintain laboratory data for a minimum of five years. Any clients having data stored at the laboratory will be notified. The laboratory will transfer records to the clients who requested the analysis. Any data that the client cannot or will not take will be held in storage the required five years, and then will be discarded.

7.5 Other Requirements

7.5.1 Other documentation and records required by the standard, such as training documentation, sample receipt documentation, standard and reagent documentation, are discussed in the pertinent sections of the quality system.

8.0 INTERNAL AUDITS AND MANAGEMENT REVIEWS

8.1 Internal Audits

The QAO is responsible for organizing a complete review of all laboratory systems on at least an annual basis. The QAO or their designee may perform this review as long as the reviewer is independent of the function being reviewed.

- 8.1.1 The review must be performed by Laboratory Director or QAO.
- 8.1.2 Checklists are used to assist the audit procedure. This ensures that there is documentation of what items were checked and the corresponding results.
- 8.1.3 Deficiencies discovered during the auditing process are rectified and documented using the corrective action process. Minor deficiencies that can be immediately fixed may be noted in the audit report as being completed at the time of the audit and are not required to be documented with a formal corrective action.
- 8.1.4 If audit findings cast doubt on the correctness or validity of calibrations or analytical results, immediate corrective action must be taken.
- 8.1.5 Specific parts of the review are detailed below.
 - 8.1.5.1 Quality Systems review. The overall quality system is reviewed

using a checklist developed for this purpose. A checklist may be derived from the NELAC laboratory audit checklist or other reliable source. It may be modified as needed to meet the situation of the laboratory. Checklists are not controlled documents, but tools to remind the auditor of items to check and to provide a mechanism for documenting the items reviewed.

- 8.1.5.2 Quality Assurance Plan Review. The Quality Assurance Plan is reviewed at least annually. The review is designed to ensure that laboratory personnel are complying with its policies and procedures. At a minimum, the review will consist of reading the manual on an annual basis, deleting, updating and modifying the contents of the manual, and conducting refresher training for the laboratory personnel on the updates and changes of the manual.
- 8.1.5.3 Training files. Training files must be reviewed to ensure that the training for all of the methods each analyst is using is up to date and appropriately documented.
- 8.1.5.4 Proficiency Testing records. PT sample records are reviewed to verify that all required elements have been addressed.Additionally, the Laboratory Director or QAO will track all PT results to ensure that there are PT results for all certified parameters at the required twice-annual frequency.
- 8.1.5.5 Review of records—a selection of records, which may include data, sample receiving, thermometer calibration, balance and weight calibrations, etc., will be reviewed. The record review will be documented on the checklist. The review will consist of ensuring the records meet the requirements listed in laboratory procedures and policies.
- 8.1.5.6 Review of purchasing of certified standards. The laboratory QAO will review the electronic system that tracks certificates of purchased certified or reagents. The review will also consist of reviewing the standard preparation logbooks for completeness and adherence to laboratory policy and procedure. The review will be documented on the checklist.
- 8.1.5.7 Review of quality control schemes is performed when the laboratory QAO reviews the methodology performed by the laboratory personnel as stated in Section 4.1.3.
- 8.1.6 Laboratory Method Standard Operating Procedures-The Laboratory

Coordinator, QAO or designee will compare the laboratory SOP for each certified method to the actual laboratory practice at least once every two years.

- 8.1.6.1 The comparison to the method is performed by taking each section of the method and comparing it to the laboratory's SOP. If anything has changed, for example a new instrument has been introduced to the method, or if errors are discovered, the laboratory SOP will be revised. The laboratory may develop a checklist to aid in this comparison.
- 8.1.6.2 The comparison of the SOP to laboratory practice is accomplished by interviewing and/or observing the laboratory personnel performing the method. The laboratory may develop a checklist to aid in this comparison. The review may be documented using a form or by writing directly on an uncontrolled copy of the SOP.
- 8.1.7 Review of Quality Control Data. Quality Control Data is reviewed on an on-going basis at the time data is reported. Reviewer will take appropriate action if trends are identified that would negatively impact data quality.

8.2 Management Review

- 8.2.1 The Laboratory Management is responsible for performing an annual management review of the laboratory. The review is performed by the Laboratory Director's supervisor. The focus of the management review is on the sufficiency of the Quality Assurance Plan and system to meet the standards set by NDEP.
- 8.2.2 The review will include but is not limited to the following items:
 - 8.2.2.1 The suitability of policies and procedures, including data integrity procedures
 - 8.2.2.2 Results of the annual assessment
 - 8.2.2.3 Results of proficiency testing samples
 - 8.2.2.4 Corrective and preventive actions
 - 8.2.2.5 Results of any external assessments, e.g., certification assessments
 - 8.2.2.6 Any changes in the volume or type of work, particularly anticipated changes
 - 8.2.2.7 Review of client complaints or other client feedback
 - 8.2.2.8 Any other relevant factors, such as quality control activities, resources, and staff training.
- 8.2.3 A record of the discussions included in the review will be kept on file in

the laboratory.

8.2.4 Any deficiencies identified during the management review will be rectified using the corrective action system described in the QAP. Documentation will be kept (using the corrective action system) to verify that the actions are completed within the time frame agreed upon during the management review.

Any preventive actions identified will be dealt with as described in the Preventive Action section of this QAP. Preventive actions must also be documented.

9.0 PERSONNEL TRAINING

9.1 General

- 9.1.1 The laboratory is required to ensure the competence of all personnel who operate equipment, perform environmental tests, evaluate results and sign reports. Personnel in training must be directly supervised until they have demonstrated capability for the task being performed. Personnel performing specific tasks must be qualified based on appropriate education, training, experience and/or demonstrated skill, as required.
- 9.1.2 The laboratory must have sufficient personnel with sufficient education, training, technical knowledge and experience to perform the activities of the laboratory.
- 9.1.3 All personnel are required to understand and comply with all quality assurance and quality control requirements that pertain to their job. The combination of training and experience must allow personnel to have a specific knowledge of their particular function as well as a general knowledge of laboratory operations, test methods, QA/QC procedures and records management.
- 9.1.4 In the event contract personnel are used in the laboratory, they must be properly supervised and meet all training requirements for the position they hold. This compliance must be documented.
- 9.1.5 The laboratory must maintain current job descriptions of all personnel in the laboratory.

9.2 Specific Requirements

9.2.1 Each analyst must demonstrate capability for each test method used in the laboratory initially, prior to reporting samples using the method, and on an

annual basis thereafter. The training must be documented. Specific requirements and procedures are detailed in the "Training" SOP.

- 9.2.2 Each analyst must read, understand, and agree to abide by all sections of the quality system that apply to their position. This must be performed and documented as described in the "Training" SOP.
- 9.3 Data Integrity Training

The laboratory is required to have in place a program to detect and prevent improper, unethical, or illegal actions. The program in place in the laboratory includes the following elements

- Data integrity training
- Documentation signed by each employee
- In-depth, periodic monitoring of data integrity
- Documentation of data integrity procedures.
- 9.3.1 Data integrity training is required as a part of the initial new employee orientation and annually thereafter. The following requirements will be met in the training
- 9.3.2 All topics must be documented in writing and provided to all trainees.
- 9.3.3 Topics must include the following items
 - The relationship of the laboratory mission to the critical need for honesty and full disclosure in all data reporting
 - The importance of proper narration where collected data may be useful, but are in one sense or another partially deficient
 - Definitions and examples of improper, unethical, or illegal actions
 - A description of the program for prevention and detection of these types of actions
 - Defined consequences for violating the data integrity policy.
 - How and when to report data integrity issues
 - Record keeping requirements.

At the conclusion of each data integrity training session, laboratory personnel will be required to sign a statement that they understand and agree to abide by the data integrity provisions in the laboratory.

9.4 Ethics Training

9.4.1 All employees involved in the handling process of samples will undergo an ethics training program. In the absence of a formal NDEP program for ethics Silver State Analytical labs has chosen to use the New York Association of Approved Environmental Laboratories (NYAAEL) program. All employees involved in the sample handling process will undergo the initial NYAAEL initial ethics program course shortly after initial hire. In addition all employees involved in the sample handling process are also required to complete the ethics refresher course each year offered by NYAAEL. Certification that this training has been completed will be stored in the Employees permanent training file.

10.0 ACCOMODATION AND ENVIRONMENTAL CONDITIONS

10.1 General Considerations

- 10.1.1 The laboratory must ensure that all of the laboratory facilities, including but not limited to the physical space and layout, energy sources, lighting and environmental conditions are such that they allow correct performance of the environmental tests.
- 10.1.2 The laboratory must also ensure that environmental conditions do not invalidate the tests being performed. This is true in the laboratory as well as for testing performed away from the laboratory.
- 10.1.3 Access to the laboratory is controlled. Only authorized laboratory personnel are allowed past the office area into the areas of the laboratory where analyses are performed. In the event that a person must enter the laboratory they will sign the visitor's log and be supervised by a laboratory employee for the extent of their time in the laboratory.
- 10.2 Laboratory Description
 - 10.2.1 The Las Vegas laboratory is located at 3638 E. Sunset Rd. Suite 100, Las Vegas, NV 89120 and has sufficient workspace for conducting all laboratory activities. The Reno Laboratory is located at 4587 Longley Lane, No. 2, Reno, NV 89502 and has sufficient work space for conducting all laboratory activities per the NDEP scoping letter.
 - 10.2.2 The laboratories have adequate storage space to contain and store all needed supplies, reagents, and equipment.
 - 10.2.3 The laboratories have adequate lighting and ventilation for the work performed. Temperature and humidity are maintained with instrument and

analytical considerations in mind.

10.3 Environmental Conditions

- 10.3.1 The laboratory monitors and controls all environmental conditions that affect the test methods used in the laboratory, including all those that are required by a specific test method.
- 10.3.2 The ambient temperature of the laboratory is maintained appropriately for performing pH measurements and measuring DO in the BOD test. The laboratory is generally maintained between 68 76 °F. Laboratory ambient temperature will be adjusted if samples are consistently outside the desired range.
- 10.4 Housekeeping
 - 10.4.1 Laboratory personnel should keep unused glassware put away except during use to minimize clutter in the work areas.
 - 10.4.2 Laboratory benches are kept clean appropriate to the tests being run.
 - 10.4.3 Work spaces, walkways, laboratory benches and other work areas are kept clear and uncluttered.
 - 10.4.4 No other specific procedures are required to prevent cross contamination from one procedure to another.

11.0 ENVIRONMENTAL TEST METHODS AND METHOD VALIDATION

- 11.1 Test Methods
 - 11.1.1 The laboratory uses only methods from recognized methods compendia such as *Standard Methods for the Examination of Water and Wastewater*, Annual Book of ASTM Standards and methods published by the Environmental Protection Agency. If the laboratory ever needs to use methods that are not from a recognized source, they will be fully validated as described in NELAC Chapter 5. Since it is unlikely that such methods will ever be required, the validation process is not included in the written quality system of the laboratory.
 - 11.1.2 When choosing methods to apply to client samples, the laboratory ensures that all analyses for which the results are to be submitted for regulatory purposes are performed using methods certified by the accrediting body.

- 11.1.3 The laboratory uses appropriate methods for all other laboratory operations, including sampling, transport, sample receipt, sample handling, storage and preparation of samples and, where appropriate, for the estimation of measurement uncertainty and statistical evaluation of data.
- 11.1.4 The laboratory maintains instructions for all processes where the absence of such instructions could jeopardize the results of its analyses. All such instructions are kept up to date and are readily available to laboratory personnel.
 - 11.1.4.1 The instrument manuals provided by the manufacturer are the instructions used for instrument operation.
 - 11.1.4.2 Instructions for laboratory processes that are not analytical methods are contained in this QAP or in related SOPs.
 - 11.1.4.3 SOPs for analytical methods in this QAP
- 11.1.5 The laboratory maintains a list of all methods for which accreditation is sought.
- 11.1.6 All methods used by the laboratory are fully documented in Standard Operating Procedures. The format to be used when writing SOPs is specified in Section 3 of this QAP.
- 11.2 Validation
 - 11.2.1 Prior to implementation in the laboratory, each method must be demonstrated to be functional in the laboratory with a Demonstration of Capability. The DOC must be performed at the implementation of a method and again every time there is significant change in equipment, personnel, or method. Since the DOC is required for every analyst prior to method performance, no additional method DOC is required. Details on performing the DOC are located in the SOP.

12.0 UNCERTAINTY OF MEASUREMENT

- 12.1 Uncertainty of Measurement
 - 12.1.1 It is required that the laboratory have a process for estimating the uncertainty of measurement for each reported parameter, if applicable. These values will be reported whenever they are requested by a client. It

is unlikely that a client of the laboratory will ever request the uncertainty associated with any values reported by this laboratory. Nevertheless, the laboratory has a procedure for developing uncertainty values.

- 12.1.2 If uncertainty values are requested by the client, the laboratory will attempt to make a determination as to whether the client is interested in obtaining the uncertainty values associated with the laboratory performance or with the entire measurement process.
 - 12.1.2.1 If the client is interested only in the laboratory uncertainty, this can be determined by developing control charts of LCS determinations.
 - 12.1.2.1.1 Chart the LCS values for at least 20 analyses. For pH analyses, use the second source standard values.
 - 12.1.2.1.2 Determine the 95% confidence limits for the charted values. Determine the standard deviation of the values and express it as a percent of the LCS target value. Multiply the standard deviation (in percent) by a factor of two. This value will provide the confidence interval in the uncertainty expression.
 - 12.1.2.1.3 Determine the average of the LCS recovery data. Express it as a percent of the target value. This will provide a measure of the systematic bias of the laboratory measurement.
 - 12.1.2.1.4 The client data can then be reported with an uncertainty interval for either a single value or an average of more than one value. To determine the uncertainty interval, multiply the value or average value, whichever is desired, by the 2SD value (in percent, expressed as a decimal) determined above. Determine the upper limit by adding the result to the reported value or average value. The result from the reported value or average value. The result of this calculation is the uncertainty interval expressed in the same units as the result.
 - 12.1.2.2 Correct the uncertainty interval for the systematic bias determined above by dividing the values obtained for the upper and lower limits of the uncertainty interval by the bias determined above (in percent, expressed as a decimal).

12.1.3 Determination of total uncertainty including sampling and matrix effects is beyond the scope of this QAP.

13.0 CONTROL OF DATA

- 13.1 Data Collection
 - 13.1.1 Calculations and data transfers must be verified in an appropriate and systematic manner.
 - 13.1.2 All analyses in the laboratory have a bench sheet designed for them that guides the analyst to record all of the information required.
 - 13.1.3 Data is recorded on the bench sheets promptly at the time of the analysis. Proper documentation procedures must be used as described in Section 7 of this QAP. Analysts review the QC information at the time of analysis.
 - 13.1.4 The analyst signs or initials and dates the bench sheet to indicate that they have performed the steps indicated and that the analysis meets acceptance criteria or has exceptions that are noted in the comments section of the bench sheet.
 - 13.1.5 When the analyst has finished the analysis, another person in the laboratory checks the bench sheet for the following items.
 - All required information has been recorded on the bench sheet.
 - QC criteria have been met or exceptions are documented in the comments section of the bench sheet.
 - Manual calculations are spot checked to verify accuracy.
 - Data that was originally captured manually is correctly transferred to the electronic version of the bench sheet.
 - 13.1.6 When these checks have been completed, the reviewer signs or initials and dates the bench sheet to document that the review has been performed.
 - 13.1.7 The data from the bench sheet is then entered into an Excel spreadsheet.
- 13.2 Automated calculations
 - 13.2.1 Some analyses in the laboratory have spreadsheets that have been designed to perform the calculations necessary to generate the reportable results. All spreadsheets created for the laboratory will be validated for

use prior to implementation.

- 13.2.2 This validation will typically consist of a manual confirmation of the calculations performed by the spreadsheet. This verification will be kept on file in the laboratory.
- 13.3 Software Validation
 - 13.3.1 Instrument software provided by the instrument vendor or by a recognized third-party vendor is considered to be validated by the vendor.
 - 13.3.2 Office software applications such as Word and Excel are considered to be validated by the vendor.
 - 13.3.3 Any software applications designed in the laboratory must be validated by the laboratory. See the section above for a description of the validation procedure for spreadsheets. This same process is followed if any other types of applications are designed in the laboratory.
- 13.4 Data Integrity
 - 13.4.1 All records shall be maintained in a manner that facilitates documentation tracking and allows historical reconstruction of all analytical events and ancillary procedures that produced the resultant sample analytical data. The system shall link all documentation through the final analytical result. This may be accomplished through either direct or cross-references to specific documentation. The system shall be straightforward and shall facilitate the retrieval of all working files and archived records for inspection and verification purposes. Final reports, data summaries, or other condensed versions of data that have been prepared by external parties shall be linked to internal records by an unequivocal cross-referencing mechanism (laboratory ID numbers).
 - 13.4.2 Entries into all records must be written legibly and must be made with waterproof ink. All documentation entries shall be signed or initialed by responsible staff. Entries in records shall not be obliterated by erasures or markings (whiteout products are not to be used).
 - 13.4.3 All corrections to record-keeping errors shall be made by one line marked through the error. The individual making the correction shall sign (or initial) and date the correction.
 - 13.4.4 When a sample collection, preservation or handling anomaly is noted, the report and corrective action will be verified by a second sample receipt technician.
 - 13.4.5 The chemistry technician checks the final reports against the original COC when the final report is generated. The data entry for results is

checked within the analytical units and validated by the laboratory Director.

- 13.4.6 Hard copies of final reports are kept in folders and filed using the following guidelines: by year, by assigned lab number
- 13.4.7 Lab numbers are filed in descending order. All COCs are kept in the file with the reduced data. All final reports can be linked to internal records via lab number. Results may be accessed by the data user via computer after analysis is completed and approved.

Any software applications designed in the laboratory must be validated by the laboratory. See the section above for a description of the validation procedure for spreadsheets. This same process is followed if any other types of applications are designed in the laboratory

14.0 EQUIPMENT

- 14.1 General
 - 14.1.1 The laboratory furnishes all of the equipment necessary to perform the analyses for which certification is sought.
 - 14.1.2 Equipment and the software associated with it, if applicable, is capable of achieving the accuracy required by the specific analytical methods.
 - 14.1.3 All equipment having an effect on the accuracy or validity of analytical results must be calibrated or verified prior to being put into service and on a continuing basis.
 - 14.1.4 Prior to use each working day, all balances, ovens, refrigerators, freezers, and incubators are checked with NIST-traceable references in the expected working range.
 - 14.1.5 Acceptability for use is based on the needs of the analysis or application for which it is used.
 - 14.1.6 All equipment, including both hardware and software, must be safeguarded from adjustments which would invalidate the test results.
- 14.2 Calibration of Analytical Instruments
 - 14.2.1 General Considerations
 - 14.2.1.1 Calibration procedures are described in detail in the analytical method SOP.

- 14.2.1.2 Sufficient raw data records must be retained to permit reconstruction of the instrument calibration. Data must include the 14.2.1.2.1 calibration date
 - 14.2.1.2.1 calibration us 14.2.1.2.2 test method
 - 14.2.1.2.2 test include 14.2.1.2.3 instrument
 - 14.2.1.2.4 analysis date
 - 14.2.1.2.5 analyte name
 - 14.2.1.2.6 analyst's initials or signature
 - 14.2.1.2.7 concentration and response
 - 14.2.1.2.8 the equation or other mathematical terms used to reduce instrument responses to concentration. Records of the mathematical equations used by on-board software are not required.
- 14.2.1.3 Samples must be quantitated using the initial calibration.
- 14.2.2 Initial Calibration
 - 14.2.2.1 All initial instrument calibrations must be verified with a standard obtained from another source, such as another manufacturer or a second, independent lot from the same manufacturer. Traceability must be to a national standard when one is available.
 - 14.2.2.2 Criteria for acceptance of the initial calibration must be established and included in the method SOP.
 - 14.2.2.3 The lowest calibration standard is the lowest concentration for which quantitative data are reported. Any data reported below the lower quantitation limit must be qualified on the final report as having a greater uncertainty.
 - 14.2.2.4 The highest calibration standard defines the upper limit of the calibrated range of the instrument. Any data reported from concentrations above the upper standard must be qualified on the final report as having a greater uncertainty.
 - 14.2.2.5 If initial calibration results do not meet the acceptance criteria defined in the method or method SOP, corrective actions must be performed and all associated samples reanalyzed. If this is not possible, the data must be reported with appropriate qualification.
 - 14.2.2.6 If the reference method does not specify the number of

calibration standards required, the minimum number is two, one of which must be at the limit of quantitation, not including blanks or zero standards.

14.2.3 Continuing Calibration Verification

- 14.2.3.1 When an initial calibration is not performed on the day of analysis, the validity of the initial calibration must be verified prior to sample analysis using the continuing calibration verification process.
- 14.2.3.2 Calibration must be verified for each compound, element, or other discrete chemical species, except for multicomponent analytes where a representative chemical related substance or mixture can be used. In some analytical procedures, the same solution preparation may meet the requirements to be both the CCV and the LCS. In this case, the requirements of both may be met by a single analysis of the solution.
- 14.2.3.3 Instrument calibration verification must be performed:
 - at the beginning and end of each analytical batch
 - whenever it is expected that the analytical system may be out of calibration or might not meet the verification acceptance criteria
 - if the time period for the most previous calibration verification has expired
 - for analytical systems that contain a calibration verification requirement
 - at the rate defined within the referenced method
- 14.2.3.4 In addition to other data requirements noted above, the records must explicitly connect the continuing calibration verification data to the initial instrument calibration.
- 14.2.3.5 Acceptance criteria for the continuing calibration verification must be established in the laboratory method SOPs. If the CCV does not pass the criteria, corrective action must be performed.
 - 14.2.3.5.1 Routine preventative maintenance may be performed and a second CCV analyzed immediately. If the second CCV passes, sample analysis may be resumed.

- 14.2.3.5.2 If the second CCV does not pass, the laboratory may perform additional maintenance. If this option is chosen, the laboratory must demonstrate acceptable performance with analysis of two consecutive acceptable CCVs prior to re-starting analysis.
- 14.2.3.5.3 If the laboratory cannot demonstrate acceptable performance with the CCVs, a new initial calibration must be analyzed and verified before proceeding with sample analysis.
- 14.2.3.6 There are two special circumstances in which data may be reported from an analysis where the CCV was not acceptable.
 - If the acceptance criteria were exceeded high (*i.e.*, there is a high bias) and the associated samples show the analyte as non-detected, those samples may be reported.
 - If the acceptance criteria are exceeded low and the results exceed a regulatory maximum or decision level, those results may be reported.
- 14.3 Preventive Maintenance and Instrument Documentation
 - 14.3.1 All equipment must be properly maintained, inspected and cleaned. Maintenance procedures must be documented.
 - 14.3.2 Each piece of analytical equipment that requires calibration or monitoring must be uniquely identified. This is accomplished in the laboratory by using the manufacturer and model number of each piece of equipment. In the event that duplicate pieces of equipment are present in the laboratory, a different unique identifier will be added to the description.
 - 14.3.3 The laboratory maintains a log book for each instrument that includes the following information
 - The identity of the item and non-integral software, if applicable
 - The manufacturer, model number, and serial number
 - The current location of the instrument
 - A record of all maintenance carried out to date, including all routine, non-routine, and third-party vendor maintenance
 - A record of any malfunctions, modifications, or repairs
 - The date received and the date placed in service, if known

- The condition when received (*e.g.*, new, used, reconditioned), if known
- 14.3.4 The laboratory keeps copies of the instrument manuals as instructions for use. The copies are kept in or near the laboratory for easy reference.
- 14.3.5 The laboratory keeps all instrument calibration data.
- 14.3.6 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits must be taken out of service. It shall be isolated or clearly labeled or marked to be out of service until it has been repaired and shown by calibration or test to perform correctly. Additionally, the laboratory must examine the effect of the problem on previous environmental tests and shall institute the "Control of non-conforming work" procedure, if necessary.

If the laboratory ever uses equipment that is outside the control of the laboratory, or if the laboratory's equipment ever goes outside the direct control of the laboratory, the laboratory must take responsibility for checking to ensure that the equipment still functions correctly prior to returning the equipment to service in the laboratory.

15.0 MEASUREMENT TRACEABILITY

- 15.1 Measurements
 - 15.1.1 The laboratory maintains a program of measurement traceability that is detailed in various places in the quality system. All equipment must be calibrated before being put into use.
 - 15.1.1.1 Analytical instrumentation is calibrated in accordance with the Section "Equipment" of this QAP and with the analytical method SOP.
 - 15.1.1.2 Support equipment is calibrated in accordance with Section "Equipment" of this QAP.
 - 15.1.2 Laboratory equipment is demonstrated to provide the uncertainty of measurement needed through passing initial demonstrations of capability for specific methods. Support equipment is traceable to national standards through NIST-traceable thermometers and class 1 weights.
 - 15.1.3 Analytical standards are traceable to reference materials and are routinely verified through the analysis of second-source standards and participation

in Proficiency Testing programs.

- 15.1.4 Reference Standards and Traceability. The laboratory maintains a program of calibration for its reference standards to ensure traceability in SI units of measurement to international standards.
 - 15.1.4.1 Reference Thermometer
 - 15.1.4.1.1 A NIST-traceable thermometer will only be used to check the working thermometers. The calibration of this thermometer will be verified by an outside calibration vendor every five years.
 - 15.1.4.1.2 The vendor providing the thermometer calibration check will provide a certificate stating the specific metrological specification used to evaluate the thermometer. This certificate will be kept on file by the laboratory.
 - 15.1.4.1.3 The NIST-traceable thermometer is stored in a protective case and is protected from shock or extreme temperature that could disrupt the mercury column.

15.1.4.2 Reference Weights

- 15.1.4.2.1 Class 1 weights are used to check the balance calibration on a daily basis and are used for no other purposes. The Class 1 weights will be verified every five years by an outside calibration vendor and will be calibrated if necessary.
- 15.1.4.2.2 The vendor will provide a certificate of calibration stating the specific metrological specification used to evaluate the weights. This certificate will be kept on file by the laboratory.
- 15.1.4.2.3 The Class 1 weights are stored in a protective case and handled with forceps specifically for that purpose. They are handled carefully to avoid dropping them or contaminating them by touching them with anything but the forceps. Alternatively, they may be handled directly using a fresh pair of clean, non-talc gloves.

15.1.5 Reference Materials (Standards) and Reagent Traceability

- 15.1.5.1 Analytical Standards
 - 15.1.5.1.1 Analytical standards are purchased with certificates of analysis showing them to be valid reference materials.
 - 15.1.5.1.2 Procedures for preparing working standards are designed to ensure traceability to the primary analytical standard. The procedures are described in Section 16 of this QAP.
 - 15.1.5.1.3 Standards are stored in accordance with label instructions in order to preserve the integrity of the standard.
- 15.1.5.2 Documentation and Labeling of Standards, Reagents, and Reference Materials
 - 15.1.5.2.1 The laboratory maintains documented procedures for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.
 - 15.1.5.2.2 The laboratory retains records for standards, reagents and reference materials, including the following information:
 - The Manufacturer or Vendor
 - The manufacturer's Certificate of Analysis or purity (if supplied)
 - The date of receipt
 - Recommended storage conditions
 - An expiration date after which the material will not be used unless its reliability is verified by the laboratory
 - 15.1.5.2.3 The laboratory will not use prepared reagents, standards, or purchased chemicals outside the expiration date of the material.
 - 15.1.5.2.4 Original containers are labeled with an expiration date.
 - 15.1.5.2.5 Records are maintained on the preparation of standards

and reference materials. The records include information to show traceability to purchased stocks or neat compounds and include the following information.

- Reference to the method of preparation
- Date of preparation
- Expiration date
- Preparer's signature or initials
- 15.1.5.2.6 All containers of prepared standards and reference materials are labeled with a unique identifier and expiration date. The identifier is linked to the preparation records.
- 15.1.5.2.7 Reagents are prepared from reagent grade chemicals, at a minimum, unless a lesser grade of chemical is specifically listed in the reference method. Quality control checks of the method demonstrate that the reagents meet the requirements of the methods.
- 15.1.5.2.8 All containers of prepared reagents are labeled with a unique identifier, which includes the preparation date, and an expiration date.

16.0 SAMPLING

- 16.1 Silver State Analytical Laboratories offers sampling services to clients. These procedures are described in detail in the SOP *Sample Management*. Since sampling is an integral part of the service offered by the laboratory, it is important that laboratory personnel include this SOP and the procedures it describes as part of their training.
- 16.2 Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, instructions are given in the laboratory method SOP on how to obtain a representative subsample.
- 16.3 If a client requests deviations, additions, or exclusions from the procedure described in the SOP *Sample Management*, these will be recorded in detail with the appropriate sampling data and will be included in all documents containing the resulting test data. These deviations must be communicated to the appropriate personnel.
- 16.4 Laboratory Technicians working for the laboratory are required to keep records of the sampling procedure used, the identification of the sample, and any other records

necessary to identify the sampling site.

17.0 HANDLING OF SAMPLES

- 17.1 The laboratory maintains a system to identify each sample unambiguously for the life of the sample in the laboratory. This system is described in detail in the SOP *Sample Receipt and Login*.
- 17.2 Any samples or sample preparations determined to be hazardous are returned to the client for proper disposal or collected and sent to a hazardous waste disposal facility.

18.0 QUALITY CONTROL

- 18.1 General
 - 18.1.1 The laboratory is required to have quality control (QC) procedures in place to monitor the analyses performed by the laboratory. QC data must be recorded and must be subject to planned reviews. In addition to review of QC data, the following procedures are used to demonstrate continuing compliance of laboratory operations.
 - Regular use of reference materials and secondary reference materials
 - Participation in a twice-annual proficiency testing program
 - Replicate testing of spiked and unspiked samples

Each of these types of quality control checks are described elsewhere in this QAP.

18.2 Essential Quality Control Procedures

The laboratory maintains a quality control program designed to be compliant with the NDEP standards and with accepted laboratory practices.

18.2.1 The laboratory has in place the following quality controls.

- Spiked samples and blanks to be used as positive controls
- Blank samples to be used as negative controls
- Duplicate samples to be used to define variability or repeatability
- Calibrations, use of reference materials and proficiency test samples to assure accuracy
- Defined mathematical procedures to be used to generate final results from raw data
- Use of standards and reagents of appropriate quality
- Initial demonstrations of method capability to assure the selectivity

of each analytical method

- Use of Method Detection Limits to demonstrate adequate sensitivity and annual LOD/LOQ verification.
- Documented procedures in each laboratory method SOP for defining and monitoring required test conditions
- 18.2.2 Instruments are calibrated as described in Section 14.2 of this QAP and detailed in the laboratory method SOPs.
- 18.2.3 Batch QC samples are prepared with each preparation batch prepared in the laboratory. A preparation batch is a batch of samples of the same quality system matrix not to exceed a total of 20 field samples. QC samples are not counted as part of the twenty.
 - 18.2.3.1 Each batch must contain, where applicable, a Laboratory Control Sample, a Method Blank, a Matrix Spike sample and a Matrix Spike Duplicate or Matrix Duplicate sample.
 - 18.2.3.1.1 There is no appropriate Method Blank for pH analyses.
 - 18.2.3.1.2 Matrix Spike/Matrix Spike Duplicates are not required for analyses where no certified spiking solution is available (e.g. pH, BOD, Solids analyses).
 - 18.2.3.2 The preparation and evaluation of each of these QC samples is detailed in the laboratory method SOPs.
- 18.2.4 All quality control measures must be assessed and evaluated while analyses are on-going. Laboratory personnel use bench sheets to record all raw data. QC data is used to determine the usability of sample data as described later in this section.
- 18.2.5 Detection Limits and Reporting Limits
 - 18.2.5.1 The laboratory uses Reporting Limits rather than the Method Detection Limit (MDL) procedure described in 40 CFR 136, Appendix B to convey sensitivity for each analysis performed in the laboratory.
 - 18.2.5.2 Reporting limits are set using the low standard of the analysis. The laboratory strives to set the reporting limit either at a level approximately 3-5 times the approximate MDL or at a level such that the range of the analysis encompasses any significant regulatory levels.

- 18.2.5.2.1 Reporting limits must be verified annually using the following procedure.
 - 18.2.5.2.1.1 A QC sample is prepared at a concentration 1-2 times the reporting limit.
 - 18.2.5.2.1.2 The sample is analyzed by the test method.
 - 18.2.5.2.1.3 The result must be within the accuracy limits of the method or within the client-specified accuracy limits.
- 18.2.5.2.2 Reporting limit verification is not required for analyses where no certified spiking solutions are available (e.g. pH, BOD, TSS)
- 18.2.6 All quality control protocols specified in the laboratory method SOPs must be followed. These protocols must be based on the NDEP standards.

18.3 Calculations

18.3.1 Matrix spike recoveries are calculated using the following equation unless otherwise specified in the laboratory method SOP.

%R = [(SSR-SR)/SA] * 100

Where

SSR = Spiked Sample Result SR = Sample Result (Unspiked) SA = Spike Added

18.3.2 Laboratory control sample recoveries are calculated using the following equation.

%R = (CONCENTRATION FOUND ÷ TRUE CONCENTRATION) * 100

18.3.3 Duplicate precision is calculated using the following equations for Relative Percent Difference (%RPD) as is appropriate.

$$\text{%RPD} = [|V1 - V2| \div ((V1 + V2) \div 2)] * 100$$

Where V1 = Sample1 Value or % Recovery V2 = Sample1 Duplicate Value or % Recovery

19.0 REPORTING OF RESULTS

- 19.1 General Considerations
 - 19.1.1 The result of each environmental test must be reported accurately, clearly, unambiguously and objectively as well as in accordance with any specific instructions included in the test method.
- 19.2 Report Elements:
 - 19.2.1 All of the following information must either be included in the report or retained and available in the laboratory.
 - The name and address of the laboratory, the phone number, and the name of the contact person to address questions.
 - A unique identification of the test report. This identification must be placed so that every page is recognizable as part of the test report. This laboratory uses the laboratory identification number of the sample being reported. The laboratory identification number is printed on every page of the test report.
 - The name and address of the client, and the project name if applicable.
 - Identification of the method used for analysis.
 - A description of, condition of, and unambiguous identification of the sample(s) including the client identification code.
 - The date of receipt of the samples, the date and time of sample collection and the date of analysis.
 - Reference to the sampling plan and procedures used by the laboratory where these are relevant or applicable to the results.
 - The environmental test result, including units of measurement such as mg/L, identification of any failures, and, where applicable, identification as to whether results are reported on a dry weight or wet weight basis.
 - The name of the person authorizing the test result and the date of issue.
 - 19.2.2 In addition to the items listed above, the laboratory will include the following where it is necessary for interpretation of the results.
 - Deviations from the method, including failed quality control

parameters, information on specific test conditions, any other nonstandard conditions and definitions of any data qualifiers.

- Identification of any test results that did not meet all NDEP sample acceptance requirements or laboratory quality system requirements.
- Where applicable or requested by the client, a statement on the estimated uncertainty of the measurement.
- Qualification of numerical results with values outside the working range.
- 19.2.3 When the laboratory performed the sampling, the following information must be retained.
 - The date of sampling.
 - Unambiguous identification of the substance sampled.
 - The location of the sampling. This may include diagrams, sketches or photographs if necessary, but it is not required.
 - Reference to the sampling plan and procedures used.
 - Details of any environmental conditions during sampling that may have affected the interpretation of the test result.
 - Any standard or other specification for the sampling method or procedure and any deviations, exclusions, or additions from the specification. In this laboratory the sampling procedure is provided in the SOP Sampling and no additional information is usually required.
- 19.2.4 Results obtained from subcontractors must be clearly identified, including the subcontractor's name or applicable certification number. Subcontractors report results to the laboratory in writing and this report is kept for reference.
- 19.3 Prior to reporting of results, batch quality control data shall be reviewed by the Laboratory Director or designee.
- 19.4 A copy of each report must be kept by the laboratory.
- 19.5 If results are reported to the client by e-mail, telephone, FAX or other electronic means, the requirements above must be met and all reasonable steps must be taken to ensure client confidentiality.
- 19.6 If an amendment is required to a report, the following requirements will be met.
 - The amended report will meet all requirements of this section.
 - If a completely new report is required, it will be uniquely identified and make reference to the original report that it replaces.

20.0 PROFICIENCY TESTING

- 20.1 The laboratory will participate in Proficiency Testing studies twice per year for each analyte/matrix for which the laboratory is requesting certification.
 - 20.1.1 The studies must be approximately six months apart as determined by the closing date of the study. The closing dates may be no closer than five months and no longer than seven months apart without express permission from NDEP.
 - 20.1.2 Additional studies, if required, may start no more than 15 days after the close of the previous study.
 - 20.1.3 All PT study results, regular or remedial, must be returned to the PT provider within 45 calendar days of opening of the study. For regular studies, this date is listed by the PT provider. For remedial studies, this date is the shipping date from the provider.
 - 20.1.4 Remedial PT studies must be obtained from an accredited provider and must be from a study lot that has not previously been provided to the laboratory.
 - 20.1.5 The laboratory must not subcontract the analysis of PT samples, must not communicate with any other laboratory about the contents of PT samples prior to the closing date of the study, and must not knowingly analyze PT samples for any other laboratory.
- 20.2 PT studies must be performed for each certified parameter in each of the NDEP defined matrices. Generally, for this laboratory, this only includes non-potable water, but could potentially also include potable water or solid/chemical waste.
 - 20.2.1 PT samples must be analyzed in the same manner as client samples.
 - 20.2.1.1 PT samples received as ampules are diluted according the providers instructions. The diluted sample becomes the routine samples and is added to a routine analytical batch.
 - 20.2.1.2 PT samples are prepared in the same manner as routine environmental samples except as otherwise instructed by the PT provider.
 - 20.2.1.3 PT samples will not be analyzed multiple times unless routine samples are analyzed multiple times. Results will be calculated in the same manner that results of routine samples are calculated. Multiple dilutions may be analyzed as necessary in

order to achieve results within the calibrated range of the method.

- 20.2.1.4 As much as possible, the type, composition, concentration, and frequency of QC samples analyzed with the PT sample must be the same as is analyzed with routine environmental samples.
- 20.2.1.5 Initial and continuing calibrations are analyzed at the same frequency and in the same manner as with routine environmental samples.
- 20.2.2 All raw data generated in the analysis of PT samples will be documented in the same manner as with routine samples. Copies will be kept on file for easy access if requested by the Accrediting Body.
- 20.3 PT results must be reported to the provider as required by the provider. The Laboratory Director or other signatory for the laboratory must sign the attestation statement provided with the PT samples. Copies of all report documents must be kept by the laboratory.
- 20.4 If the laboratory PT result is rated "Not Acceptable" by the PT provider, the laboratory must take corrective action using the corrective action system in the laboratory.
 - 20.4.1 Corrective actions must be reported to NDEP.
 - 20.4.2 The laboratory may, in the course of the corrective action, use QC samples provided by a PT provider. These samples may be used to help troubleshoot the analytical system, but they may not be analyzed in the same analytical batch as a PT sample.
 - 20.4.3 The laboratory may use remedial PT samples to demonstrate successful corrective action and to meet PT requirements for each certified parameter.

21.0 DATA INTEGRITY PROCEDURES

- 21.1 The laboratory is required to have in place a program to detect and prevent improper, unethical, or illegal actions. The program in place in the laboratory includes the following elements.
 - Data Integrity Training
 - Documentation signed by each employee
 - In-depth, periodic monitoring of data integrity
 - Documentation of data integrity procedures

- 21.2 Laboratory management shall review the Data Integrity Procedures annually in conjunction with the annual management review.
- 21.3 Data integrity training is required as a part of the initial new employee orientation and annually thereafter. The following requirements will be met in the training:
 - 21.3.1 All topics must be documented in writing and provided to all trainees.
 - 21.3.2 Topics must include the following items:
 - The relationship of the laboratory mission to the critical need for honesty and full disclosure in all data reporting.
 - The importance of proper narration where collected data may be useful, but are in one sense or another partially deficient.
 - Definitions and examples of improper, unethical, or illegal actions.
 - A description of the program for prevention and detection of these types of actions.
 - Defined consequences for violating the data integrity policy.
 - How and when to report data integrity issues.
 - Record keeping requirements.
 - 21.3.3 At the conclusion of each data integrity training session, laboratory personnel will be required to sign a statement that they understand and agree to abide by the data integrity provisions in the laboratory.
- 21.4 Prevention of improper, unethical, or illegal actions.
 - 21.4.1 Prevention of improper, unethical, or illegal actions begins with a zerotolerance philosophy established by the laboratory management. Laboratory management will uphold the spirit of the laboratory's data integrity procedures and will work to effectively implement the requirements of these procedures.
 - 21.4.2 The laboratory also maintains a no-fault reporting policy for data integrity issues.
 - 21.4.2.1 The no fault policy is intended to encourage personnel to report suspected violations of the data integrity policy.
 - 21.4.2.2 Personnel may report suspected violations of this policy confidentially. Investigations that may be required will be carried out in a confidential manner as long as possible.

- 21.4.2.3 If any laboratory personnel observe behavior that they believe is improper, unethical, or illegal, they should report that behavior to the Laboratory Director
- 21.4.2.4 The laboratory management will assure that personnel will not be punished for reporting their observation of improper, unethical, or illegal activities to supervisory personnel.
- 21.4.3 Gross deviations from specified procedures should be investigated for potential improper, unethical, or illegal actions. Findings of fraud should be prosecuted to the fullest extent of the law.
- 21.4.4 The program begins with a presentation of the data integrity policy to all new hires during their initial city orientation.
- 21.4.5 Annual refresher training is provided to all laboratory personnel.
- 21.4.6 Internal audits include in-depth data monitoring in every analytical section.
- 21.4.7 Proficiency Testing samples are analyzed twice yearly. Assignments are rotated among analysts to verify competency.
- 21.5 Investigations
 - 21.5.1 If a report is received of a potential violation of the laboratory's data integrity procedures, further review is required.
 - 21.5.2 Management must ensure that the person reporting the possible violation is encouraged to give a complete reporting and that no negative actions are taken against the employee because they have reported the possible violation.
 - 21.5.3 If the laboratory's auditing program reveals evidence of inappropriate actions or vulnerabilities related to data integrity, further review is required.
 - 21.5.4 A review may indicate that the possible problem is not of concern and may be closed. If the review indicates potential issues of concern, a thorough investigation will be conducted.
 - 21.5.4.1 All investigations will be handled in a confidential manner until such time as a follow up evaluation, full investigation, or other appropriate actions have been completed and the issues

clarified.

21.5.4.2 All investigations that result in finding of inappropriate activity must be documented and the documentation must include any disciplinary actions involved, corrective actions taken, and all notifications of clients. All documentation must be kept for at least five years.

22.0 Mining Program

- 22.1 All laboratories submitting data to the State of Nevada for the purposes of mining and mining related purposes must be approved as of August 01, 2013.
- 22.2 Laboratory management shall review the Data Integrity Procedures annually in conjunction with the annual management review.
- 22.3 Data integrity training is required as a part of the initial new employee orientation and annually thereafter. The following requirements will be met in the training:

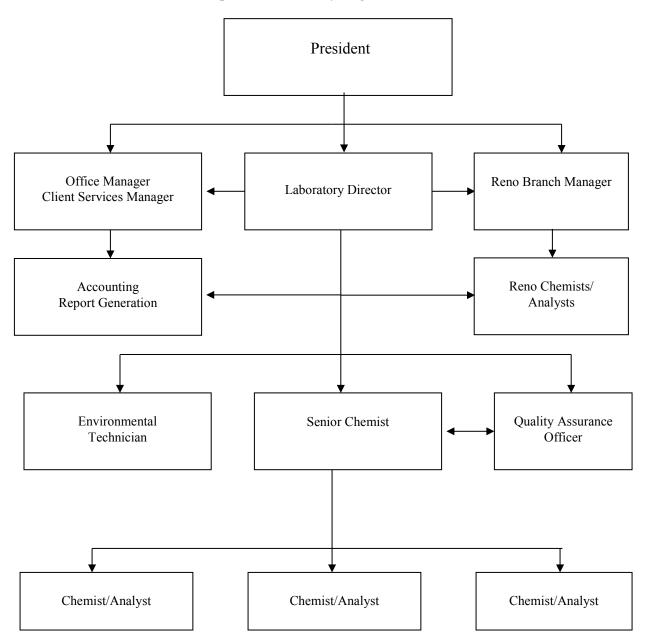
22.3.1 All topics must be documented in writing and provided to all trainees.

Appendix 1 Organizational Chart

ORGANIZATIONAL STRUCTURE

Silver State Analytical Laboratories, Inc.

Corporate/Laboratory Organizational Chart



Appendix 2 Certified Method List

Methods				
	Method ID	Analyte	Las Vegas	Reno
SDWA (potable)	9223B – Colilert 18 (21 st) P/A	Total Coliform and E. coli, p/a	X	Pending
(F	IDEXX Quanti-Tray (21 st) by Colilert18	Total Coliform and E. coli, mpn	X	Pending
	SM 300.0	Chloride	Х	Non-reg
	SM 300.0	Fluoride	Х	Non-reg
	SM 300.0	Nitrite	Х	Non-reg
	SM 300.0	Nitrate	Х	Non-reg
	SM 300.0	Sulfate	Х	Non-reg
	SM 300.0	Nitrite – Nitrate	Х	Non-reg
	SM 2510 B (21 st)	Conductivity	NR	Pending
	SM 2550 B (21 st)	Temperature	NR	Pending
	SM 4500 (H+) B (21 st)	pH	NR	Pending
	SM 4500 (CL-) D (21 st)	Chloride	NR	Pending
CWA	EPA 1664A	Hexane Extractable Material (HEM)	X	1 01101118
(non-	EPA 200.7	Aluminum	X	
potable)	EPA 200.7	Antimony	X	
Methods	EPA 200.7	Arsenic	Х	
victious	EPA 200.7	Barium	Х	
	EPA 200.7	Beryllium	Х	
	EPA 200.7	Boron	Х	
	EPA 200.7	Cadmium	Х	
	EPA 200.7	Calcium	Х	
	EPA 200.7	Chromium	X	
	EPA 200.7	Cobalt	X	
	EPA 200.7	Copper	X	
	EPA 200.7	Iron	X	
	EPA 200.7	Lead	Х	
	EPA 200.7	Magnesium	Х	
	EPA 200.7	Manganese	Х	
	EPA 200.7	Molybdenum	X	
	EPA 200.7	Nickel	X	
	EPA 200.7	Potassium	X	
	EPA 200.7	Selenium	X	
	EPA 200.7	Silver	X	
	EPA 200.7	Sodium	X	
	EPA 200.7	Strontium	X	
	EPA 200.7 EPA 200.7	Thallium Vanadium	X X	
	EPA 200.7 EPA 200.7	Zinc	X	

EPA 200.7	Titanium	Non-Reg
EPA2130B	Turbidity	X
EPA 245.2	Mercury	Х
EPA 300.0	Chloride	Х
EPA 300.0	Fluoride	Х
EPA 300.0	Nitrate-N	Х
EPA 300.0	Nitrite-N	Х
EPA 300.0	Sulfate	Х
EPA 335.2	Cyanide, Total	Х
EPA 420.1	Phenol	Х
EPA 5220B	Chemical Oxygen Demand	Х
EPA 624	1,1,1 -Trichloroethane	Х
	1,1,2,2-Tetrachloroethane	Х
	1,1,2-Trichloroethane	Х
	1,1-Dichloroethane	Х
EPA 624	1,1 -Dichloroethene (1,1 -DCE)	X
EPA 200.7	Vanadium	Х
EPA 624	1 ,2-Dichlorobenzene	Х
EPA 624	1 ,2-Dichloroethane	Х
EPA 624	1,2-Dichloropropane	Х
EPA 624	1,3-Dichlorobenzene	X
EPA 624	1,4-Dichlorobenzene	X
EPA 624	2-Chloroethyl vinyl ether	X
EPA 624	Benzene	X
EPA 624		
	Bromodichloromethane	X
EPA 624	Bromoform	Х
EPA 624	Bromomethane (Methyl bromide)	Х
EPA 624	Carbon tetrachloride	Х
EPA 624	Chlorobenzene	Х
EPA 624	Chlorodibromomethane(Dibromochlo romethane)	X
EPA 624	Chloroethane	Х
EPA 624	Chloroform	X
EPA 624	Chloromethane (Methyl chloride)	X
EPA 624	cis-1,3-Dichloropropene	X
EPA 624	Ethylbenzene	X
EPA 624	Methylene chloride	Λ
EFA 024	(Dichloromethane)	Х
EPA 624	Tetrachloroethene (Perchloroethene, PCE)	X
EPA 624	Trichloroethene	X
EPA 624	Trichlorofluoromethane (Freon 11)	X
EPA 624	Vinyl Chloride	X
EPA 624**	Dichlorodifluoromethane	X
EPA 624**	Ethanol	X
EPA 624**		
	Isopropyl ether (DIPE)	X
EPA 624**	Methyl t-butyl ether (MTBE)	Х

1	EPA 624**	t-Amyl methyl ether (TAME)	X	
	SM 2320B 18th, 19th & 20th		X	
	SM 2320B 18th, 19th & 20th SM 2340B	Alkalinity as CaCO3		
		Hardness (calculation)	X	
	SM2540B 18th, 19th & 20th	Residue Total	Х	
	SM2540C 18th, 19th & 20th	Residue Filterable (TDS)	X	
	SM 2540D 18th, 19th & 20th	Residue Non-filterable (TSS)	Х	
	SM 2510 B (21 st)	Conductivity	Pending	Pending
	SM 2550 B (21 st)	Temperature	Pending	Pending
	SM 4500-(C1-) B 18th, 19th & 20th	Chloride	X	
	SM 4500-(Cl-) D (21 st)	Chloride		Pending
	SM 4500-C1 G 18th, 19th & 20th	Total Residual Chlorine	Х	
	SM 4500-F C 18th, 19th & 20th	Fluoride	Х	
	SM 4500-H+ B 18th, 19th & 20 th , 21 st .	pH (Hydrogen ion)	X	Pending
	SM 4500-N Org B	Kjeldahl Nitrogen Total	Х	
	SM 4500-NH3 D 19th & 20th	Ammonia as N	X	
	SM 4500-NO2 B 18th, 19th & 20th	Nitrite-N	X	
	SM 4500-P E	Ortho-phosphate as P	X	
	SM 4500-P E	Phosphorus, Total	X	
	SM5210B 18th, 19th & 20th	Biological Oxygen Demand (BOD)	X	
	SM5210B 18th, 19th & 20th	Carbonaceous Biochemical Oxygen Demand	X	
	EPA 9223B – Colilert (21 st) P/A	Total Coliform and E. coli, p/a	Pending	Pending
	EPA 9223B Colilert – Quanti-tray	Total Coliform and E. coli, mpn	X	Pending
RCRA	EPA 6010B	Aluminum	Х	
(Solids &	EPA 6010B	Antimony	Х	
Hazardous	EPA 6010B	Arsenic	Х	
Materials) /	EPA 6010B	Beryllium	Х	
(Soils)	EPA 6010B	Boron	X	
Method	EPA 6010B	Cadmium	Х	
	EPA 6010B	Chromium	Х	
	EPA 6010B	Cobalt	Х	
	EPA 6010B	Copper	X	
	EPA 6010B	Iron	X	
		Lead	Х	
	EPA 6010B	Lead		
	EPA 6010B	Manganese	X	
	EPA 6010B EPA 6010B	Manganese Molybdenum	X X	
	EPA 6010B EPA 6010B EPA 6010B	Manganese Molybdenum Nickel	X X X X	
	EPA 6010B EPA 6010B EPA 6010B EPA 6010B	Manganese Molybdenum Nickel Potassium	X X X X X	
	EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B	Manganese Molybdenum Nickel Potassium Selenium	X X X X X X	
	EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B	Manganese Molybdenum Nickel Potassium Selenium Silver	X X X X X X X	
	EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B	Manganese Molybdenum Nickel Potassium Selenium	X X X X X X X X X	
	EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B	Manganese Molybdenum Nickel Potassium Selenium Silver Sodium	X X X X X X X	
	EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B	Manganese Molybdenum Nickel Potassium Selenium Silver Sodium Strontium	X X X X X X X X X X	
	EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B EPA 6010B	Manganese Molybdenum Nickel Potassium Selenium Silver Sodium Strontium Thallium	X X X X X X X X X X X X	

EPA 7470AMercuryXEPA 8015BDiesel Range Organics (DRO, Extract able Petroleum Hydrocarbons, EPH)XEPA 8015MGasoline Range Organics (GRO, Volatile Petroleum Hydrocarbons, XX	K
able Petroleum Hydrocarbons, EPH)EPA 8015MGasoline Range Organics (GRO,	X
EPA 8015M Gasoline Range Organics (GRO,	
	x
VPH)	
EPA 8260B1,1,1,2-TetrachloroethaneX	X
EPA 8260B1,1,1 -TrichloroethaneX	
EPA 8260B1,1,2,2-TetrachloroethaneX	X
EPA 8260B 1,1,2-Trichloroethane X	X
EPA 8260B 1,1-Dichloroethane X	X
EPA 8260B1,1 -Dichloroethene (1,1 -DCE)X	X
EPA 8260B1,2,3-Trichloropropane (TCP)X	
EPA 8260B1,2,4-TrimethylbenzeneX	
EPA \$260P	
(DBCP)	X
EPA 8260B1,2-Dibromoethane (EDB, Ethylene	X
Dibromide)	
EPA 8260B1,2-DichlorobenzeneX	
EPA 8260B1,2-DichloroethaneX	
EPA 8260B1,2-DichloropropaneX	
EPA 8260B1,3,5-TrimethylbenzeneX	
EPA 8260B1,3-DichlorobenzeneX	
EPA 8260B1,4-DichlorobenzeneX	X
EPA 8260B2-Butanone (Methyl ethyl ketone,	X
MEK)	
EPA 8260B2-Chloroethyl vinyl etherX	
EPA 8260BAcetoneX	
EPA 8260BAcetonitrileX	
EPA 9045 D pH	Pending
SM 2550 B (21 st) Temperature	Pending
RCRAEPA 8260BAcrolein (Propenal)X	
(non-potable EPA 8260B Acrylonitrile X	
Water)EPA 8260BBenzeney	
Method EPA 8260B Bromodichloromethane X	
EPA 8260BBromoformX	X
	X
	X
	X
EPA 8260B Chlorobenzene X	X
EPA 8260B Chlorodibromomethane	X
(Dibromochloromethane)	
EPA 8260BChloroethaneX	
	X
EPA 8260BChloromethane (Methyl chloride)X	
EPA 8260Bcis-l,2-DichloroetheneX	
	X
	X
EPA 8260BEthylbenzeneX	X

EPA 8260B	Methyl isobutyl ketone (4-Methyl-2- pentanone, MIBK)	Х	
EPA 8260B	Methyl t-butyl ether (MTBE)	Х	
EPA 8260B	Methylene chloride (Dichloromethane)	Х	
EPA 8260B	Naphthalene	Х	
EPA 8260B	Styrene	Х	
EPA 8260B	Tetrachloroethene (Perchloroethene, PCE)	Х	
EPA 8260B	Toluene	Х	
EPA 8260B	Total xylenes	Х	
EPA 8260B	trans-1,2-Dichloroethene	Х	
EPA 8260B	trans-1,3-Dichloropropene	Х	
EPA 8260B	Trichloroethene	Х	
EPA 8260B	Trichlorofluoromethane (Freon 11)	Х	
EPA 8260B	Vinyl Acetate	Х	
EPA 8260B	Vinyl Chloride	Х	
EPA 8260B	Xylene, m +p	Х	
EPA 8260B	Xylene, o	Х	
EPA 8260B	Xylene, p	Х	
EPA 9040 C	pH		Pending
EPA 9050 A	Conductivity		Pending
SM 2550 B (21 st)	Temperature		Pending

Appendix 3 Reporting Limits

Data Processing in Reporting

The following table illustrates the estimated reporting limits used during reporting of analytical results by our laboratory:

	Analytical	Estimated Reporting Limits*		Duplicate	LCS
Parameters	Methods	Aqueous (mg/L)	Solid (mg/kg)	Precision (RPD)	Accuracy (% recovery)
Acidity	305.1	N/A	N/A	N/A	N/A
Alkalinity (high/low)	SM2320B	10	N/A	20	100 ± 10
Aluminum	200.7	0.05	2.5	20	100 ± 10
Aluminum	6010	0.05	2.5	20	100 ± 10
Antimony	200.7	0.05	2.5	20	100 ± 10
Antimony	6010	0.05	2.5	20	100 ± 10
Arsenic	200.7	0.05	1.0	20	100 ± 10
Arsenic	6010	0.05	1.0	20	100 ± 10
Arsenic	TCLP-1311	1.0	N/A	20	100 ± 10
Barium	200.7	0.01	0.5	20	100 ± 10
Barium	6010	0.01	0.5	20	100 ± 10
Barium	TCLP-1311	1.0	N/A	20	100 ± 10
Beryllium	200.7	0.01	0.5	20	100 ± 10
Beryllium	6010	0.01	05	20	100 ± 10
Biological Oxygen Demand	SM5210B	2	N/A	20	100 ± 10
Boron	200.7	0.50	2.5	20	100 ± 10
Cadmium	200.7	0.01	0.5	20	100 ± 10
Cadmium	6010	0.01	0.5	20	100 ± 10
Cadmium	TCLP-1311	0.	N/A	20	100 ± 10
Calcium	200.7	5.0	25	20	100 ± 10
Calcium	6010	5.0	25	20	100 ± 10
Chemical Oxygen Demand	SM5220D	5.0	N/A	20	100 ± 10
Chloride	300.0	0.5	0.5	20	100 ± 10
Chloride	SM4500ClB	0.5	0.5	20	100 ± 10
Chlorine, Total Residual	SM4500ClG	0.10	N/A	20	100 ± 10
Chromium-Total	200.7	0.01	0.50	20	100 ± 10
Chromium-Total	6010	0.01	0.5	20	100 ± 10
Chromium-Total	TCLP-1311	1.0	N/A	20	100 ± 10
Chromium (VI)	SM3500CrD	0.01	0.01	20	100 ± 10
Color	110.2	N/A	N/A	N/A	N/A
Copper	200.7	0.01	0.50	20	100 ± 10

Inorganic Analytes

	Analytical	Estimated Reporting Limits*		Duplicate	LCS	
Parameters	Methods	Aqueous Solid		Precision	Accuracy	
i ui unicter ș	1/10/11/04/5	(mg/L)	(mg/kg)	(RPD)	(% recovery)	
Copper	6010	0.01	0.50	20	100 ± 10	
Cyanide, Amenable	335.1	0.01	1.0	20	100 ± 10 100 ± 10	
Cyanide, Total	SM4500CNE	0.01	1.0	20	100 ± 10 100 ± 10	
Dissolved Oxygen	360.1	N/A	N/A	N/A	N/A	
Electrical Conductivity	SM 2510	N/A	N/A	N/A	N/A	
Fluoride	300.0	0.5	0.5	20	100 ± 10	
Fluoride	340.2	0.5	0.5	20	100 ± 10	
Hydrogen Ion (pH)	SM4500H ⁺ B	0.10	0.10	20	100 ± 10	
Ignitability	1010	N/A	N/A	20	N/A	
Iron	200.7	0.01	0.5	20	100 ± 10	
Iron	6010	0.01	0.5	20	100 ± 10	
Lead	200.7	0.01	2.5	20	100 ± 10	
Lead	6010	0.01	2.5	20	100 ± 10	
Lead	TCLP-1311	1.00	N/A	20	100 ± 10	
Magnesium	200.7	5.0	5.0	20	100 ± 10	
Magnesium	6010	5.0	5.0	20	100 ± 10	
Manganese	200.7	0.01	0.50	20	100 ± 10	
Manganese	6010	0.01	0.50	20	100 ± 10	
Mercury	245.1	0.001	0.05	20	100 ± 10	
Mercury	TCLP-1311	0.02	N/A	20	100 ± 10	
Molybdenum	200.7	0.05	2.5	20	100 ± 10	
Molybdenum	6010	0.05	2.5	20	100 ± 10	
Nickel	200.7	0.01	0.5	20	100 ± 10	
Nickel	6010	0.01	0.5	20	100 ± 10	
Nitrogen, Ammonia	SM4500NH ₃ D	0.10	1.0	20	100 ± 10	
Nitrogen, Inorganic	350.2	0.10	1.0	20	100 ± 10	
Nitrogen, Kjeldahl	SM4500N _{org} C	1.0	1.0	20	100 ± 10	
Nitrogen, Nitrate as	300.0	0.1	0.1	20	100 ± 10	
Nitrogen, Nitrate as	352.1	0.10	0.1	20	100 ± 10	
Nitrogen, Nitrite as	300.0	0.1	0.1	20	100 ± 10	
Nitrogen, Nitrite as	353.3	0.1	0.1	20	100 ± 10	
Nitrogen, Organic	351.3-350.2	1.0	1.0	20	100 ± 10	
Oil and Grease	1664A	10	10	20	100 ± 10	
Ortho Phosphorus	300.0	0.05	0.05	20	100 ± 10	
Ortho Phosphorus	SM4500PE	0.05	0.05	20	100 ± 10	
Phenolics	420.3/9067	0.05	0.1	20	100 ± 10	
Potassium	200.7	5.0	5.0	20	100 ± 10	
Selenium	200.7	0.05	2.5	20	100 ± 10	
Selenium	6010	0.05	2.5	20	100 ± 10	
Selenium	TCLP-1311	1.0	N/A	20	100 ± 10	
Silica	200.7	1.0	1.0	20	100 ± 10	
Silica	SM4500SiF	0.05	0.05	20	100 ± 10	
Silver	200.7	0.05	1.0	20	100 ± 10	

	Analytical	Estimated Reporting Limits*		Duplicate Precision	LCS
Parameters	Methods	Aqueous (mg/L)	-		Accuracy (% recovery)
Silver	6010	0.05	1.0	20	100 ± 10
Silver	TCLP-1311	1.0	N/A	20	100 ± 10
Sodium	200.7	5.0	5.0	20	100 ± 10
Sulfate	300.0	0.5	0.5	20	100 ± 10
Sulfate	375.4	0.5	0.5	20	100 ± 10
Sulfide	376.1	2.0	10.0	20	100 ± 10
Surfactants (MBAS)	425.1	0.10	1.0	20	100 ± 10
TDS	SM2540C	10.0	N/A	20	100 ± 10
Temperature	170.1	0.10	0.1	20	N/A
Thallium	200.7	0.05	2.5	20	100 ± 10
Thallium	6010	0.05	2.5	20	100 ± 10
Tin	200.7	0.20	5.0	20	100 ± 10
Tin	6010	0.20	5.0	20	100 ± 10
Titanium	200.7	0.01	0.5	20	100 ± 10
Titanium	6010	0.01	0.5	20	100 ± 10
Total Phosphorus	365.2	0.05	0.05	20	100 ± 10
TPH-DRO	8015 M	5.0	10	20	100 ± 10
TPH-GRO	8015 M	1.0	10	20	100 ± 10
TPH-Oil Range	8015 M	25.0	50	20	100 ± 10
TRPH	1664A	10	50	20	100 ± 10
TSS	SM2540D	10.0	N/A	20	100 ± 10
Turbidity	180.1	1.0	N/A	20	100 ± 10
Vanadium	200.7	0.05	2.5	20	100 ± 10
Vanadium	6010	0.05	2.5	20	100 ± 10
Zinc	200.7	0.05	2.5	20	100 ± 10
Zinc	6010	0.05	2.5	20	100 ± 10

NOTE: *: Estimated Reporting Limits are derived from the MDL by a multiplier that gives the analyst a level of certainty that the value is above the noise/background level. Also, the above table is for reference only, specific QA/QC criteria may be found in detail in other sections of this QAP or SOPs.

VOC Compounds

			g Limits*	Duplicate	LCS
	Analytical	Aqueous	Solid	Precision	Accuracy
Parameters	Methods	(mg/L)	(mg/kg)	(RPD)	(%
	00/00/	0.005	0.010	2.0	recovery)
Benzene	8260/624	0.005	0.010	20	100 ± 30
Bromobenzene	8260/624	0.005	0.010	20	100 ± 30
Bromochloromethane	8260/624	0.005	0.010	20	100 ± 30
Bromodichloromethane	8260/624	0.005	0.010	20	100 ± 30
Bromoform	8260/624	0.005	0.010	20	100 ± 30
Bromomethane	8260/624	0.005	0.010	20	100 ± 30
Acetone	8260/624	0.010	0.010	20	100 ± 30
Acrolein	8260/624	0.050	0.050	20	100 ± 30
n-Butylbenzene	8260/624	0.005	0.010	20	100 ± 30
sec-Butylbenzene	8260/624	0.005	0.010	20	100 ± 30
tert-Butylbenzene	8260/624	0.005	0.010	20	100 ± 30
Carbon tetrachloride	8260/624	0.005	0.010	20	100 ± 30
Chlorobenzene	8260/624	0.005	0.010	20	100 ± 30
Chloroethane	8260/624	0.005	0.010	20	100 ± 30
2-Choroethyl vinylether	8260/624	0.020	0.010	20	100 ± 30
Chloroform	8260/624	0.005	0.010	20	100 ± 30
Chloromethane	8260/624	0.005	0.010	20	100 ± 30
2-Chlorotoluene	8260/624	0.005	0.010	20	100 ± 30
4-Chlorotoluene	8260/624	0.005	0.010	20	100 ± 30
Dibromochloromethane	8260/624	0.005	0.010	20	100 ± 30
Dichlorodifluoromethane	8260/624	0.005	0.010	20	100 ± 30
1,2-Dibromo-3-chloropropane	8260/624	0.005	0.010	20	100 ± 30
1,2-Dibromoethane	8260/624	0.005	0.010	20	100 ± 30
Dibromomethane	8260/624	0.005	0.010	20	100 ± 30
1,2-Dichlorobenzene	8260/624	0.005	0.010	20	100 ± 30
1,3-Dichlorobenzene	8260/624	0.005	0.010	20	100 ± 30
1,4-Dichlorobenzene	8260/624	0.005	0.010	20	100 ± 30
1,1-Dichloroethane	8260/624	0.005	0.010	20	100 ± 30
1,2-Dichloroethane	8260/624	0.005	0.010	20	100 ± 30
1,1-Dichloroethene	8260/624	0.005	0.010	20	100 ± 30
cis-1,2-Dichloroethene	8260/624	0.005	0.010	20	100 ± 30
trans-1,2-Dichloroethene	8260/624	0.005	0.010	20	100 ± 30
1,2-Dichloropropane	8260/624	0.005	0.010	20	100 ± 30
1,3-Dichloropropane	8260/624	0.005	0.010	20	100 ± 30
2,2-Dichloropropane	8260/624	0.005	0.010	20	100 ± 30
1,2-Dichloropropene	8260/624	0.005	0.010	20	100 ± 30 100 ± 30
cis-1,3-Dichloropropene	8260/624	0.005	0.010	20	100 ± 30 100 ± 30

Parameters	Analytical Methods	Estin Reporting Aqueous (mg/L)		Duplicate Precision (RPD)	LCS Accuracy (%
trang 1.2 Dishlanannana	8260/624	0.005	0.010	20	recovery)
trans-1,3-Dichloropropene	8260/624	0.005	0.010	20	100 ± 30
Ethylbenzene					100 ± 30
Hexachlorobutadiene	8260/624	0.005	0.010	20	100 ± 30
Isopropylbenzene	8260/624	0.005	0.010	20	100 ± 30
p-Isopropyltoluene	8260/624	0.005	0.010	20	100 ± 30
Methylene chloride	8260/624	0.005	0.010	20	100 ± 30
Naphthalene	8260/624	0.005	0.010	20	100 ± 30
n-Propylbenzene	8260/624	0.005	0.010	20	100 ± 30
Styrene	8260/624	0.005	0.010	20	100 ± 30
1,1,1,2-Tetrachloroethane	8260/624	0.005	0.010	20	100 ± 30
1,1,2,2-Tetrachloroethane	8260/624	0.005	0.010	20	100 ± 30
Tetrachloroethylene	8260/624	0.005	0.010	20	100 ± 30
Toluene	8260/624	0.005	0.010	20	100 ± 30
Trichlorofluoromethane	8260/624	0.005	0.010	20	100 ± 30
1,2,3-Trichlorobenzene	8260/624	0.005	0.010	20	100 ± 30
1,2,4-Trichlorobenzene	8260/624	0.005	0.010	20	100 ± 30
1,1,1-Trichloroethane	8260/624	0.005	0.010	20	100 ± 30
1,1,2-Trichloroethane	8260/624	0.005	0.010	20	100 ± 30
Trichloroethene	8260/624	0.005	0.010	20	100 ± 30
1,2,3-Trichloropropane	8260/624	0.005	0.010	20	100 ± 30
1,2,4-Trimethylbenzene	8260/624	0.005	0.010	20	100 ± 30
1,3,5-Trimethylbenzene	8260/624	0.005	0.010	20	100 ± 30 100 ± 30
Vinyl Chloride	8260/624	0.005	0.010	20	100 ± 30 100 ± 30
Vinyl Acetate	8260/624	0.010	0.010	20	100 ± 30 100 ± 30
Xylenes	8260/624	0.005	0.010	20	100 ± 30 100 ± 30
MTBE	8260/624	0.005	0.010	20	100 ± 30 100 ± 30

*: The above table is for reference only. Methods EPA 624, 625, 8270, 8080/8081, 8021 may have different windows of acceptance for the LCS than Stated above and should be reviewed in specific SOPs.

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Appendix 4

Major Equipment List Laboratory Equipment/Instrumentation HP 5890 Series II GC x2 HP 5971 Series Mass Selective Detector x2 Tekmar LSC 2000 Concentrator x2 Archon Automated Sampler Tekmar ALS 2016 Auto sampler x2 GC 5890 Series II GC/FID HP 7673 Tabletop Auto sampler x2 HP 5972 Series Mass Selective Detector SRI 8610C GC/FID Perkin Elmer Optima 3000DV ICP Neslabs CFT33 Refrigerated Recirculator Perkin Elmer AS90 Auto sampler Perkin Elmer AS91 Controller US General US660V Air Compressor Dionex DX-120 IC **Dionex AS40 Automated Sampler** Dionex LCS 5000 with Automate Sampler Hydra AA Automated Cold Vapor Mercury Analysis System HF Scientific Micro100 Turbidimeter Horizon Technologies Oil & Grease 1000XL Extractor Horizon Technologies SpeDex 3000 Controller Horizon Technologies Speedvap III Hach COD Reactor Incubator MIDI Cyanide Distillation Apparatus Buchi K314 Distillation Unit Genesys 20 Spectrophotometer Nanopure Ultrapure Water System model 4741 VWR Symphony SB80PI desktop meter Orion 420A desktop meter x2 IEC Clinical Centrifuge Thermolyn type 1400 Furnace Tyler Sieve Shaker model RX-24 Binder Model BD53UL incubator **IDEXX** Quanti-Tray Sealer 2X VWR model 2026 Incubator VWR 1300U Drying Oven VWR 1320U Drying Oven Blue M OV-12A Drying Oven Orion 850A Dissolved Oxygen Bench Top Meter Denver Instrument Co. AA250 Analytical Balance Sartorius GMBH Analytical Balance

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Sargent Welch SW210 Appendix 5 Definitions

Accuracy: the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator.

Analyst: the designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

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 NDEP.)

Assessment Criteria: The measures established by NDEP and applied in establishing the extent to which an applicant is in conformance with NDEP requirements.

Assessor: one who performs on-site assessments of accrediting authorities and laboratories' capability and capacity for meeting NDEP requirements by examining the records and other physical evidence for each one of the tests for which accreditation has been requested.

Audit: a systematic evaluation to determine the conformance to quantitative and qualitative specification for some operational function or activity.

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 to 20 environmental samples of the same NDEP-defined matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various environmental matrices and can exceed 20 samples.

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. Blanks include:

Equipment blank: a sample of analyte-free media that has been used to rinse common sampling equipment to check effectiveness of decontamination procedures.

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.

Instrument blank: a clean sample (e.g. distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination.

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.

Blind Sample: a sub-sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process.

Calibration: to determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument, or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements.

Calibration blank: a zero standard, one that has not been subject to any of the sample preparation process. 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 the routine analytical results where stated by the analytical method.

Calibration Curve: the graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.

Calibration Method: a defined technical procedure for performing a calibration.

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

Certified Reference Material (CRM): a reference material one or more of whose property values are certified by a technical valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

Chain of Custody Form (COC): 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; collector; time of collection; preservation; and requested analyses.

Chronic toxicity: a description of the state that occurs when the survival, growth, or reproduction for either test species exposed to a dilution of sixty nine (69) percent effluent (or lower) is

significantly less (at the 95 percent confidence level) than the survival, growth or reproduction of the control specimens.

Composite sample: a sample collected over a 24-hour period by either an automated or manual mechanical means.

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.

Continuing Calibration Verification (CCV): a standard used to demonstrate continuing compliance with calibration criteria of an instrument. The CCV is typically a mid-range standard and is analyzed periodically during and at the end of an analytical sequence. Under NDEP requirements, the concentration of the CCV must be varied over time.

Contract: any agreement regarding analysis (written or verbal) between the client and the laboratory.

Corrective Action: the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

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

Data Reduction: the process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useable form.

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

Demonstration of Capability (DOC): a procedure to establish the ability of the analyst to generate results of acceptable accuracy and precision.

Detection Limit: the lowest concentration or amount of the target analyte that can be identified, measured, and reported with confidence that the analyte concentration is not a false positive value. See Method Detection Limit.

Federal Water Pollution Control Act (Clean Water Act, CWA): the enabling legislation under 33 U.S.C 1251 et seq., Public Law 92-50086 Stat. 816, that empowers EPA to set discharge limitations, write discharge permits, monitor, and bring enforcement action for non-compliance.

Finding: an assessment or audit conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding is normally a deficiency and is normally

accompanied by specific examples of the observed condition.

Governmental Laboratory: as used in these standards, a laboratory owned by a federal, state, or tribal government; includes government-owned contractor-operated laboratories.

Grab sample: for monitoring requirements, a grab sample is defined as a single "dip and take" sample collected at a representative point in the discharge stream.

Holding Times (Maximum Allowable Holding Times): the maximum times that samples may be held prior to analysis and still be considered valid or not compromised. (40 CFR Part 136 or other applicable regulations).

Inspection: an activity such as measuring, examining, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformance is achieved for each characteristic.

Laboratory: a body that calibrates and/or tests.

Laboratory Control Sample (LCS): a QC sample of similar matrix to the analytical samples, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intralaboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

Laboratory Duplicate: (also called Matrix Duplicate) aliquots of a sample taken from the same container under laboratory condition and processed and analyzed independently.

Legal Chain of Custody Protocols: Procedures employed to record the possession of samples from the time of sampling until analysis and are performed at the special request of the client. These protocols include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples by the laboratory. In addition, these protocols document all handling of the samples within the laboratory.

Matrix: the substrate of a test sample. In this laboratory, all samples are of the aqueous/non-potable water matrix

Aqueous (for batch and quality control use) or Non-Potable water (for fields of accreditation use): any aqueous sample excluded from the definition of Drinking Water matrix or Saline/Estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.

Drinking Water: any aqueous sample that has been designated a potable or potential water source.

Matrix Duplicate: (also called Laboratory Duplicate) aliquots of a sample taken from the same container under laboratory condition and processed and analyzed independently.

Matrix Spike (MS): a QC sample prepared by adding a known mass of target analyte to a specified amount of field sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used to determine the effect of the matrix on a method's recovery efficiency.

Matrix Spike Duplicate (MSD): a second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery of each analyte.

May: denotes a permitted, but not required action.

Method Detection Limit (MDL): 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 or applicable test methods.)

Must: denotes a required action or result.

National Institute of Standards and Technology (NIST): an agency of the US Department of Commerce's Technology Administration that is working with EPA, State, NELAC, and other public and commercial entities to establish a system under which private sector companies and interested States can be accredited by NIST to provide NIST-traceable proficiency testing (PT) to those laboratories testing drinking water and wastewater.

National Environmental Laboratory Accreditation Conference (NELAC): formerly a voluntary organization of State and Federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP. This organization has been replaced by The Nelac Institute (TNI).

National Environmental Laboratory Accreditation Program (NELAP): the overall National Environmental Laboratory Accreditation Program of which NELAC is a part.

National Pollution and Discharge Elimination System (NPDES): the guidelines governing the discharge of wastes into streams, rivers, lakes, holding ponds, and wetlands.

National Voluntary Laboratory Accreditation Program (NVLAP): a program administered by NIST that is used by providers of proficiency testing to gain accreditation for all compounds/matrices for which NVLAP accreditation is available, and for which the provider intends to provide NELAP PT samples.

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

NELAC Standards: accreditation standards promulgated by NELAC, currently used by NELAP. It contains procedures for consistently evaluating and documenting the ability of laboratories performing environmental measurements to meet nationally defined standards established by National Environmental laboratory Accreditation Conference (NELAC).

Performance Audit: the routine comparison of independently obtained qualitative and quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory.

Performance Based Measurement System (PBMS): a set of processes wherein the data quality needs, mandates or limitation of a program or project are specified and serve as criteria for selecting measurement processes which will meet those needs in a cost-effective manner.

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 may be expressed as standard deviation, relative standard deviation, variance, range, percent difference or relative percent difference. This laboratory typically uses relative percent difference.

Preservation: refrigeration and/or reagents added at the time of sample collection (or later) to maintain the chemical and/or biological integrity of the sample.

Primary Accrediting Body: the agency or department designated at the Territory, State or Federal level as the recognized authority with responsibility and accountability for granting NELAC accreditation for a specified field of testing.

Proficiency Testing (PT): a means of evaluating a laboratory's performance under controlled conditions relative to a set of criteria through analysis of unknown samples provided by an external source.

Proficiency Testing Study Provider: any person, private party, or government entity that meets stringent criteria to produce and distribute NDEP PT samples, evaluate study results against published performance criteria and report the results to the laboratories, primary accrediting authorities and NDEP.

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

Protocol: a detailed written procedure for field and/or laboratory operation (e.g. sampling,

analysis) which must be strictly followed.

Quality Assurance: an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

Quality Assurance Plan: 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.

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.

Quality Control: the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users.

Quality Control Sample: an uncontaminated sample matrix spiked with known amounts of analytes from a source independent from the calibration standards. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

Quality System: a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

Quantitation Limits: levels, concentrations, or quantities of target of a target variable (e.g. target analyte) that can be reported at a specified degree of confidence.

Range: the difference between the minimum and the maximum of a set of values.

Raw Data: any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g. tapes which have been transcribed verbatim, data and verified accurate by signature), the exact copy or exact transcript may be submitted.

Recognition: previously known as reciprocity. The mutual agreement of two or more parties (i.e., States) to accept each other's finding regarding the ability of environmental testing

laboratories in meeting NELAC standards.

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

Reference Method: a method of known and documented accuracy and precision issued by an organization recognized as competent to do so.

Reference Standards: a standard, generally of the highest metrological quality available at a given location, from which measurements made at the location are derived.

Replicate Analyses: the measurements of the variable of interest performed identically on two or more sub-samples of the same sample within a short time interval.

Requirement: denotes a mandatory specification; often designated by the term "shall" or "must".

Resource Conservation and Recovery Act (RCRA): the enabling legislation under 42 USC 321 et seq. (1976), that gives EPA the authority to control hazardous waste from the "cradle-to-grave", including its generation, transportation, treatment, storage, and disposal.

Safe Drinking Water Act (SDWA): the enabling legislation, 42 USC 300f et seq. (1974), Public Law 93-523), that requires EPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations.

Sample Management: (also called Sample Tracking) procedures employed to record the possession of the samples from the time of sampling until analysis, reporting, and archiving. These procedures include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples to the laboratory. In addition, access to the laboratory is limited and controlled to protect the integrity of the samples.

Selectivity: (Analytical chemistry) the capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances.

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

Shall: denotes an action or result that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation.

Should: denotes a guideline or recommendation whenever noncompliance with the specification is permissible.

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 Operating Procedure (SOP): a written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.

Standardized Reference Material (SRM): a certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method.

Statistical Minimum Significant Difference (SMSD): the minimum difference between the control and a test concentration that is statistically significant; a measure of test sensitivity or power. The power of a test depends in part on the number of replicates per concentration, the significance level selected, e.g., 0.05, and the type of statistical analysis. If the variability remains constant, the sensitivity of the test increases as the number of replicates is increased.

Supervisor: the individual designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees, supply and instrument adequacy and upkeep, quality assurance/quality control.

Surface water: all water which is open to the atmosphere, and subject to surface runoff.

Laboratory Coordinator: individual who has overall responsibility for the technical operation of the environmental testing laboratory.

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

Test: a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate.

Test Method: an adoption of a scientific technique for a specific measurement problem, as documented in a laboratory SOP or published by a recognized authority.

Testing Laboratory: a laboratory that performs tests.

Test Sensitivity/Power: the minimum significant difference between the control and test concentration that is statistically significant. It is dependent on the number of replicates per concentration, the selected significance level, and the type of statistical analysis.

The Nelac Institute: a voluntary organization of State and Federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting

environmental laboratories. A subset of NELAP. This organization has replaced the National Environmental Laboratory Accreditation Conference (NELAC).

Traceability: the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

Validation: the process of substantiating specified performance criteria.

Verification: confirmation by examination and provision of evidence that specified requirements have been met.

Water Pollution audit (WP): a blind audit sample purchased by the laboratory, which checks the laboratory efficiency and accuracy in analyzing ground water and wastewater samples.

Water Survey audit (WS): a blind audit sample purchased by the laboratory, which checks the laboratory efficiency and accuracy in analyzing drinking water samples.

Work Cell: a well-defined group of analysts that together perform the method analysis. The members of the group and their specific functions within the work cell must be fully documented.

Parameter	Analytical Method	Container	Storage & preservation	Minimum Sample Volume	Maximum Holding Times
Acidity	305.1	Plastic/Glass	4°C	100ml	14 day
Alkalinity	SM2320B	Plastic/Glass	4°C	100ml	14 days
Ammonia-N	350.1	Plastic/Glass	H_2SO_4	400 ml	28 days
Bromide	300.0	Plastic/Glass	None	50ml	28 days
COD	410.4	Plastic/Glass	4°C/H ₂ SO ₄	50ml	28 days
Chloride	300.0/325.3/9251	Plastic/Glass	None	50ml	28 days
Cyanide (total	335.2/9010/3500	Plastic/Glass/	NaOH	500ml	14 days
& amenable)	CN-C&E	Teflon	C ₆ H ₈ O ₆		
TDS	2540C/160.1	Plastic/Glass	4°C	100ml	7 days
Fluoride	340.2/300.0	Plastic/Glass	4°C	300ml	28 days
TSS	160.2	Plastic/Glass	4°C	100ml	7 days
pН	150.1	Plastic/Glass	4°C	40ml	Immediate
TKN	351.2	Plastic/Glass	4°C/H ₂ SO ₄	500ml	28 days
Nitrate-N	300.0/353.2	Plastic/Glass	4°C	100ml	48 hours
Nitrite-N	300.0/351.2	Plastic/Glass	4°C	100ml	48 hours
Nitrate + Nitrite-N	300.0/353.2	Plastic/Glass	4°C/H ₂ SO ₄	100ml	28 days
Ortho-PO ₄	365.2/300.0	Plastic/Glass	Filter/4°C	50ml	48 hours
Phenolics (total)	420.1	Glass	4°C/CuSO ₄ / H ₂ SO ₄	1000ml	24 hours
PO ₄ -Total	365.2	Plastic/Glass	4°C/H ₂ SO ₄	250ml	28 days
Conductance	120.1/2510	Plastic/Glass	4°C	100ml	28 days
Total Hardness (CaCO ₃)	130.2/2340B	Plastic/Glass	4°C/HNO ₃	100ml	180 days
TOC	SSSA/ASTM 2579A/9060/415. 1/5310C	Plastic/Glass/ Teflon	4°C/HCL/ H ₂ SO ₄	500ml/250g	28 days (soil/water)
Turbidity	180.1	Plastic/Glass	4°C	100ml	48 hours
Metals-all	200.7/200.8/6010/ 6020/7000 series	Plastic/Glass/ Teflon	4°C/HNO ₃	500ml	180 days
Metals- Mercury	245.1/7470A/ 7471A	Plastic/Glass/ Teflon	4°C/HNO ₃	500ml	28 days in glass/14 days in plastic
Metals-Cr	7196A	Plastic/Glass/ Teflon	4°C	500ml	24 hours from sampling
TRPH	418.1	Glass/Teflon	4°C/H ₂ SO ₄	1000ml	28 days
Oil/Grease	413.1	Glass/Teflon	4°C/H ₂ SO ₄	1000ml	28 days
TPH-GRO	8015M	Glass	4°C/Na ₂ S ₂ O ₃ / HCL	1000ml	14 days
TPH-GRO	8015M P&T	Glass	4°C/Na ₂ S ₂ O ₃ / HCL	1000ml	14 days
TPH-DRO	8015M	Glass	None	1000ml	7 days to extraction 40 days after

Appendix 6 Sample Storage, Preservation Guide and Hold Times

					extraction
Parameter	Analytical Method	Container	Storage & preservation	Minimum Sample Volume	Maximum Holding Times
Aromatic Volatile Org.	8020	Glass	4°C/Na ₂ S ₂ O ₃ / HCL	3x40ml	14 days
Purgeable Halocarbons	8010B	Glass	4°C/Na ₂ S ₂ O ₃ / HCL	3x40ml	14 days
VOC	624/8260	Glass	4°C/Na ₂ S ₂ O ₃ ; HCL	3x40ml VOA vials	14 days preserved 7 days un-pres.
SVOC	625/8270	Glass	4°C/Na ₂ S ₂ O _{3/} HCL	1000ml	7/14 days for extraction; 40 days to analysis
Chlorinated Herbicides	8150B	Glass	4°C pH 5-9	1000ml	7/14 days for extraction; 40 days to analysis
Pest./PCBs	8080A/8140	Glass	4°C pH 5-9	1000ml	7 days to extraction for water 14 days to extraction for soils
Polycyclic Aromatic Hydrocarbons (PAHs)	8310	Glass	4°C/Na ₂ S ₂ O ₃	1000ml	7/14 days to extraction; 40 days to analysis
TCLP	1311	Glass-Teflon lined	4°C	1000ml 500 grams	180 days to extraction- metals; 14 days for VOAs extraction and 40 days to analysis; 28 days to Hg extraction and analysis

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Appendix 7

Resumes

The following resumes are attached as representative of the Technical Staff at Silver State Analytical Laboratories, Inc. but not an exhaustive list of staff members.

- John Sloan, Laboratory Director
- Steve West Senior Technician
- George Schuler-Technician
- Edward Tullman, III Senior Chemist
- Chad Langille Chemist
- Casey Romeo-Chemist
- Tim Sweeney Reno Branch Manager
- Carly Wood Chemist
- Lewis Bergstrom-Technician
- David Frohnen President

John Sloan 9490 Thunder Sky #102 Las Vegas, NV 89178

Education

University of Nevada-Reno Bachelor of Science, Biochemistry Spring 2003

Work Experience

August 2010 - Present Silver State Analytical Laboratories Las Vegas, Nevada

Laboratory Director

Some of the responsibilities of Laboratory Director are:

- Coordinating and overseeing all operations of the laboratory, including budgeting, supply requisitions, new equipment purchasing, and general management.
- Overseeing the development and implementation of strict quality assurance and control programs.
- Developing and maintaining client relationships, including the supervision of all projects and new client development.
- Supervising all laboratory testing, analyses, performance evaluations, and reporting to ensure compliance with client, local, state and federal standards.
- Supervising the training and continuing education of all management and laboratory staff.
- Providing technical support for management and laboratory personnel.
- Overseeing laboratory staffing and the maintenance of laboratory equipment and facilities.
- Performing special analytical testing and method development as needed.

2006- 2010 Silver State Analytical Laboratories Las Vegas, Nevada

Analytical Chemist

Some of the responsibilities of Analytical Chemist included:

- Conducting laboratory testing and analyses in the inorganic laboratory in accordance with the Safe Drinking Water Act (SDWA), Clean Water Act (CWA), and Resource Conservation and Recovery Act (RCRA).
- Analyzing samples by Ion Chromatography, Spectroscopy, Colorimetry, Gravimetric methods and various other Wet Chemistry methods.
- Writing, editing, and coordinating laboratory results in a written report for clients.
- Maintaining knowledge of testing and analytical policies and procedures to ensure compliance with client, local, state and federal standards..
- Performing laboratory testing with due diligence to ensure quality of work and safety in the workplace.
- Maintaining appropriate record keeping for quality assurance and control standards.
- Receiving and recording samples for testing.
- Assisting laboratory supervisors with projects as needed.

Stephen A. West

Experience	2011-Present Senior Te Bottle preparation/pr Composite and grate Monitors and record Prepares soils for an Miscellaneous samp Sample log-in and tr Test equipment calif	Las Vegas, NV	
	2003-2011 Si Technicia Field sampling of so Bottle preparation/pr Composite and grad Monitors and record Prepares soils for ar Sample log-in and tr	Las Vegas, NV calibrations	
Education	2000-2003 Pursuing a Bacheloi	Snow College r of Science degree in Environmental Stu	Manti, UT udies
•	1996-2000 High School Diplom	Park City High School a	Park City, UT

Edward J. Tullman III

2128 Club Meadows Dr. Henderson, NV 89074 Cell: (702) 553-9953 Email: spaghed@gmail.com

EMPLOYMENT OBJECTIVE

A Laboratory Technician position that will utilize my education in the fields of biology and chemistry, and previous two years of experience as an intern at the Las Vegas Valley Water District (LVVWD)

TECHNIQUES (Biology)

- Prepared media plates for growing bacterial cultures at LVVWD and University of Nevada Las Vegas (UNLV)
- Completed microbiology lecture and lab courses at UNLV
- Assisted in viral extractions from water samples at LVVWD
- Used glassware dishwashers, autoclaves and vacuum filtration systems at LVVWD and UNLV

TECHNIQUES (Chemistry)

- Experienced with sample preparations required for treating water samples and associated chemicals in accordance with EPA guidelines at LVVWD
- Performed organic extractions on Haloacetic Acids (HAA) at LVVWD
- General skills: Conductivity, pH, titration, centrifugation, melting point determination, eudiometry, calorimetric, absorption spectrometry (for testing of chlorine, zinc, and iron samples), specific gravity and turbidity measurements

EDUCATION

2005-2010 UNLV: B.S. degree in Biology with a minor in Chemistry, GPA: 3.2

2001-2005 Coronado High School: Advanced Diploma, GPA: 3.6

EMPLOYMENT

9/2011-Pres. Chemist, Silver State Analytical Laboratories, Inc.:

- Prepared samples for analysis and conducted analyses of phosphate, sulfates, sodium, phenols, nitrogen and other parameter following SOP's.

- Prepared reagents and solutions for the chemistry laboratory

- Entered sample data into Laboratory Computer system

- Keep log books of sample check in, equipment calibrations, temperatures and other qa/qc data.

4/2011-9/2011 Environmental Technician, Silver State Analytical Laboratories, Inc.:

- Collected field samples and logged in same following Chain of Custody and other procedures.

- Prepared sample bottles and preservatives per EPA protocols.

- Prepared reagents and solutions for the chemistry laboratory

- Entered sample data into Laboratory Computer system

- Keep log books of sample check in, equipment calibrations, temperatures and other qa/qc data.

2007-2009 Chemistry Intern III, LVVWD:

- Prepared samples for analysis of phosphate, total organic carbon, dissolved organic carbon, trihalomethane and HAA

- Prepared reagents and solutions for the chemistry laboratory

- Entered sample data into Laboratory Information Management

Systems (LIMS) for phosphate digestion, bulk ferric chloride, and bulk zinc orthophosphate samples

- Neutralized and disposed of organic/inorganic hazardous waste

- Performed media and sample preparations for the microbiology laboratory

- Collected and tested water from reagent water systems for free and total chlorine to ensure no chlorine contamination existed

- Performed calibrations on various laboratory instrumentation

AWARDS AND SKILLS

- Nevada State Millennium Scholarship, awarded in 2005

- Completed calculus I, II, III, differential equations and calculus-based physics beyond college degree requirements
- Software: LIMS, Microsoft Office Suite, Sigmaplot and Minitab

Chad Langille

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Objective

To strive for a position that provides an opportunity for personal growth and professional achievement.

Education

University of Nevada, Reno August 2008 – May 2012 B.S. Biochemistry and Molecular Biology, Chemistry Minor; GPA 3.767

Green Valley High School

August 2004 – June 2008

Work Experience

Silver State Analytical Laboratories, Inc. – Chemist January 2014 – Present

Molycorp Minerals, LLC - Chlor-Alkali Chemist

May 2013 - January 2014

Collaborate with peers and supervisors to start-up a Chlor-Alkali/Brine Purification laboratory; Familiar with ordering, purchasing, and setup of laboratory equipment; Develop methods and procedures for the identification of impurities in the Chlor-Alkali process; Communicate effectively with operators, chemists, and engineers; CPR and MSHA certified

Molycorp Minerals, LLC - Department of Technology - Process Development Scientist

October 2012 – May 2013

Responsible for high-yield product experimentation/verification (sample preparation→chemical analysis→data interpretation); Comfortable with various organic/inorganic chemical instrumentation; Develop methodology to enable a higher-yield of product and minimize environmental impact; Work in one of the world's leading rare earth and rare metals companies; MSHA certified

University of Nevada - Department of Cell Biology and Physiology - Lab Researcher/Assistant

May 2011 – May 2012

Contributed to a Cell Biology and Physiology Lab environment by utilizing proper laboratory technique; Built valuable relationships with graduate students and professors; Operated independently and utilized cognitive reasoning

University of Nevada - Joe Crowley Student Union Employee – Lead Audio/Visual/IT Technician March 2009 – May 2012

Oversaw all audio and visual aspects of the Student Union; Conducted inventory of equipment; Organized and maintained set-ups, takedowns, and turnovers; Assigned duties to employees in an organized and timely manner; Provided customer service by means of oral and written communication

Renown Medical Center - Hospital Volunteer

January 2011 - September 2011

Assisted those in need of information and direction; Familiar with proper phone etiquette and professional surveying; Experience in same-day surgery, emergency medicine, and pediatrics; Shadowed numerous surgeries under a registered anesthesiologist

Whitney Ranch Recreation Center Employee – Recreation Assistant III March 2005 – August 2010 Managed day care facility, incorporating enrichment in youth; Planned and organized a variety of popular events and activities; Provided a comfortable working environment for staff and participants; Familiar with Microsoft Office (Word, Excel, PowerPoint, Outlook)

Honors and Awards

College of Agriculture, Biotechnology, and Natural Resources Dean's List Fall 2008, Spring 2009, Fall 2010, Spring 2012

The National Society of Leadership and Success - Sigma Alpha Pi Chapter

Golden Key International Honor Society Member

Skills

- Successfully completed a thesis on the investigation of piRNA-like activity and influence in somatic cell tissues in *Mus musculus*
- Familiar with various laboratory procedures and techniques, including: scientific/research lab etiquette, pipetting, centrifugation, homogenization, culturing cells, cell sorting, polymerase chain reaction (PCR), gel electrophoresis, gel imaging and analysis, bioinformatic analysis, gas/ion/column chromatography, mass spectrometry (ICP-MS), high performance liquid chromatography (HPLC), etc.
- Comfortable with organic/inorganic chemical instrumentation consisting of: dilutions, titrations, autotitrations, muffle furnace/high heat use, gravitational/vacuum/syringe filtration, fusion disk preparation and X-ray fluorescence (XRF), atomic absorption spectroscopy (AA), inductively coupled plasma atomic emission spectroscopy (ICP-AES), total organic carbon (TOC) analysis, particle size dispersion (PSD), ultraviolet-visible spectroscopy (UV-VIS), etc.

Activities

Big Brothers Big Sisters of Northern Nevada – Big Brother (began in August 2010) "Big" of a 9 year-old; Plan weekly activities to better improve his lifestyle and life choices Maintaining a healthy and active lifestyle, learning, preserving the environment, and listening to music

References

Reno, NV 89557

Robert P. Finnegan (702) 269-6060 President Finnegan Erickson Associates 2821 W. Horizon Ridge Parkway Suite 200 Henderson, NV 89052

Nicole Ortogero (808) 721-2246 Graduate Assistant University of Nevada, Reno 1664 N. Virginia St Dr. Patricia Ellison (775) 784-4561 Assistant Professor Howard Medical Science, Office 153 1664 N. Virginia St. Reno, Nevada 89557

Deaon Clausell (775) 232-5283 Technology Services Coordinator Joe Crowley Student Union 1664 N. Virginia St. Reno, Nevada 89 Timothy M. Sweeney 6280 Stone Valley Dr. Reno, NV 89523 (H) 775-747-2538 (C) 775-376-0776 timmkt4u@yahoo.com

PROFESSIONAL HISTORY

2011-Present	Branch Manager, Silver State Analytical Labs
2006 - 2011	Terminal Operations Supervisor, AmeriGas
1997 - 2006	Special Projects Manager, Pezonella Associates, Inc.
1992 - 1997	Marketing & Public Relations, Broadbent & Associates, Inc.
1983 - 1992	Vice President, Norris Fuel & Supply Co., Inc.

SUMMARY

Currently I am Branch Manager for Silver State Analytical Labs in Reno, Nevada. The scope of my duties include the management of a soil, water and air analytical laboratory and sales and rental of environmental sampling equipment.

PROFESSIONAL EXPERIENCE

2006 - Present Branch Manager, Silver State Analytical Labs, Reno, NV,

- Assured safe and efficient operation of the Office and Laboratory Facility.
- Ensured proper documentation, reporting, and quality control in accordance to the Quality Assurance Control guidelines.
- Oversaw Standard Operations Procedures and were followed to guarantee quality defensibility was not questioned.

2006 - 2011 Terminal Supervisor, AmeriGas Terminal, Reno, NV,

- Assured safe and efficient operation of the shipping storage facility.
- Ensured proper documentation, reporting, of all incidents and accidents.
- Maintenance of compressors, pumps and other equipment at the Terminal.
- Managed inventory and performed calculations to ensure slippage was less than 2% (averaged .5%)
- Monitored and tested propane for specification variations and odorization.
- Instructed and monitored drivers and their equipment to ensure our loading procedures were followed.
- Drove down costs by adhering to budget that I helped in establishing and ensure minimization of utilities.
- Contributed in the development of the Operations Safety Manuel and Process Safety Management for the existing and expansion.

1997 - 2006 Special Projects Manager, Pezonella Associates, Inc., Reno, NV, I performed the following:

- Negotiated of acceptable budget and terms.
- Created numerous proposals and Requests for Qualifications.
- Worked closely with regulators for our clients.
- Interpreted construction schedules and structural blueprints.

- Designed and utilized the pumping system for monitoring groundwater.
- Coordinated all marketing brochures, signs and promotional items for direct marketing.
- Assisted staff in the efforts to keep the Statement of Qualifications current.

1992 - 1997 Marketing & Public Relations, Broadbent & Associates, Inc., Reno & Las Vegas, NV,

- Communicated with contractors, environmental consultants, insurance companies, and regulators.

- Created numerous proposals and Requests for Qualifications.
- Coordinated all marketing brochures, signs, banners and promotional items.
- Assisted staff in the ongoing efforts to keep the Statement of Qualifications current.
- Assisted in the development of a marketing plan.
- Established a more cost effective way to keep track of future Requests for Proposal.
- Developed procedures to improve communication with potential and existing clients.
- Developed marketing lists for a quarterly mailing.

1967 - 1992 Vice President of Operations, Norris Fuel & Supply Companies, Inc., Sparks, NV. Prior to reaching the position of Vice President began served as an hourly employee in every aspect of the company.

- Oversaw the fleet was maintained cost effectively by Norris's own or out sourced shop.
- Developed a Safety program including quarterly safety meetings for the drivers.
- Supervised a staff of fifty employees of various job descriptions.

- Directed the acquisitions of petroleum products from major and independent oil companies.

- Determined the petroleum price to be sold to customers and verified through billing invoicing.

- Developed and administered a budget for an operation with gross sales of twelve million dollars per year.

- Directed efforts to develop new markets through management of a sales force.

COMPUTER EXPERIENCE

IBM compatible Microsoft including MS-DOS and Windows, Timberline and Platinum software. MS Project, EXCEL, Word, Claris MacDraw, Filemaker, Now Up To Date, Now Contact, PowerPoint, and Territory Manager.

PROFESSIONAL COURSES AND SEMINARS

2008 CTEP Training Basic Principles and Practices

2008 CTEP Training Transfer System Operations

2008 AmeriGas Rail Terminal Training

2007 TARGA Propane Safety Seminar

2000 Marketing/ Goal Setting Seminar, Reno, NV

1991 Financial Analysis, Valley Bank of Nevada, Reno, NV

1989 Human Resource Management Techniques, Reno, NV

1988 Credit Management Workshop, T.B.Edlick, Inc., Sacramento, CA

1976 two semesters University of Nevada, Reno, NV., General Studies

PROFESSIONAL AFFILIATIONS

- Scout Master for Troop 152 of Boy Scouts of America
- Chairman of the City of Reno Environmental Committee
- Member of the Western Petroleum Marketers Assoc.
- Member of the California Independent Oil Marketers Assoc.
- Member of the Nevada Mining Assoc. (NMA),
- Member of the Nevada Mining Assoc. (NMA), Environmental Committee

- Member of the Nevada Mining Assoc. (NMA), Miner's Pick supplier organization •
- Past Secretary of the City of Reno Environmental Committee Past President of the City of Reno Environmental Committee •
- •
- Past member of the Board of Directors of the Nevada Motor Transport Assoc. •
- Past member of the Board of Directors of the Western Petroleum Marketers Assoc.
- Past President and Treasurer of the Oil Heat Institute of Northern Nevada
- Past Sec/Treas. of the Board of Directors of Norris Fuel Co., Inc.
- Past Sec/Treas. of the Board of Directors of Norris Supply Co., Inc. •

REFERENCES

Excellent references available on request

Lewis Bergstrom

Laboratory Technician – Analyst Silver State Analytical Laboratories, Inc. 4587 Longley Lane, No. 2 Reno, NV 89502 Ibergstrom@ssalabs.com

Experience

Lab Technician - Analyst, June 2014 - Present

Silver State Analytical Laboratories, Inc., Reno, Nevada

- Unload and receive samples from clients then verify them against the Chain of Custody
- Prepare bottle kits for clients for their sample collection
- Sample storage and disposal
- Gravimetric analysis for hexane extractable materials (EPA method 1664)
- Wet chemistry analyses using ISE probes, pH and titrations.
- Microbiological testing and some photo colorimetric tests.

Lab Technician, 2012-2014

TestAmerica, Phoenix, Arizona

- Unload and receive samples from clients then verify them against the Chain of Custody
- Prepare bottle kits for clients for their sample collection
- Sample storage and disposal
- Drinking water sampling for microbiological analysis
- Solvent extractions on water and soil samples (EPA methods 3510 and 3545)
- Gravimetric analysis for hexane extractable materials (EPA method 1664)

Lab Technician, 2010-2012

McClelland Laboratories, Sparks, Nevada

- Responsible for starting, maintaining, and ending environmental procedures
- Performed analysis on aqueous solutions for: pH, redox, conductivity, alkalinity (as CaCO3), acidity (as CaCO3), irons and sulfates.
- Helped develop the lab Standard Operating Procedure.

• Experienced in data entry and clerical functions using Microsoft Office and Adobe.

Shift Supervisor, 2005-2006/2008-2010

Starbucks Coffee Company, Reno, Nevada

- Managed store when Store Manager wasn't present.
- Worked in a high-volume, high-stress work environment while upholding company standards for customer service and quality of product.
- Handled store deposits, tip distribution, and maintained the store supply orders.
- Managed a team of up to eight people at a time.

Home Delivery Technician, 2006-2008

Select Comfort, Reno, Nevada

- Set up and delivery of beds throughout Northern Nevada and Northeastern California.
- Worked independently from immediate management.
- Developed a "self-starter", responsible work ethic.

Education

Truckee Meadows Community College, Reno, NV Undergraduate Studies

Carson High School, Carson City, NV High School Diploma

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Carly Wood

Chemist – Technical Director Silver State Analytical Laboratories, Inc. 4587 Longley Lane, No. 100 Reno, NV 89502 cwood@ssalabs.com

SUMMARY: College graduate (honors) with a degree in chemistry and over 3 years of professional level experience in an environmental testing laboratory. Experience in CA-ELAP and NDEP regulatory program. Experienced in wet chemistry, Ion Chromatograph, GC/MS, photospectrometer and other instruments. Proficient in QC program implementation.

EDUCATION:

Bachelors of Science in Chemistry - 2011 Southern Oregon University, Ashland, OR

Graduated Cum Laude with a BS in Chemistry, ACS certified Biochemistry Analytical Development:

- Instrumentation and Techniques for Data Analysis
- Analyzing and Interpreting Data
- Independent senior research performed

GENERAL SKILLS:

- Leadership qualities
- Team player
- Hard worker
- Dedicated
- Proactive

ENVIRONMENTAL LAB SKILLS:

- Chemistry Degree
- Collegiate experience with lab instruments: FT-IR, NMR, UV/VIS, GC/MS, HPLC, and Raman
- Strong analytical skills
- Experience with lab software (LIMS, excel)
- Lab safety officer
- Follow SOPs

- Punctual
- Quality communicator
- Excellent problem-solving abilities
- Friendly
- Experience in an environmental lab
- Experience with wastewater, storm water, drinking water, and soil
- Environmental lab experience with IC and UV/VIS instrumentation
- CWEA lab analyst Grade 2 certificate
- Trained on various wet chemistry and microbiological test analyses
- TEST ANALYSIS: (test analyses currently trained to perform)

<u>Microbiological</u> Coliform testing (multi-tube, presence/absence, quanta-tray) HPC, HPC simplate BOD/CBOD

Cl₂, pH, DO, EC, Turbidity Alk, Hard, Ca Ammonia (by: titrimetric, phenate, probe), TKN

Chemistry

Colorimetric total phosphate and ortho-phosphate Colorimetric nitrites, T&L, Silica Chlorophylls

TSS, TDS, TS%, VS%, SS	Cr6, MBAS, CN ⁻ , COD	Colors and Odors
	IC ions: F, CI, NO2, NO3, Ortho-	Titrimetric sulfite and sulfate
	phosphate, SO4	

PROFESSIONAL EXPERIENCE:

Silver State Analytical Laboratory – Reno, NV

May 2014 to Present

Chemist – Technical Director (August 2014 – Present)

Lead analyst and technical director for environmental testing laboratory. Performs microbiological testing, wet chemistry, photospectrometer tests and anions by IC methods. Follows EPA and SM protocols, revises SOP's, implements PT and other regulatory programs. Supervises laboratory technician/analyst. Technical resource for Reno laboratory.

Chemist (May 2014 – August 2014)

Lead analyst for environmental testing lab. Performed tests and all documentation following EPA/NDEP requirements and following approved SOP's. Reagent log in, sample prep. Testing performance using wet chem, gravimetric, photospectrometer, and IC methods. Documented and checked work following approved QC protocols.

Sierra Foothill Laboratory - Jackson, CA

September 2011 to May 2014

Technical Specialist (June 2013 to Present)

Conducts special studies, responsible for implementing new wet chemistry testing procedures, sub lab data entry into LIMS, lab data calculation and entry into LIMS, ship samples to sub labs, CoC creation, assisted and prepared for ELAP audit, audit experience with ELAP and USBR, laboratory safety officer, monthly QA/QC, instrument calibration, revised SOPs, prepare various chemical reagents as needed, perform various chemistry and microbiological analyses stated above in the test analysis section, assists management, beginning to learn about permits

El Dorado Lab Lead Analyst (on-site contract at El Dorado Irrigation District) (April 2012 to June 2013) Media preparation, performed various wet chemistry and microbiological analyses as stated in the test analysis section, prepared reagents, data calculation and entry into LIMS, interacted with plant operators and EID personnel, coordinated with wet chemistry and microbiology leads from Sierra Foothill Lab main facility, monthly QA/QC, instrument calibration, aliquot samples to various containers, delivered courier samples, revised SOPs, responsible for lab cleaning, answered telephone calls. This is a SDWA lab.

Micro Lab Analyst (September 2011 to April 2012)

 Prepared reagents as needed, perform various microbiological analyses as stated in the test analysis section, performed various BOD and solid analysis, monthly QA/QC, instrument calibration, data entry in LIMS

Folsom Lake Hyundai - Folsom, CA

Parts and Service Receptionist

- Answered telephones, interacted with customers, accepted customer payment for car services, filed customer service records, organized and prepared folders for customer service records, opened/closed parts and service shop, closed out cash drawer weekly
- Reason for leaving: Accepted job offer with Sierra Foothill Laboratory

Ashland Community Hospital - Ashland, OR

July 2010 to September 2010

August 2011 to September 2011

Hospital Quest Services Volunteer (~40 hours)

• Set up hospital rooms for new patients, customer service and help desk, food delivery for patients

Southern Oregon University Women's Basketball - Ashland, OR June 2009 to July 2009 Basketball Camp Coach

• Organized and coached high school participants, group counselor, dorm monitor, supervised participants outside of scheduled practice times

REFERENCES:

<u>Name</u>	Relationship	Phone Number	Email
Rachel Kaua	Supervisor	209.768.7108	hiak3@comcast.net
Andrea McGuckin	Co-worker	209.256.3959	andreamcguckin@gmail.com
Tyler Laczynski	Personal	775.771.2597	tyler.laczynski.1@ang.af.mil

David J. Frohnen 11 Isleworth Drive Henderson, NV 89052 dfrohnen@ssalabs.com

Phone (702) 348-8375 E-mail:

TECHNICAL/SCIENTIFIC MANAGEMENT – ENVIRONMETNAL COMPLIANCE

- Certified Laboratory Management
- Water/WW Operations
 Customer Service and Business Operations
- Environmental Quality Compliance
- Environmental Engineer
- Utility Planning, Construction &

- Operations
- Accomplished leader with repeated success in diverse industries. Experience in environmental quality compliance including laboratory methods and supervision. Proficient in regulation development and compliance.
- M.B.A. Management; B.S. Civil Engineering. P.E. in AZ, CA, OR, WA, and NV. Real Estate Licensee.

EXPERIENCE

2010 – Present, Silver State Analytical Laboratories, Inc., Las Vegas, NV President

Supervise day-to-day operations and executive functions of a Nevada Certified Environmental Testing Laboratory with operations in Las Vegas and Reno, Nevada. Establish overall Quality program, procurement of analytical instruments, staffing and customer service functions of lab providing quality services in SDWA, CWA, RCRA, materials, food safety and general chemistry in support of industry and the environment. Staff of 10.

2002 – 2010, Stanley Consultants, Inc., Las Vegas, NV

Vice-President and Manager, Las Vegas Office

International Engineering, Environmental, and Construction Management firm providing services to governments, private/commercial developers, utilities, public agencies and various industrial, healthcare and education entities.

Directed two office locations with 100 members (total) in engineering, surveying and construction services - selling to clients involved in land development/home building, commercial real estate, transportation, and water/wastewater infrastructure projects and master plans. Billings in excess of \$10 million per year.

- Re-focused office with poor history of profitability to profitable sales, management, and fiscal accountability. Recruited staff for critical skill set needs and grew staff from 20 members in 2002 to 100 in 2006 through organic growth. Implemented many programs for training to improve financial performance, quality, and service.
- Established, staffed and grew a start-up office in Kingman, Arizona to service the Northwest Arizona area.
- As Group Manager and PM, led completion of infrastructure for 1900-acre master planned community in North Las Vegas. Expedited schedules, completed designs and coordinated with multiple stakeholders and agencies.
- Applied expertise in environmental engineering, regulatory compliance and water treatment to assist

varied clients in planning, designing, constructing and operating infrastructure projects including chemical process engineering and laboratory protocols. Insuring environmental compliance and quality operations.

1997 – 2001, United Metal Technologies, Las Vegas, NV.

President – Chief Operating Officer

\$20 million, multi-state manufacturer servicing OEM's in electronics, telecom, medical, semiconductor, and gaming.

- Responsibility for all operations, including sales, estimating, engineering, production, quality, and customer service. Oversaw 200 personnel through 8 direct reports. Reported to Chairman of Parent Company.
- Grew company from 1 location, 20-persons, \$1.8 million in sales to 7 locations, 200 personnel and \$20 million sales. Implemented aggressive LBO program, acquiring/integrating 6 companies in CA and NV.
- Grew internally through expanding service offerings, introducing turnkey assembly services, powder coating, chrome plating, and enhanced engineering design services. Put systems/procedures in place for large multi-state operation. Responsible for environmental compliance and implemented quality programs.

1990 – 1997, **American Water Works Company (formerly Citizens Utilities Company),** Stamford, CT. \$1 billion Company, with \$100 million in revenues providing water services, \$30 million of which is in Arizona.

Director-Operations/Assistant General Manager, Phoenix, AZ. 1992 - 1997

Promoted from California subsidiary to high-growth Arizona market with responsibility of business and technical operations of 7 distinct investor-owned water utilities. Activities included daily service and facility maintenance of \$100+ million in plant assets, construction projects, environmental compliance, long-range planning, staff development, and marketing. Oversaw 60 personnel through 6 direct reports. Served on several corporate teams.

- Led \$30 million statewide organization in providing high-quality, cost-effective water and wastewater service.
- Grew business through winning unregulated service contracts, making acquisitions, plus constructing new facilities. Emphasis on quality service and environmental compliance, major nutrient removal upgrade project.
- Served as expert witness before State Board, providing testimony that resulted in rate increases and greater revenues.
- Researched state law and developed effective water resource plans in arid southwest. Participated in development of regulations that minimized negative impacts to our industry. Participated in regional and national water policy.

Manager, Engineering and Construction, Sacramento, CA. 1990 - 1992

Planned, designed, and managed construction of all water facilities for 7 operating companies serving 250,000 people in Northern California. Oversaw 6 engineers, technicians and inspection personnel, plus multiple contractors.

- Performed system master planning and strategic business plans. Managed annual capital budget of \$15 million.
- Marketed services to land developers, wrote proposals, and negotiated/implemented development contracts.

- Streamlined design processes and fast tracked water project constructions.
 - Designed water improvement project, completed competitive application, and won \$3 million in state funding.
- Directed effective responses to floods and earthquakes, minimizing service interruption and damage to facilities.
 - Rebuilt water systems plus negotiated contested insurance claim, winning \$600,000 award.
- Served as expert witness in rate proceedings. Filed written testimony, conducted public forums on water quality, environmental compliance and other subjects. Stood trial.
- Directed water quality and conservation programs. Integrated new regulations into long range planning.

1989 - 1990, Nolte and Associates, Sacramento, CA.

Associate Engineer – Project Manager (Consulting Engineer)

Performed civil and environmental engineering services for industrial clients, land developers, and government. Grew firm's revenues via marketing activities, preparing proposals, contracting services, as well as through prospecting.

- Completed studies, designs, project/construction management, and operations on various water/waste projects.
- Served as regulatory and public relations liaison. Dealt with public agencies during entitlement/enforcement work.
- Developed solutions for master planned communities, land developers, food processors, manufacturers, utilities, government, and institutional facilities.

1983-1989

ALCOA (formerly Reynolds Metals Company), Longview, WA.

Project Engineer/Project Manager

Planned, designed, and constructed projects for modernizing aluminum smelting, manufacturing, and chemical processing plants, expanding facilities and achieving environmental compliance. Performed process, manufacturing, and facilities engineering within large self-contained complex. Projects included a deep water port, 20 mgd water system, advanced technology wastewater plants, buildings, casting pits, and other facilities to support an aluminum and chemical processing plant covering 700 acres and employing 1200 personnel.

• Directed all research, design, and construction of advanced technology industrial waste treatment plant. Served as general contractor saving more than \$500,000 in capital and \$250,000 in first year's O&M (1987 dollars).

EDUCATION

M.B.A., University of Portland, Portland, Oregon.

Concentration in policy/strategic planning, general management, and finance.

B.S.C.E., University of Idaho, Moscow, Idaho.

4.0 GPA within civil/environmental engineering major while 4-year starter on Division I football team.

MEMBERSHIPS, TRAINING, & LICENSES

Member – ACEC – NV President, ASCE, AWWA, NAIOP, NDA, Air & Waste Mgmt., AEG, WEF, NRWA, NMA.

The Business of Engineering Consulting, American Council of Engineering Companies, October 2006. **Commercial Real Estate,** University of Nevada Las Vegas, 9-month Certificate Program – completed in 2004.

Residential Land Development, American Society of Civil Engineers Continued Education Course – 2003.

Center for Creative Leadership – Leadership Development Program, a high-level professional curriculum for developing senior executives in six-day retreat/workshop/observation environment.

Leadership Breakthrough Training. Intensive leadership development program offered by Rapport Leadership Institute.

Public Utilities Reports. Comprehensive correspondence course for utility managers.

Utility Finance and Accounting. Completion of intensive workshop offered by Financial Accounting Institute, with focus on utility finance/accounting issues as well as deregulation.

Malcolm Baldrige National Quality Award. Completion of comprehensive training and application of concepts used for TQM programs based on the National Award Criteria. Member of corporate review team.

Registered Professional Engineer - Civil, states of Arizona, California, Oregon, Washington, and Nevada.

Certified Water/Wastewater Operator, highest level possible --states of Arizona and California (lapsed).

Licensed Real Estate Sales Agent, State of California (lapsed).

PUBLICATIONS, PRESENTATIONS & AWARDS

"Plan, Deploy, Review - A Business Planning Process Empowering Associates for Superior Results" presented and published June 1996 at the American Water Works Association Annual Conference and Exposition, Toronto, Ontario, Canada.

"Replacing Water Meters for Optimal Economic Value" presented May 1996 at Arizona Water and Pollution Control Association Annual Conference, Tucson, AZ. Presented and published June 1996 at the American Water Works Association Annual Conference and Exposition, Toronto, Ontario, Canada.

"Deep Well Injection of High Salinity Food Processing Wastewater" presented and published in February 1991 at the 18th annual CWPCA Industrial and Hazardous Waste Conference and Exhibition sponsored by California Water Pollution Control Association and WEF.

Tau Beta Pi, Phi Kappa Phi, and Silver Lance Honorary Societies.

CHARLENE REESE SALINAS

Home Phone: 702-818-5993

cssalinas@yahoo.com

SUMMARY

Over the last 30+ years, I have dealt with many regulatory agencies in various capacities. I am very familiar with compliance to pertinent laws, regulations and rules and the possible consequences when compliance is not met. Having written and validated many analytical methods for EPA, FDA, USDA and OSHA regulated data, I have extensive experience in writing technical/analytical reports and am familiar with the writing process involved. All QA/QC programs are to ensure that the data is believable and defendable and to ensure that there are records to back up the numbers. In my current position, I do internal audits and have, in the past, done external third party audits while employed by other companies. I have investigated non-compliance issues and have been on root cause analysis teams. This only touches on my experiences in Quality Programs. I also have extensive hands-on experience with the following instrumentation:

GC/MS	GC(All Detectors)	HPLC
GC/TOF	LC/TOF	UPLC
IC	ICP/MS	IR
UV/VIS	UV/Fluorescence	TLC
Chemiluminescence	Raman	TGA
AA	FT/NIR	Calorimeters
Scintillation Counters	Ultracentrifuges	Process Analyzers
Area Monitors	Personnel Monitors	SEM/XRD

EDUCATION

Masters of Arts, Chemistry

University of South Dakota, Vermillion, South Dakota Thesis: The Synthesis and Characterization of Lead IV Polyesters

PROFESSIONAL EXPERIENCE

SILVER STATE ANALYTICAL LABORATORIES, Las Vegas, Nevada 2014-Present Principal Chemist

- Special Projects
- Aid in state certification/recertification of methods
- Write SOP's
- Train technicians as needed

CONAGRA FOODS, Omaha, Nebraska

Senior Chemist

- Deputy Laboratory Quality Specialist (ISO 17025:2007 Laboratory)
 - Performed annual internal audit of Management Systems procedures against ISO 17025:2005 Standards
 - Performed internal audit of in scope test methods

2009-2012

- Performed audits of new methods to be put into scope
- When Laboratory Quality Specialist is absent, backfilled his position
- Checked notebooks and data for QC compliance (control charts for Laboratory Control Samples and limits for ICV and ICC)
- Attended an 8 hr. course on How to Perform Root Cause Analysis (RCA)
- Lead Root Cause Analysis investigations for non-compliance
- Laboratory Safety Officer
 - Wrote laboratory Safety Program
 - Provided annual training for laboratory personnel
 - Tested safety equipment according to schedule
 - Disposed of waste solvents and chemicals
 - Designed/engineered/found ergonomic equipment and/or procedures when necessary
- Support Food Safety and other projects
 - Developed analytical instrument methods for compounds of interest if none are available
 - Operated SEM (Scanning Electron Microscope) and x-ray reflectance for elemental analysis to help resolve customer complaints and plant issues

NOVARTIS CONSUMER HEALTH, Lincoln, Nebraska **Contract (Aerotek) Chemist for Analytical Development**

- Worked within cGMP protocols
- Worked on methods development
- Provided analytical support for projects
- Wrote protocols for methods and method transfers
- Wrote validation protocols
- Wrote final validation reports
- Created Excel spreadsheet to track corrective and preventive actions (CAPAs) and wrote monthly update reports with statistic to determine where and why most of the CAPAs were generated
- Sent out samples to third party laboratories when needed
- Was on Laboratory Safety Team

EXXONMOBIL CHEMICAL COMPANY, Baton Rouge, Louisiana

Senior Engineer (Analyzer) 2004-2006

- Developed and executed analyzer projects
- Upgraded obsolete and unsupported analyzers
- Recommended analyzers for new applications
- Technical support for existing analyzers
- Installed analyzer to monitor feed stock to a reactor which increased efficiency and productivity.
- Found a less expensive analyzer to replace 4 "Bad Actors" which were obsolete and needed replacing. To replace like for like would have cost \$26,000 per unit, but found a like function for \$3500 saving \$22,500 per analyzer.

Plant Engineer (Analyzer) 2001-2004

- Provided necessary support for analyzers and project developments.
- A CEMS system on a Thermal Oxidizer was having drift problems and was having to report it to the State Department of Environmental Quality. Solved the problem and saved an environmental incident.

2006-2009

2001-2006

OCCIDENTAL CHEMICAL COMPANY, Ingleside, Texas **Industrial Hygiene Duties:**

1991-2001

- Managed personnel and air monitoring portion of the Industrial Hygiene Program and wrote the Industrial Hygiene Plan
- Member of the HAZMAT response team.
- Planned and administered monitoring schedule
- Determined methods
- Calibrated and repaired sampling equipment
- Audited third party laboratories
- Reviewed data and notified personnel
- Updated personnel records

Analyzer Specialist Duties:

- Troubleshoot process analyzers
- Reconcile data from QC laboratory with process analyzers and field laboratory
- Train Analyzer Technicians and provide maintenance schedules
- Spec out and install new analyzers when necessary to achieve monitoring goals of process engineers
- Write and present data
- Defend Environmental data to State regulatory agency and EPA when called upon

Major Process projects as Plant Chemist:

- Major research saved the company over \$500K/yr. on waste disposal
- Solved a process problem that had been an issue for 50 years
- Resolved analytical differences between process analyzers and laboratory data
- Reconfigured in-line GC's and improved other process analyzers
- Was involved in designing a field lab and specified analyzer for an expansion of VCM unit (received a bonus for both)
- Resolved off spec product issues and found a way to salvage the product without re-working it
- Help with turn around (planned downtime for plant maintenance) to determine causes of corrosion, pitting, plugging that was not normal

VULCAN MATERIALS COMPANY, Geismar, Louisiana

1989-1991

Projects Chemist

- Environmental projects:
 - Development and implementation of sampling and analytical protocols for incinerator test burns
 - o Plant-wide waste stream characterization
 - Coordination of sampling, analysis and data compilation for NPDES permit renewal
 - o Laboratory wide environmental analytical method improvements
- Process projects:
 - Process instrumentation and control optimization,
 - o Catalyst recovery and waste minimization
 - Optimization of distillation towers
 - Efficiency improvements in effluent processing unit
 - Identification and resolution of materials compatibility issues in several units

1989-1991

1986-1989

- Routine Duties
 - Oversight and data interpretation of scheduled environmental samples
 - Provide requested special analyses by operations, engineering and environmental groups
 - o Select and performance monitoring of contract laboratories
 - Instrument troubleshooting
- Non-routine duties
 - Determine and implement sampling and analytical protocols for spills and upset conditions
 - Identifying and interpreting Federal and State regulations for plant and corporate user groups

SGS CONTROL SERVICES, St. Rose, Louisiana Environmental Laboratory Manager/GC/MS Specialist

- Managed extraction and wet chemistry technicians
- Client contact
- Data review
- QA/QC and invoicing
- Operated and maintained GC/MS
- Mass spectral interpretation.

DURIO CONSULTING SERVICES, Luling, Louisiana

Environmental Chemist

- Evaluated environmental laboratory programs for various industries
- Reviewed laboratory data for clients
- General environmental consulting

Industrial Hygiene Technician

- Acted as Owner's Agent overseeing asbestos removal contractors and their crews at work site
 - Monitored progress and integrity of enclosures
 - Monitored personnel during removal
 - Final physical worksite inspection
 - Final clean air sampling
 - Performed fiber count analysis beginning, during and final stages of removal
- Collected potential asbestos samples and performed required analyses (PLM for identification of asbestos)
- Provided training for other technicians in contractor oversight and asbestos analyses.

OCHSNER MEDICAL FOUNDATION, New Orleans, Louisiana 1985-1986 Technical Specialist

- Served as Mass Spectroscopist/Toxicologist in medical chemistry laboratory
- Maintained and operated the GC/MS, developed analytical methods of drug analyses and qualitative analyses for drug screening
- Worked with Occupational Health Department for pre-employment drug screening
- Prepared specimens
- Troubleshoot and repaired other analyzers as needed
- Performed other needed analysis along with the Medical Technologist staff

WEST-PAINE LABORATORIES, Baton Rouge, Louisiana GC/MS Laboratory Manager/Mass Spectroscopist

1982-1985

1976-1977

- Managed two GC/MS operators and two extraction technicians.
- Installed new instruments and trained operators.
- Developed and wrote procedure programs for data reduction for GC/MS.
- Established as an expert witness on laboratory practices, protocols and mass spectral interpretation in state of Louisiana.

ENVIRONMENTAL PROTECTION SYSTEMS, Jackson, Mississippi 1981-1982

Analyst

- Operated and created calibration tables for GC's
- Developed extraction methods and prepared standards
- Operated GC/MS
- Redesigned extraction preparation laboratory to increase efficiency.

UNIVERSITY OF MISSISSIPP MEDICAL CENTER, Jackson, Mississippi 1980-1981 Research Associate

- Managed laboratory and technicians
- Designed, prepared and assisted in experiments
- Proofread and edited papers and seminar outlines for post-doctoral fellow and professors
- Kept records of receipt and usage of radioactive materials and controlled drugs
- Made final approval of purchasing supplies, chemicals and animals

AMAX COAL COMPANY, Gillette, Wyoming

Analyst at Mine Site

- Prepared sample by riffling and pulverizing
- Analyzed coal product (ash, sulfur, BTU)
- Analyzed bore samples (more extensive analysis) for new areas
- Collected samples from conveyer belts when cutters were down

CHARLENE REESE SALINAS

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April 8, 2016

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

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 4, 09/18/2015) 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

cc: Harry Van Den Berg, AECOM

TestAmerica Irvine



SOP CF No. IR-QAM_r4-CF1 Effective Date: 10/26/2015 Page No.: 1 of 2

FACILITY SOP ATTACHMENT

SOP NUMBER: IR-QAM, Rev. 4 (09/18/2015)	CHANGE FORM ID: CF1
SOP TITLE: Quality Assurance Manual	
REASON FOR ADDITION OR CHANGE (Use additional she	ets if necessary):
Change in approval signatories.	· OA
CHANGE OR ADDITION (Use additional sheets if necessary)	
The current Title Page (page 2 of 187) has been updated to reflect the Irvine facility. See attached.	t recent management changes at
Prepared By: D. Dawes	
APPROVED BY:	
	6-15
Laboratory Director Date	
	-26-2015
Quality Assurance Manager Date	
	26-15
Technical Manager Date	
Control Copy Number	

TestAmerica Irvine



SOP CF No. IR-QAM_r4-CF1 Effective Date: 10/26/2015 Page No.: 2 of 2

Title Page Attachment
Document No.: IR-QAM Revision No.: 4 Effective Date: 09/18/2015 Page 2 of 187 Title Page:
The Fage.
Quality Assurance Manual Approval Signatories
Laboratory Director - Linda Scharpenberg Date
Quality Assurance Manager – Maria Friedman Date
Dulta Julion 10-26-15 Technical Manager Debby Wilson Date
Company Confidential & Proprietary



Document No.: IR-QAM Revision No.: 4 Effective Date: 09/18/2015 Page 1 of 187

Quality Assurance Manual

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Title Page:

Quality Assurance Manual Approval Signatories

Date

Laboratory Director and Technical Manager - Fred Haley

Quality Assurance Manager - Maria Friedman

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REFERENCED CORPORATE DOCUMENTS

Document Reference	Title	
CA-Q-M-002	Corporate Quality Management Plan	
CW-L-P-004	Ethics Policy	
CW-L-S-002	Internal Investigation of Potential Data Discrepancies and Determination for Data Recall	
CW-Q-S-001	Corporate Document Control & Archiving	
CA-L-P-002	Contract Compliance Policy	
CA-L-S-002	Subcontracting Procedures	
CW-F-S-007	Capital Expenditure, Controlled Purchase Requests & Fixed Asset Capitalization	
CW-F-P-002	Company Wide Authorization Matrix	
CW-F-P-004	Procurement and Contracts Policy	
CA-Q-S-001	Acid & Solvent Lot Testing and Approval	
CW-E-M-001	Environmental Health and Safety Manual	
CA-T-P-001	Qualified Products List	
CW-Q-S-003	Internal Auditing	
CW-Q-S-004	Management Systems Review	
CW-Q-WI-003	Management Systems Review Checklist	
CW-Q-S-002	Writing a Standard Operating Procedure (SOP)	
CA-Q-S-006	Detection Limits	
CA-Q-S-002	Acceptable Manual Integration Practices	
CA-I-P-002	Electronic Reporting and Signature Policy	

REFERENCED LABORATORY DOCUMENTS

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

SECTION 3

INTRODUCTION, SCOPE, AND APPLICABILITY

3.1 INTRODUCTION AND COMPLIANCE REFERENCES

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

The QAM has been prepared to assure compliance with TNI Standard, dated 2009, Volume 1 Modules 2 and 4. In addition, the policies and procedures outlined in this manual are compliant with TestAmerica's CQMP (Corporate Quality Document No. CA-Q-M-002) and the various accreditation and certification programs listed in Appendix 3. The CQMP provides a summary of TestAmerica's quality and data integrity system. It contains requirements and general guidelines under which all TestAmerica facilities shall conduct their operations.

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

- EPA 600/4-88/039, Methods for the Determination of Organic Compounds in Drinking Water, EPA, Revised July 1991.
- EPA 600/R-95/131, *Methods for the Determination of Organic Compounds in Drinking Water,* Supplement III, EPA, August 1995.
- EPA 600/4-79-019, Handbook for Analytical Quality Control in Water and Wastewater Laboratories, EPA, March 1979.
- <u>Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW846)</u>, Third Edition, September 1986, Final Update I, July 1992, Final Update IIA, August 1993, Final Update II, September 1994; Final Update IIB, January 1995; Final Update III, December 1996; Final Update IV, January 2008.
- Federal Register, 40 CFR Parts 136, 141, 172, 173, 178, 179 and 261.
- Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-R-05-004, January 2005)
- Statement of Work for Inorganics & Organics Analysis, SOM and ISM, current versions, USEPA Contract Laboratory Program Multi-media, Multi-concentration.
- APHA, Standard Methods for the Examination of Water and Wastewater, 18th, 19th, 20th, 21st, 22nd, and on-line Editions.
- Toxic Substances Control Act (TSCA)

3.2 TERMS AND DEFINITIONS

A QA Program is a company-wide system designed to ensure that data produced by the laboratory conforms to the standards set by state and/or federal regulations. The program functions at the management level through company goals and management policies, and at the analytical level through SOPs and QC. The TestAmerica program is

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

Refer to Appendix 2 for the Glossary/Acronyms.

3.3 SCOPE / FIELDS OF TESTING

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

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

3.4 MANAGEMENT OF THE MANUAL

3.4.1 <u>Review Process</u>

The template on which this manual is based is reviewed annually by Corporate Quality Management personnel to assure it remains in compliance with Section 3.1. This manual itself is reviewed annually by senior laboratory management to assure that it reflects current practices and meets the requirements of the laboratory's clients and regulators as well as the CQMP. Occasionally, the manual may need changes in order to meet new or changing regulations and operations. The QA Manager will review the changes in the normal course of business and incorporate changes into revisions of the document. All updates will be reviewed by the senior laboratory management staff. The laboratory updates and approves such changes according to the procedures in laboratory SOP No. IR-QA-DOC.

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SECTION 4

MANAGEMENT REQUIREMENTS

4.1 <u>OVERVIEW</u>

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., CEO, Executive VP of Operations, Corporate Quality, etc.). The laboratory's operational and support staff work under the direction of the Laboratory Director. The organizational structure for both Corporate and TestAmerica Irvine is presented in Figure 4-1.

4.2 ROLES AND RESPONSIBILITIES

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

4.2.1 Additional Requirements for Laboratories

The responsibility for quality resides with every employee of the laboratory. All employees have access to the QAM, are trained to this manual, and are responsible for upholding the standards therein. Each employee carries out his/her daily tasks in a manner consistent with the goals and in accordance with the procedures in this manual and the laboratory's SOPs. Role descriptions for Corporate personnel are defined in the CQMP. This manual is specific to the operations of TestAmerica's Irvine laboratory.

4.2.2 Chief Executive Officer

The CEO is a member of the Board of Directors and is ultimately responsible for the quality and performance of all TestAmerica facilities. The 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

Executive Vice President of Operations

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

4.2.4 <u>Vice President of Operations</u>

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, Technical & Operations Support

The Vice President reports directly to the CEO. With the assistance of all laboratory and senior management team members as well as the Executive Committee, the VP has the responsibility for the establishment, general overview and Corporate maintenance of the Quality Assurance and Environmental, Health and Safety Program within TestAmerica. The VP supports the CEO in decisions regarding long-term planning, resource allocation and capital expenditures. Additional responsibilities include:

- Review of QA/QC aspects of Corporate SOPs, national projects and expansions or changes in services.
- Maintenance of Corporate Policies, Quality Memorandums and SOPs. Maintenance of data investigation records that are reported to Corporate Management.
- Work with various organizations outside of TestAmerica to further the development of quality standards and represent TestAmerica at various trade meetings.
- With the assistance of the Corporate Senior Management Teams and the EHS Directors, development and implementation of the TestAmerica Environmental, Health and Safety Program.

4.2.6 Vice President of Client Service

The VP of Client Services leads the 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 Executive Director of Quality and EHS

The Executive Director of Quality and EHS reports directly to the VP of Quality, Technical & Operations Support. With the aid of the Executive Committee, Laboratory Directors, Quality Directors and QA Managers, the Exec. Director of Quality & EHS has the responsibility for the establishment, general overview and Corporate maintenance of the Quality Assurance Program within TestAmerica. Additional responsibilities include:

- Review of QA/QC 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.

4.2.8 Quality Assessment Director

The Quality Assessment Director reports to the Exec. Director of Quality & 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 Exec. Director of Quality & EHS, the Quality Assessment Director has the responsibility for the establishment, general overview and maintenance of the Analytical Quality Assurance Program within TestAmerica.

4.2.9 Quality Compliance Director

The Quality Compliance Director reports to the Exec. Director of Quality & 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 Exec. Director of Quality & EHS, the Quality Compliance Director has the responsibility for the establishment, general overview and maintenance of the Analytical Quality Assurance Program within TestAmerica.

4.2.10 Quality Systems Director

The Quality Systems Director reports to the Exec. Director of Quality & 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 Exec. Director of Quality & EHS, the Quality Systems Director has the responsibility for the establishment, general overview and maintenance of the Analytical Quality Assurance Program within TestAmerica.

4.2.11 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, EHS, Legal, IT, Sales) for both quality and operational functions. The Quality Information Manager reports to the Exec. Director of Quality & 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.

4.2.12 <u>Technical Services Director</u>

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.

4.2.13 Ethics and Compliance Officers

TestAmerica has designated two senior members of the Corporate staff to fulfill the role of ECO – Exec. Director of Quality and EHS and the Corporate Counsel. Each ECO acts as a back-up to the other ECO and both are involved when data investigations occur. Each ECO has a direct line of communication to the entire senior Corporate and lab management staff.

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

The ECOs monitor and audit procedures to determine compliance with policies and to make recommendations for policy enhancements to the CEO, 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.

4.2.14 Chief Information Officer

The CIO is responsible for establishing, implementing and communicating TestAmerica's 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 LIMS at the various TestAmerica facilities.

4.2.15 Environmental Health and Safety Managers (Corporate)

The EHS Managers report directly to the Exec. Director of Quality and 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 DOT focal point and providing technical assistance to location management.
- Serving as Hazardous Waste Management main contact and providing technical assistance to location management.

4.2.16 Laboratory Director

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

The Laboratory Director shall:

- Ensure that all tasks performed at the laboratory are conducted according to the requirements of this QAM and appropriate QAPPs (if applicable).
- Ensure that all analysts and supervisors have the appropriate education and training to properly carry out the duties assigned to them and ensures that this training has been documented.

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

4.2.17 <u>QA Manager</u>

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. Corporate Quality may be used as a resource in dealing with regulatory requirements, certifications, and other QA-related concerns.

The QA Manager shall:

- Serve as the focal point for QA/QC in the laboratory.
- Have functions independent from laboratory operations for which he/she has QA oversight.

- Have the final authority to accept or reject data and to stop work in progress in the event that procedures or practices compromise the validity or integrity of analytical data.
- Communicate and monitor standards of performance to ensure that systems are in place to produce the level of quality defined in this document.
- Identify areas where corrective action is required and ensure implementation and completion of the resulting action.
- Notify laboratory management of deficiencies in the quality system and ensure corrective action is taken. Procedures that do not meet the standards set forth in the QAM or laboratory SOPs shall be investigated following the procedures outlined in Section 12 and, if deemed necessary, may be temporarily suspended during the investigation.
- Objectively monitor standards of performance in QA/QC without outside (e.g., managerial) influence.
- Maintain, improve, and evaluate the corrective action database and the corrective and preventive action systems.
- Prepare monthly reports to management.
- Maintain, approve, and implement the QAM.
- Conduct internal system and data audits to monitor laboratory conformance to the QAM, SOPs, and policies.
- Provide and document employee training regarding quality system, ethics, and client confidentiality.
- Evaluate the thoroughness and effectiveness of training.
- Review and approve documentation of analyst training records (e.g., demonstration of capability).
- Review and approve MDL studies and MDL verification, method validation studies, and statistical control limits.
- Have documented training and/or experience in QA/QC procedures and the laboratory's Quality System.

Have a general knowledge of the analytical test methods for which data audit/review is performed (and/or have the means of getting this information when needed).

- Provide assistance in the development and approval of laboratory management documents including SOPs as well as the control, revision, and distribution thereof.
- Direct the controlled distribution of laboratory quality documents.
- Oversee laboratory participation in performance evaluation programs and regulatory certification and accreditation programs.
- Monitor and communicate to management regulatory changes that may affect the laboratory.

- Act as point of contact regarding QA matters for the laboratory, including external audits.
- Develop suggestions and recommendations to improve quality systems.
- Comply with the 2009 TNI Standard.

4.2.18 <u>Technical Manager</u>

The Technical Manager's scope of responsibility ranges from the new-hire process and existing technology through the ongoing training and development programs for existing analysts and second- and third-generation instrumentation. At TestAmerica Irvine, the Laboratory Director is also the Technical Manager.

The Technical Manager shall:

- Exercise day-to-day supervision of laboratory operations for the appropriate field of accreditation and reporting of results.
- Monitor the validity of the analyses performed and data generated in the laboratory to assure reliable data. This activity begins with the review and support of all new business contracts, ensuring data quality, analyzing internal and external nonconformances to identify root cause issues, implementing the resulting corrective and preventive actions, and facilitating the data review process (training, development, and accountability at the bench).
- Review and approve, with input from the QA Manager, proposals from marketing, in accordance with an established procedure for the review of requests and contracts.
- Manage laboratory operations: work scheduling, sample tracking, and prompt reporting of results.
- Supervise and train employees, set goals and objectives for the employees, and achieve the quality objectives of the laboratory.
- Determine qualifications required for technical positions and evaluate job candidates against those requirements.
- Certify technical laboratory employees based on education and background to ensure that employees have demonstrated capability in the activities for which they are responsible.
- Enhance efficiency and improve quality through technical advances and improved LIMS utilization.
- Forecast capital needs based on instrument life cycle and manage asset inventory.
- Coordinate audit responses with the Operations Group.
- Comply with the 2009 TNI Standard.

4.2.19 Operations Manager

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

The Operations Manager shall:

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

4.2.20 Department Manager

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

The Department Manager shall:

- Manage the department's laboratory operations including work scheduling, sample tracking, analysis, data review, and prompt reporting of results.
- Ensure that all tasks performed by the department are conducted according to the requirements of the QAM, laboratory SOPs, policies, and QAPPs (if applicable).
- Perform frequent SOP reviews to ensure that current practices are consistent with the published SOP. Changes in procedures or deviations from the SOP must be immediately reported to the Operations Manager and the QA Manager for approval and update to the applicable SOP.

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

4.2.21 <u>Analyst</u>

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

The analyst shall:

Perform analyses based on understanding of and conformance to the requirements of the QAM, laboratory SOPs, policies, and QAPPs (if applicable).

Ensure sample analysis is completed within specified holding time, and immediately notifies the Department Manager if holding time will not be met.

- Ensure that all steps related to sample analysis are timely and completely documented, with integrity and accuracy.
- Document standard and sample preparation, instrument calibration and maintenance, and data calculations and review in logbooks, laboratory notebooks, bench sheets, and in the LIMS, as appropriate.
- Document all nonconformance situations, instrument problems, matrix effects, and QC failures, which might affect the quality and reliability of

the data, in logbooks, laboratory notebooks, bench sheets, and in an NCM using the NCM program in the LIMS, as appropriate.

- Report changes or deviations from the SOPs to the Department Manager, who will then report the changes or deviations to the Operations Manager and the QA Manager.
- Perform 100% initial technical review of sample preparation, calculations, qualitative identification, and raw data, with the authority to stop, accept, or reject data based on conformance with well-defined QA/QC criteria. This review must be completed prior to submitting data for second-level review.
- Perform second-level review of data, as appropriate.
- Report analytical results within the specified TAT.
- Suggest method improvements to the Department Manager.
- Identify, initiate, and implement corrective actions through root-cause analysis and investigations.
- Monitor, calibrate, and maintain support laboratory equipment such as refrigerators, freezers, water systems, process meters, and gas supply systems, as necessary.

4.2.22 Manager of Project Management

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.

The Manager of Project Management shall:

- Oversee training and growth of the Project Management team.
- Act as technical liaison for the Project Management team.
- Provide human resource management support to the Project Management team.
- Assist PMs with responses to client inquiries or with resolutions to problems or complaints.
- Ensure that client specifications, when known, are met by communicating project and QA requirements to the laboratory.
- Notify Department Managers or supervisors of incoming projects and sample delivery schedules.
- Discuss with client any project-related problems, resolve service issues, and coordinate technical details with the laboratory staff.
- Monitor the status of projects in-house to ensure timely and accurate delivery of reports.
- Prepare price quotes or project bids.

4.2.23 Project Manager

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

The PM shall:

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

4.2.24 Sample Control Supervisor

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

The Sample Control Supervisor shall:

- Supervise the department's laboratory operations including, but not limited to, courier scheduling, initiation of container lot testing, sample container order preparation, sample receiving and tracking, shipping, and login.
- Ensure that all tasks performed by the department are conducted according to the requirements of the QAM, laboratory SOPs, policies, and QAPPs (if applicable).

- Perform frequent SOP reviews to ensure that current practices are consistent with the published SOP. Changes in procedures or deviations from the SOP must be immediately reported to the Operations Manager and the QA Manager for approval and update to the applicable SOP.
- Assist PMs and analysts in resolving inconsistencies and problems with samples received.
- Assist in routing workshare and subcontract analyses.
- Report nonconforming situations to the Operations Manager and the QA Manager.
- Provide written responses to external and internal audit issues.
- Identify, initiate, and implement corrective actions through root-cause analysis and investigations.
- Ensure all logbooks are reviewed, maintained current, and are properly labeled or archived.

4.2.25 Environmental Health and Safety Coordinator

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

The EHS Coordinator shall:

- Conduct ongoing and necessary safety training for current and new employees.
- Assist in developing and maintaining the Chemical Hygiene/Safety Manual.
- Oversee the inspection and maintenance of general safety equipment (e.g., fire extinguishers, safety showers, eyewash fountains, etc.) and ensure prompt repairs when needed.
 - Supervise and schedule fire drills and emergency evacuation drills.
 - Ensure that general protective equipment are available when needed.

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

 Oversee hazardous waste accumulation and disposal, and maintain all hazardous waste-related documentation such as manifests, biennial reports, and waste profiles.

4.3 DEPUTIES

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

Table 4-1. Key Personnel and Deputies

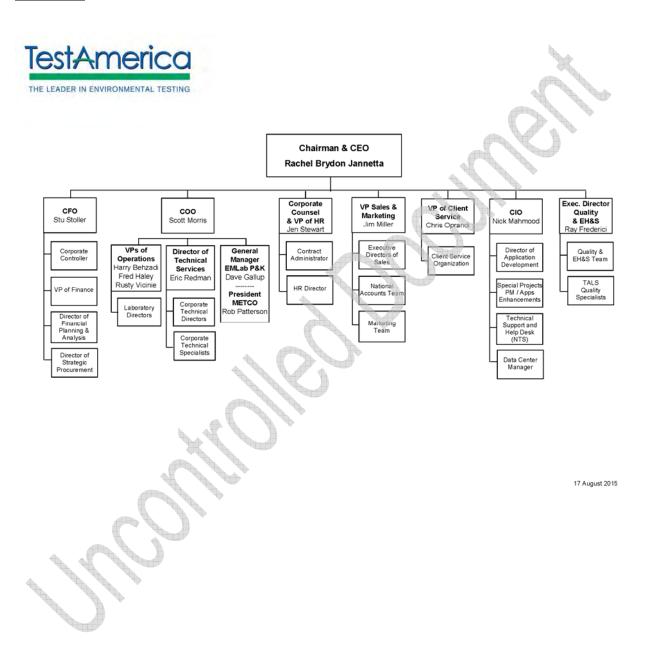
Key Personnel	Deputy ¹
Laboratory Director ²	Operations Manager
QA Manager	Senior QA Specialist
Operations Manager	Laboratory Director
Department Manager	Department Group Leader
Manager of Project Management	Manager of Project Manager Assistants
EHS Coordinator	Laboratory Director

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

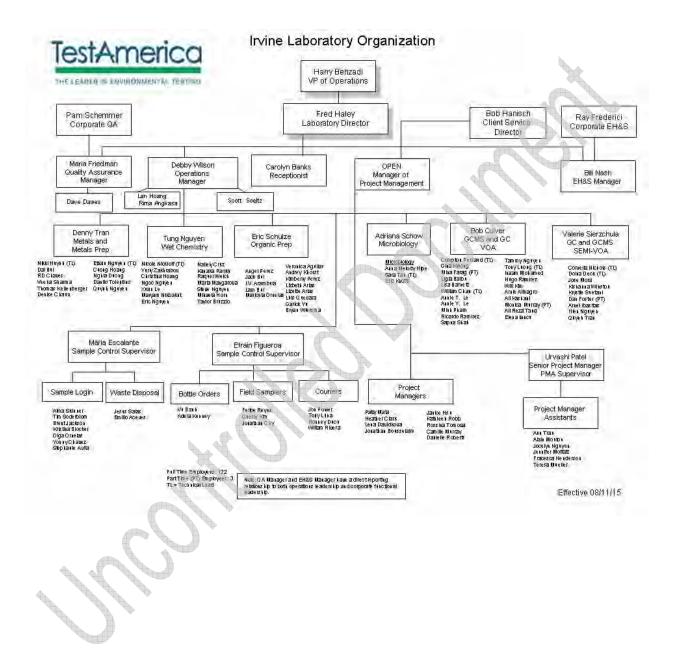
be notified in writing.

Figure 4-1. Corporate and Laboratory Organization Charts

Corporate



TestAmerica Irvine



SECTION 5

QUALITY SYSTEM

5.1 QUALITY POLICY STATEMENT

It is TestAmerica's Policy to:

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

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

5.2 ETHICS AND DATA INTEGRITY

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

- An Ethics Policy (Corporate Legal Document No. CW-L-P-004) and Employee Ethics Statements
- ECOs
 - A Training Program
- Self-governance through disciplinary action for violations

A confidential mechanism for anonymously reporting alleged misconduct and a means for conducting internal investigations of all alleged misconduct (Corporate Legal SOP No. CW-L-S-002)

- Procedures and guidance for recalling data, if necessary (Corporate Legal SOP No. CW-L-S-002)
- Effective external and internal monitoring system that includes procedures for internal audits (Section 15)

- Producing results that are accurate and include QA/QC information that meets client's pre-defined DQOs
- Presenting services in a confidential, honest, and forthright manner
- Providing employees with guidelines and an understanding of the Ethical and Quality Standards of our industry
- Operating our facilities in a manner that protects the environment and the health and safety of employees and the public
- Obeying all pertinent federal, state, and local laws and regulations, and encouragement to other members of our industry to do the same
- Educating clients as to the extent and kinds of services available
- Asserting competency only for work for which adequate personnel and equipment are available and for which adequate preparation has been made
- Promoting 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:

- <u>QAM</u> Each laboratory has a laboratory-specific QAM.
- <u>Corporate SOPs and Policies</u> 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.
- <u>Work Instructions</u> Subsets of procedural steps, tasks, or forms associated with an operation of a management system (e.g., checklists, pre-formatted bench sheets, forms).
- Laboratory SOPs General and Technical
- Laboratory QA/QC Policy Memoranda
- <u>QAS</u> Controlled documents that list client-specific project requirements. The QAS can be supplemented with Work Instructions, if necessary.

Order of Precedence

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

• CQMP

5.3.1

- Corporate SOPs and Policies
- Laboratory QA/QC Policy Memorandum
- Laboratory QAM
- Laboratory SOPs and Policies

- Other (Work Instructions, memos, flow charts, QAS, 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 QAM shall take precedence over the CQMP in those cases.

5.4 QA/QC OBJECTIVES FOR THE MEASUREMENT OF DATA

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

QA can be defined as the integrated system of activities that ensures that a product or service meets defined standards.

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

RFPs and QAPPs provide a mechanism for the client and the laboratory to discuss the DQOs in order to ensure that analytical services closely correspond to client needs. The client is responsible for developing the QAPP. In order to ensure the ability of the laboratory to meet the DQOs specified in the QAPP, clients are advised to allow time for the laboratory to review the QAPP before being finalized. Additionally, the laboratory will provide support to the client for developing the sections of the QAPP that concern laboratory activities.

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

5.4.1 Precision

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

5.4.2 <u>Accuracy</u>

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

EPA and/or other regulatory programs. Accuracy is defined as the degree of bias in a measurement system. Accuracy may be documented through the use of LCS and/or MS. A statement of accuracy is expressed as an interval of acceptance recovery about the mean recovery.

5.4.3 <u>Representativeness</u>

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

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

5.4.4 <u>Comparability</u>

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

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

5.4.5 <u>Completeness</u>

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 <u>Selectivity</u>

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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 <u>Sensitivity</u>

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

5.5 CRITERIA FOR QUALITY INDICATORS

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

5.6 STATISTICAL QUALITY CONTROL

Statistically-derived precision and accuracy limits are required by selected methods (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 LIMS (dated and approved by the QA Manager). All historical limits can be queried from the LIMS. If a method defines the QC limits, the method limits are used.

If a method requires the generation of historical limits, the laboratory develops such limits from recent data in the QC database of the LIMS, following the guidelines described in Section 24. All calculations and limits are documented and dated when approved and effective. On occasion, clients request contract-specified limits for a specific project.

Current QC limits are entered and maintained in the LIMS analyte database. As sample results and the related QC are entered into LIMS, the sample QC values are compared with the limits in LIMS to determine if they are within the acceptable range. The analyst then evaluates if the sample needs to be 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 trends to determine if adjustments need to be made to the current QC limits or if a need for corrective action is indicated. All findings are documented and kept on file. Refer to laboratory SOP No. IR-QA-CNTRLIM for more details regarding generation of control limits and development of control charts.

5.7 QUALITY SYSTEM METRICS

In addition to the QC parameters discussed above, the entire quality system is evaluated on a monthly basis through the use of specific metrics (refer to Section 16). These metrics are used to drive continuous improvement in the laboratory's Quality System.

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SECTION 6

DOCUMENT CONTROL

6.1 <u>OVERVIEW</u>

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

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

Corporate Quality posts Corporate Manuals, SOPs, Policies, Work Instructions, White Papers, and Training Materials on the company Intranet site. These Corporate documents are only considered controlled when they are read on the Intranet site. Printed copies are considered uncontrolled unless the laboratory physically distributes them as controlled documents. A detailed description of the procedure for issuing, authorizing, controlling, distributing, and archiving Corporate documents is found in Corporate SOP No. CW-Q-S-001. The laboratory's internal document control procedure is defined in SOP No. IR-QA-DOC.

The laboratory posts SOPs and Policies on the local QA server. These documents are only considered controlled when they are read on the local QA server. Access to these documents via the local QA server is restricted to viewing only; documents cannot be printed. Additionally, copying of these documents is prohibited. The QA department will provide an uncontrolled copy (watermarked or labeled as "Uncontrolled") upon request.

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

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

6.2 DOCUMENT APPROVAL AND ISSUE

The pertinent elements of a document control system for each document include a unique document title and number, pagination, the total number of pages of the item or an 'end of document' page, the effective date, the revision number, and the laboratory's name. The QA department is responsible for the maintenance of this system.

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

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

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

6.3 PROCEDURES FOR DOCUMENT CONTROL POLICY

For changes to the QAM, refer to the procedures discussed in Section 3.4. For changes to SOPs, refer to laboratory SOP No. IR-QA-DOC.

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

Uncontrolled copies must not be used within the laboratory.

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

6.4 OBSOLETE DOCUMENTS

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

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SECTION 7

SERVICE TO THE CLIENT

7.1 <u>OVERVIEW</u>

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

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

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

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

Electronic or hardcopy deliverable requirements are evaluated against the laboratory's capacity for production of the documentation.

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

The laboratory informs the client of the results of the review if it indicates any potential conflict, deficiency, lack of accreditation, or inability of the laboratory to complete the work satisfactorily. Any discrepancy between the client's requirements and the laboratory's capability to meet those requirements is resolved in writing before

acceptance of the contract. It is necessary that the contract be acceptable to both the laboratory and the client. Amendments initiated by the client and/or TestAmerica, are documented in writing.

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

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

7.2 REVIEW SEQUENCE AND KEY PERSONNEL

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

For routine projects and other simple tasks, a review by the PM is considered adequate. The PM confirms that the laboratory has any required certifications, that it can meet the client's data quality and reporting requirements and that the laboratory has the capacity to meet the client's TAT needs. It is recommended that, where there is a sales person assigned to the account, an attempt should be made to contact that sales person to inform them of the incoming samples.

For new, complex, or large projects, the proposed contract is given to the CRM or CRM 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 Corporate Legal Document No. CA-L-P-002.

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

- Contract Administrator
- VP of Operations
- Laboratory Operations Manager
- Laboratory Manager of Project Management
 - Laboratory PM
- Laboratory and/or Corporate Technical Managers
- Laboratory and/or Corporate IT
- AEs
- Laboratory and/or Corporate Quality
- Laboratory and/or Corporate EHS
- Laboratory Director reviews the formal laboratory quote and makes final acceptance for their facility

The CRM, Contract Administrator, AE, or Client Relations Manager then submits the final proposal to the client.

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

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

7.3 DOCUMENTATION

Appropriate records are maintained for every contract or work request. All stages of the contract review process are documented and include records of any significant changes. These records are kept on file with the assigned laboratory PM.

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

Records are maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract. The PM keeps a phone log or e-mail documentation of conversations with the client. These records are stored with the project or client folder, as appropriate, and become part of the project records.

7.3.1 Project-Specific Quality Planning

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

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

The laboratory has established procedures in order to ensure that communication is inclusive and effective. These include, but are not limited to, use of project memos and QAS; discussion/notification during daily production meetings; conducting meetings with the project teams; and/or conducting start-up meetings between the laboratory personnel and the client. Whenever a new or revised technical SOP or SOP Change Form is issued, QA will notify all PMs if there are any changes that will affect how final results will be reported compared to the previous revision. QA and the PM will work together to ensure the client is properly notified of the change. Changes in a technical SOP that should be considered with regards to impact on client data include, but are not limited to:

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

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

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

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

7.4 SPECIAL SERVICES

The laboratory cooperates with clients and their representatives to monitor the laboratory's performance in relation to work performed for the client. It is the laboratory's goal to meet all client requirements in addition to statutory and regulatory requirements. The laboratory has procedures to ensure confidentiality to clients (Sections 15 and 25).

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

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

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

7.5 CLIENT COMMUNICATION

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

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

7.6 <u>REPORTING</u>

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

7.7 CLIENT SURVEYS

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

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

SECTION 8

SUBCONTRACTING OF TESTS

8.1 <u>OVERVIEW</u>

For the purpose of this QAM, the phrase "subcontract laboratory" refers to a laboratory external to the TestAmerica laboratories. The phrase "worksharing" refers to internal transfers of samples between the TestAmerica laboratories. The term outsourcing refers to the act of subcontracting tests.

When contracting with our clients, the laboratory makes commitments regarding the services to be performed and the data quality for the results to be generated. When the need arises to outsource testing for our clients because of project scope, changes in laboratory capabilities, capacity, or unforeseen circumstances, we must be assured that the subcontractors or worksharing laboratories understand the requirements and will meet the same commitments we have made to the client. Refer to Corporate Legal Document No. CA-L-S-002.

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

PMs and AEs 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 client folder or 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 regulatory agencies (e.g., USDA) or contracts, may require notification prior to placing such work.

8.2 QUALIFYING AND MONITORING SUBCONTRACTORS

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

- The first priority is to attempt to place the work in a qualified TestAmerica laboratory.
- Firms specified by the client for the task. Documentation that a subcontractor was

designated by the client must be maintained with the project file. This documentation can be as simple as placing a copy of an e-mail from the client in the client folder or project folder.

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

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

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

- **8.2.1** Once the appropriate accreditation and legal information is received by the laboratory, it is evaluated for acceptability (where applicable) and forwarded to the Corporate 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 assignment.
- **8.2.2** The client will assume responsibility for the quality of the data generated from the use of a subcontractor they have requested the laboratory to use. The qualified subcontractors on the Intranet site are known to meet minimal standards. TestAmerica does not certify laboratories. The subcontractor is

on our approved list and can only be recommended to the extent that we would use them.

- **8.2.3** The status and performance of qualified subcontractors will be monitored periodically by the Corporate Contracts and/or Quality departments. Any problems identified will be brought to the attention of TestAmerica's Corporate Finance or Corporate Quality personnel.
 - Complaints shall be investigated. Documentation of the complaint, investigation, and corrective action will be maintained in the subcontractor's file on the Intranet site. Complaints must be posted using the Vendor Performance Report.
 - Information must be updated on the Intranet when new information is received from the subcontract laboratories.
 - Subcontractors in good standing will be retained on the Intranet listing. The QA Manager will notify all TestAmerica laboratories, Corporate Quality, and Corporate Contracts if any laboratory requires removal from the Intranet site. This notification will be posted on the Intranet site and emailed to all Laboratory Directors, QA Managers, and Sales personnel.

8.3 OVERSIGHT AND REPORTING

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

Prior to sending samples to the subcontract laboratory, the PM confirms their certification status to determine if it is current and scope-inclusive. The information is documented in a Subcontracted Sample Form (Figure 8-1) and the form is retained in the client folder or project folder. For TestAmerica laboratories, certifications can be viewed on the company's TotalAccess Database.

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

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

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

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

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

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

8.4 CONTINGENCY PLANNING

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

No

No

No

No

No

Figure 8-1.

Example - Subcontracted Sample Form

Date/Time:

Subcontracted Laboratory Information:

- Subcontractor's Name:
- Subcontractor Point of Contact:
- Subcontractor's Address:
- Subcontractor's Phone:
- Analyte/Method:
- Certified for State of Origin:
- TNI Certified:
- USDA Permit (__Domestic __ Foreign)
- A2LA (or ISO 17025) Certified:
- CLP-like Required: (Full doc required)
- Requested Sample Due Date: (Must be put on COC)
- Client POC Approval on file to Subcontract Samples to Sub Laboratory

Project Manager:

Laboratory Sample # Range: (Only of Subcontracted Samples)

Laboratory Project Number (Billing Control #):

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

PM Signature	Date
•	

Yes_

Yes

Yes

Yes

Yes

SECTION 9

PURCHASING SERVICES AND SUPPLIES

9.1 OVERVIEW

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

Contracts will be signed in accordance with Corporate Finance Document No. CW-F-P-002. RFPs will be issued where more information is required from the potential vendors than just price. Process details regarding procurement are available in Corporate Finance Policy No. CW-F-P-004. RFPs allow TestAmerica to determine if a vendor is capable of meeting requirements such as supplying to all of the TestAmerica laboratories, meeting required quality standards, and adhering to necessary ethical and environmental standards. The RFP process also allows potential vendors to outline any additional capabilities they may offer.

9.2 GLASSWARE

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

9.3 REAGENTS, STANDARDS, AND SUPPLIES

Purchasing guidelines for equipment and reagents must meet with the requirements of the specific method and testing procedures for which they are being purchased. Solvents and acids are pre-tested in accordance with Corporate Quality Document No. CA-Q-S-001.

9.3.1 Purchasing

Chemical reagents, solvents, glassware, and general supplies are ordered as needed to maintain sufficient quantities on hand. Materials used in the analytical process must be of a known quality. The wide variety of materials and reagents available makes it advisable to specify recommendations for the name, brand, and grade of materials to be used in any determination. This information is contained in the laboratory SOPs.

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

9.3.2 Receiving

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

Methods in use in the laboratory specify the grade of reagent that must be used in the procedure. If the quality of the reagent is not specified, analytical reagent grade will be used. It is the responsibility of the analyst to check the procedure carefully for the suitability of grade of reagent.

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

The laboratory assumes a five year expiration date on inorganic dry chemicals and solvents, unless noted otherwise by the manufacturer or by the reference source method. Chemicals/solvents should not be used past the manufacturer's or SOP's expiration date.

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

Compressed gases in use are checked for pressure and secure positioning daily. To prevent a tank from going to dryness, or introducing potential impurities, the pressure should be closely watched as it decreases to approximately 15% of the original reading, at which point it should be replaced. For example, a standard sized laboratory gas cylinder containing 3,000 psig of gas should be replaced when it drops to approximately 500 psig. The quality of the gases must meet method or manufacturer specification or be of a grade that does not cause any analytical interference.

Water used in the preparation of standards or reagents must have a specific conductivity of less than 1- μ mho/cm (or specific resistivity greater than 1.0

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

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

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

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

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

9.3.4 Storage

Reagent and chemical storage is important from the aspects of both integrity and safety. Light-sensitive reagents may be stored in brown-glass containers. Storage conditions must meet the Corporate EHS Document No. CW-E-M-001 and laboratory SOPs or manufacturer instructions.

9.4 PURCHASE OF EQUIPMENT / INSTRUMENTS / SOFTWARE

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

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

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

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

9.5 <u>SERVICES</u>

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

9.6 SUPPLIERS

TestAmerica selects vendors through a competitive proposal/bid process, strategic business alliances, or negotiated vendor partnerships (contracts). This process is defined in Corporate Finance Policy No. CW-F-P-004. The level of control used in the selection process is dependent on the anticipated spending amount and the potential impact on TestAmerica business. Vendors that provide test and measuring equipment, solvents, standards, certified containers, instrument-related service contracts, or subcontract laboratory services shall be subject to more rigorous controls than vendors that provide off-the-shelf items of defined quality that meet the end use requirements. The JD Edwards purchasing system includes all suppliers/vendors that have been approved for use.

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

Any issues of vendor performance are to be reported immediately by the laboratory staff to the Corporate Purchasing Group by completing a Vendor Performance Report.

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

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

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

Figure 9-1.

New Instrumentation Checklist

To be completed by the department: Department: ID Number:			
ID Number:			
			<u>NA</u>
Date Installed:		4	
Method(s) Performed:			
·:			Ĵ
Type*:	1-11		
Manufacturer:			
Model Number:			
Serial Number: *IC, GC, Autosampler, Balance, ASE etc.	2		
Serial Number:	Applicable	Date/ Initials	Comments
Serial Number: *IC, GC, Autosampler, Balance, ASE etc. 'o be completed by QA:	Applicable Yes No	Date/ Initials	Comments
Serial Number: *IC, GC, Autosampler, Balance, ASE etc. To be completed by QA:		Date/ Initials	Comments
Serial Number: *IC, GC, Autosampler, Balance, ASE etc. To be completed by QA: Item Maintenance/monitoring logbook created	Yes No	Date/ Initials	Comments
Serial Number: *IC, GC, Autosampler, Balance, ASE etc. To be completed by QA: Item Maintenance/monitoring logbook created IT informed (so data backup process can be updated)	Yes No	Date/ Initials	Comments
Serial Number: *IC, GC, Autosampler, Balance, ASE etc. Yo be completed by QA: Item Maintenance/monitoring logbook created IT informed (so data backup process can be updated) Instrument tagged with ID number	Yes No Yes No Yes No Yes No	Date/ Initials	Comments
Serial Number: *IC, GC, Autosampler, Balance, ASE etc. 'o be completed by QA: Item Maintenance/monitoring logbook created IT informed (so data backup process can be updated) Instrument tagged with ID number Instrument ID number entered into Element	Yes No Yes No Yes No Yes No	Date/ Initials	Comments

SECTION 10

COMPLAINTS

10.1 OVERVIEW

The laboratory considers an effective client complaint handling processes to be of significant business and strategic value. Listening to and documenting client concerns captures 'client knowledge' that enables our operations to continually improve processes and client satisfaction. An effective client complaint handling process also provides assurance to the data user that the laboratory will stand behind its data, service obligations, and products.

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

The laboratory has procedures for addressing both external and internal complaints with the goal of providing satisfactory resolution to complaints in a timely and professional manner.

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

The process of complaint resolution and documentation utilizes the procedures outlined in Section 12. The laboratory utilizes the NCM program in the LIMS or the laboratory's iCAT program, as appropriate, to document complaints and the corrective actions performed.

10.2 EXTERNAL COMPLAINTS

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

Complaints fall into two categories: correctable and non-correctable. An example of a correctable complaint would be one where a report re-issue would resolve the complaint. An example of a non-correctable complaint would be one where a client complains that their data was repeatedly late. Non-correctable complaints 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 nonconformances, training issues, internal audit findings, and deviations from methods. Corrective actions may be initiated by any staff member who observes a nonconformance and shall follow the procedures outlined in Section 12. In addition, Corporate Management, Sales and Marketing, and IT may initiate a complaint by contacting the laboratory or through the corrective action system described in Section 12.

10.4 MANAGEMENT REVIEW

The number and nature of client complaints is reported by the QA Manager to the Laboratory Director, the VP of Operations, and the Corporate Quality Director in the QA monthly report. Monitoring and addressing the overall level and nature of client complaints and the effectiveness of the solutions is part of the annual Management Systems Review (Section 16).

SECTION 11

CONTROL OF NONCONFORMING WORK

11.1 OVERVIEW

When data discrepancies are discovered or deviations and departures from laboratory SOPs, policies, and/or client requests have occurred, corrective action is taken immediately. First, the laboratory evaluates the significance of the nonconforming work. Then, a corrective action plan is initiated based on the outcome of the evaluation. If it is determined that the nonconforming work is an isolated incident, the plan could be as simple as adding a qualifier to the final results and/or making a notation in the case narrative. If it is determined that the nonconforming work is a systematic or improper practices issue, the corrective action plan could include a more in depth investigation and a possible suspension of an analytical method. In all cases, the actions taken are documented using the laboratory's corrective action system (refer to Section 12).

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

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

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

11.2 RESPONSIBILITIES AND AUTHORITIES

Corporate Legal SOP No. CW-L-S-002 outlines the general procedures for the reporting and investigation of data discrepancies and alleged incidents of misconduct or violations of TestAmerica's data integrity policies as well as the policies and procedures related to the determination of the potential need to recall data. Under certain circumstances, the Laboratory Director, the Technical Manager, or the QA Manager may authorize departures from documented procedures or policies. The departures may be a result of procedural changes due to the nature of the sample, a one-time procedure for a client, QC failures with insufficient sample to re-analyze, etc. In most cases, the client will be informed of the departure prior to the reporting of the data. Any departures must be well documented using the laboratory's corrective action procedures. This information may also be documented in logbooks and/or data review checklists, as appropriate. Any impacted data must be referenced in a case narrative and/or flagged with an appropriate data qualifier.

Any misrepresentation or possible misrepresentation of analytical data discovered by any laboratory staff member must be reported to facility Senior Management (Laboratory Director, QA Manager, and Operations Manager) within 24 hours of discovery. The reporting of issues involving alleged violations of the company's Data Integrity or Manual Integration procedures <u>must</u> be conveyed to an ECO, Exec. Director of Quality & EHS, and the laboratory's Corporate Quality Director within 24 hours of discovery.

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

The Laboratory Director, QA Manager, ECOs, Corporate Quality, Executive VP of Operations, 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 Legal SOP No. CW-L-S-002 distinguishes between situations when it would be appropriate for laboratory management to make the decision on the need for client notification (written or verbal) and data recall (report revision) and when the decision must be made with the assistance of the ECOs and Corporate Management. Laboratory level decisions are documented and approved using the laboratory's standard nonconformance/corrective action reporting in lieu of the data recall determination form contained in Corporate Legal SOP No. CW-L-S-002.

11.4 PREVENTION OF NONCONFORMING WORK

If it is determined that the nonconforming work could recur, further corrective actions must be made following the laboratory's corrective action system. On a monthly basis, the QA department evaluates nonconformances to determine if any nonconforming work 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 analyte or test fully back on line. In some cases, that may not be necessary if all appropriate personnel have already agreed there is a problem and there is agreement on the steps needed to bring the method, target analyte, or test fully back on line.

The QA Manager will also initiate a corrective action report, as described in Section 12, if one has not already been started. A copy of any meeting notes and agreed upon steps should be faxed or e-mailed by the laboratory to the appropriate VP of Operations and member of Corporate Quality. This fax/e-mail acts as notification of the incident.

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

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

SECTION 12

CORRECTIVE ACTION

12.1 OVERVIEW

A major component of TestAmerica's QA Program is the problem investigation and feedback mechanism designed to keep the laboratory staff informed on quality-related issues and to provide insight to problem resolution. When nonconforming work or departures from policies and procedures in the quality system or technical operations are identified, the corrective action procedure provides a systematic approach to assess the issues, restore the laboratory's system integrity, and prevent recurrence. Corrective actions are documented using the NCM program in the LIMS or the iCAT, as appropriate. Refer to Figure 12-1 and 12-2, respectively.

12.2 GENERAL

Problems within the quality system or within analytical operations may be discovered in a variety of ways, such as QC sample failures, internal or external audits, PT performance, client complaints, staff observation, etc.

The purpose of a corrective action system is to:

- Identify nonconformance events and assign responsibility for investigating.
- Resolve nonconformance events and assign responsibility for any required corrective action.
- Identify systematic problems before they become serious.
- Identify and track client complaints and provide resolution.
- **12.2.1** <u>NCM</u> The NCM program in the LIMS is used to document nonconformances (e.g., anomalies and deficiencies). The types of nonconformances to be reported include, but are not limited to, the following:
 - Deviations from an established procedure or SOP
 - QC outside of limits
 - Isolated reporting/calculation errors
 - Client complaints requiring report revisions
 - Discrepancies in materials / goods received vs. manufacturer packing slips
- **12.2.2** <u>**iCAT**</u> The iCAT program is used to document incidents and complaints that are not considered isolated incidents, as well as those that require greater flexibility in the assignment and tracking of corrective actions and associated communications than is afforded by the NCM program. The types of incidents and complaints to be reported in the iCAT include, but are not limited to, the following:

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

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

12.3 CLOSED-LOOP CORRECTIVE ACTION PROCESS

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

12.3.1 <u>Cause Analysis</u>

- Upon discovery of a nonconformance event, the event must be defined and documented. An NCM or an iCAT record must be initiated, someone is assigned to investigate the issue, and the event is investigated for cause. Table 1 provides some general guidelines on determining responsibility for assessment.
- The cause analysis step is the key to the process as a long-term corrective action cannot be determined until the cause is determined.
- If the cause is not readily obvious, the Operations Manager, the Laboratory Director, or the QA Manager are consulted.

12.3.2 Selection and Implementation of Corrective Actions

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

12.3.3 Root Cause Analysis

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

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

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

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

12.3.4 Monitoring of the Corrective Actions

- The Laboratory Director, Technical Manager, and the QA Manager are responsible to ensure that the corrective action taken was effective.
- Ineffective actions are documented and re-evaluated until acceptable resolution is achieved. The Technical Manager is accountable to the Laboratory Director to ensure final acceptable resolution is achieved and documented appropriately.
- Each NCM is entered into the LIMS for tracking purposes and a monthly summary of all corrective actions is available for review to aid in ensuring that the corrective actions have taken effect.
- The QA Manager reviews monthly NCMs and iCAT issues for trends. Highlights are included in the QA monthly report (refer to Section 16). If a significant trend develops that adversely affects quality, an audit of the area is performed and corrective action implemented.
- Any out-of-control situations that are not addressed acceptably at the laboratory level may be reported to the Corporate Quality Director by the QA Manager, indicating the nature of the out-of-control situation and problems encountered in solving the situation.

12.3.5 Follow-up Audits

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

(Also refer to Section 15.1.4, Special Audits.)

12.3.6 <u>Timeline for corrective action responses</u>

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

12.4 TECHNICAL CORRECTIVE ACTIONS

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

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

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

To the extent possible, samples shall be reported only if all QC measures are acceptable. If the deficiency does not impair the usability of the results, data will be reported with an appropriate data qualifier and/or the deficiency will be noted in the case narrative. Where sample results may be impaired, the PM is notified via the NCM and appropriate corrective action (e.g., re-analysis) is taken and documented.

12.5 BASIC CORRECTIONS

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

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

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

Figure 12-1.

Example – NCM Program in LIMS

📙 NCM Create	NCM Create/Edit						_ 🗆 ×					
New	Edit	🖹 Сору	XDelete	🖨 Print	🙌 Fi	ind	Doc's	C NCM	1#	🗸 Set to Read	y	
Lab Ser NCM ⁻	M ID: 123 ction: login Type: Other - Ani egory: Anomaly	omaly	m			1/16/2012 1/20/2012	2:44:30 PM 11:24:58 AM			is: Closed iy: Gonzales, S Need Co	Steve	
Narrative Inte	ernal Comments							Af	fected Item	ns		
B I 1		= X B		/ IDs =	IDs				- Add	- Remove		
	e that EPA Metho			anisters for s	sampling an	nd analysis.	Use of		1	Description		Final Report
air sample	bags constitute:	s a modification	to the method.						Method: 340-235-2 Volatile Organic Co			
QA approve	ed on 1-19-2012;	ok to report		⊳ĭ					Method: 340-235-3 Volatile Organic Co			
									Method: 340-235-1 Volatile Organic Co			
Detail/History								No	otifications	1		
#	User Name	Entry Date	BIU	AEE		B 8 4	0 🖂 💱		- Add	- Remove		
▶ 1 Fri	edman, Maria	1/19/2012 1	QA approved	on 1-19-201:	2; ok to repo	ort				r Name	Notice Level	Verification Type
			**** Previous	NCM Narrati	ive Text ****				Friedmar Riley, Be	n, Maria O	Level 1 Level 2	Review
			Please note t canisters for constitutes a	hat EPA Meth sampling an	hod TO-15 d d analysis. I	describes th Use of air s			niey, De	2411		11C ATEAN

Figure 12-2.

Example – iCAT Program

	Help	ADD N								X.	
Jser Logged In: DaystromW Status: Open 🔹 Filter: For Any 👻											
	# Openeo By	Opened On	Туре	<u>Subject</u>	<u>Client</u>	<u>Status</u>	<u>Due Date</u>	Action Item Total	Open Action Items	Pending QA <u>Review</u>	Action Due From
Select	8 Wilson	2/21/2013	Data Report Issue - Incomplete Data	MRL Reporting		Open	4/30/2013	3	1	2	SchowA
Select	1 Wilson	2/22/2013	Service Issue - Other	Disposal Requirements		Open	4/30/2013	1	1	0	DaystromW
Select	2 Wilson	3/15/2013	Data Report Issue - Other	Procedure Changes	Chevron Refinery	Open 🍐	4/2/2013	1	1	0	DawesD
Select	3 Wilson	3/15/2013	Technical Issue - QC Data	Special EDD	Ecology Auto Parts	Open	4/19/2013	1	1	0	DaystromW
Select	4 Wilson	3/15/2013	Data Report Issue - Errors	Notice of Violation	CH2/Honeywell	Open	4/30/2013	5	1	4	DawesD
Select	5 Wilson	3/19/2013	Data Report Issue - Other	Arizona Reporting	4	Open	4/30/2013	1	0	1	
Select	81 Friedmar	M 3/28/2013	Audit Finding: external	Tesoro Audit 2013	Tesoro	Open	4/30/2013	3	0	3	
<u>Select</u>	35 Friedmar	V 3/28/2013	Audit Finding: external	AZ Audit 2013	AZDHS	Open	3/28/2013	23	5	11	BanhA, HoangL, SchowA
Select	9 Wilson	4/1/2013	Service Issue - Other	Vials leaking	American Inc for Eaton	Open	4/30/2013	3	1	0	PatelP
Select	10 Wilson	4/2/2013	PT and Double Blind Failures	Failed NDMA PT sample for Aerojet	CRA for Aerojet Project	Open	4/12/2013	3	0	3	
<u>Select</u>	11 Friedmar	₩ 4/2/2013	Audit finding: internal	Logbooks		Open	4/8/2013	7	5	2	BanhA, NguyenT, PatelP, SchowA, TranD
Select	14 Wilson	4/4/2013	Technical Issue - Other	URS PAH Project	URS	Open	5/1/2013	4	3	1	BanhA, ReddyS, SierzchulaV
Select	16 Wilson	4/7/2013	Data Report Issue - Incomplete Data	Did not log in 524	City of San Juan Capistrano	Open	4/15/2013	5	2	2	Harris AW, Wilson D
Select	47 Wilson	4/7/2013	Technical Issue - Other	525 contamination issue	TestAmerica Phoenix	Open	4/30/2013	1	0	1	
Select	48 Wilson	4/7/2013	Audit Finding: external 🦱	608 analytes being inactivated	various	Open	4/30/2013	1	1	0	beauchaine
Select	49 Wilsont	4/7/2013	Other	Cyanide default RL		Open	4/30/2013	1	1	0	SchowA
elect	50 Wilson	4/7/2013	Other	Policy for MDL and RL's on Summary Analytes		Open	5/15/2013	2	1	1	FriedmanN
elect	51 Hoangl	4/9/2013	Audit finding: internal	Checklist		Open	5/15/2013	1	1	0	HoangL
Select	4 Hoangl	4/9/2013	Audit finding: internal	EPA 3546		Open	5/10/2013	1	1	0	BanhA

Figure 12-3.

Example – Corrective Action Report

Correct	tive Action Report
LABORATORY:	
Source of Issue: Date Initiated:	
Initiated By::	
Responsible for Investigation:	
Description of Problem:	
beschption of Froblem.	
Investigation Summary:	
Root Cause Analysis	
The immediate cause(s) include:	
The underlying cause(s) include:	
Corrective Action Plan	11
o correct the immediate problem, the following	actions will (welle) taken.
o prevent recurrence of this problem, the follow	ving actions will (were) taken:
	ving actions will (were) taken:
	ving actions will (were) taken:
Corrective Action Plan Approved By:	ving actions will (were) taken:
Corrective Action Plan Approved By:	ving actions will (were) taken:
Corrective Action Plan Approved By: QA Manager	
To prevent recurrence of this problem, the follow Corrective Action Plan Approved By: QA Manager Laboratory Director	
Corrective Action Plan Approved By: QA Manager	Date
Corrective Action Plan Approved By: QA Manager _aboratory Director Monitoring of Corrective Action Statu	Date Date
Corrective Action Plan Approved By: QA Manager Laboratory Director Monitoring of Corrective Action Statue enter schedule for on-going assessments of cor	Date Date Date S rective action status. When follow-up performed, enter name
Corrective Action Plan Approved By: QA Manager Laboratory Director Monitoring of Corrective Action Statu enter schedule for on-going assessments of cor and date of person who performed the independ	Date Date
Corrective Action Plan Approved By: QA Manager Laboratory Director Monitoring of Corrective Action Statu enter schedule for on-going assessments of cor and date of person who performed the independ	Date Date Date S rective action status. When follow-up performed, enter name
Corrective Action Plan Approved By: QA Manager Laboratory Director Monitoring of Corrective Action Statu enter schedule for on-going assessments of cor and date of person who performed the independ Corrective Action Closed By:	Date Date Date Date S rective action status. When follow-up performed, enter name lent assessment and a statement of completion]
Corrective Action Plan Approved By: QA Manager Laboratory Director Monitoring of Corrective Action Statu enter schedule for on-going assessments of cor	Date Date Date S rective action status. When follow-up performed, enter name
Corrective Action Plan Approved By: QA Manager Laboratory Director Monitoring of Corrective Action Statu enter schedule for on-going assessments of cor and date of person who performed the independ Corrective Action Closed By:	Date Date Date S Trective action status. When follow-up performed, enter name lent assessment and a statement of completion]
Corrective Action Plan Approved By: QA Manager Laboratory Director Monitoring of Corrective Action Statu enter schedule for on-going assessments of cor and date of person who performed the independ Corrective Action Closed By:	Date Date Date S Trective action status. When follow-up performed, enter name lent assessment and a statement of completion]
Corrective Action Plan Approved By: QA Manager Laboratory Director Monitoring of Corrective Action Statu enter schedule for on-going assessments of cor and date of person who performed the independ Corrective Action Closed By:	Date Date Date S Trective action status. When follow-up performed, enter name lent assessment and a statement of completion]
Corrective Action Plan Approved By: QA Manager Laboratory Director Monitoring of Corrective Action Statu enter schedule for on-going assessments of cor and date of person who performed the independ Corrective Action Closed By:	Date Date Date S Trective action status. When follow-up performed, enter name lent assessment and a statement of completion]
Corrective Action Plan Approved By: QA Manager Laboratory Director Monitoring of Corrective Action Statu enter schedule for on-going assessments of cor and date of person who performed the independ Corrective Action Closed By:	Date Date Date Date S rective action status. When follow-up performed, enter name lent assessment and a statement of completion]

Table 12-1.

Example – General Corrective Action Procedures

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

QC Activity (Individual Responsible for Initiation/Assessment)	Acceptance Criteria	Recommended Corrective Action
MS and MSD (Analyst, Data Reviewer)	- % Recovery and RPD within limits specified in the LIMS	 If the acceptance criteria for duplicates or matrix spikes are not met because of matrix interferences, the acceptance of the analytical batch is determined by the validity of the LCS. If the LCS is within acceptable limits the batch is acceptable. The results of the duplicates, matrix spikes and the LCS are reported with the data set. For matrix spike or duplicate results outside criteria, the data for that sample shall be reported with qualifiers.
Surrogates (Analyst, Data Reviewer)	- % Recovery within limits of method or within three standard deviations of the historical mean. See LIMS.	 Individual sample must be re-analyzed (to verify matrix interference, if any). Place comment in LIMS report. Surrogate results outside criteria shall be reported with qualifiers.
Method Blank (Analyst, Data Reviewer)	< RL ^{1, 2}	 Re-analyze Method Blank. If still positive, determine source of contamination. If necessary, reprocess (i.e., digest or extract) entire sample batch. Report method blank results. Qualify the result(s) if the concentration of a targeted analyte in the Method Blank is at or above the reporting limit AND is > 1/10 of the amount measured in the sample.
PT Samples (QA Manager, Technical Manager, Department Manager)	- Criteria supplied by PT provider/supplier.	 Any failures or warnings must be investigated for cause. Failures may result in the need to repeat a PT study to show the problem is corrected. Certifying agencies must be informed of the results of the investigation of failures and the planned or performed corrective actions.

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

than ½ the RL. ² Except as noted below for certain compounds, or if specified otherwise by the client, the method blank should be below the MDL. Concentrations up to 5X RL will be allowed for the ubiquitous laboratory and reagent contaminants: Methylene chloride, Toluene, Acetone, 2-Butanone, and Phthalates **provided** they appear in similar levels in the reagent blank and client samples. This allowance presumes that the MDL is significantly below any regulatory limit to which the data are to be compared and that blank subtraction will not occur. For Benzene and Ethylene dibromide (EDB) and other analytes for which regulatory limits are extremely close to the MDL, the method blank must be below MDL.

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

Table 12-2.

Timeline for Corrective Action Responses

Type of Corrective Action Response	Response Time
Acknowledgment (R&U) of QA Policies (either electronic or hardcopy)	1 to 14 calendar days, as designated by the QA Manager based on urgency of corrective action
Acknowledgment (R&U) of SOPs and SOP Revisions	14 to 30 calendar days, as designated by the QA Manager based on urgency of corrective action
Acknowledgment (R&U) of QA Manual and QA Manual Revisions	30 calendar days, or as designated by the QA Manager
Acknowledgment (R&U) of Published Methods	30 calendar days
Internal audit findings	7 to 30 calendar days, as designated by the QA Manager based on urgency of corrective action
External audit findings	7 to 30 calendar days, as designated by external auditor based on client requirements
Data Recall Investigations	3 to 7 days, as designated by QA Manager or Corporate QA Director
Client complaints	1 to 14 calendar days, as designated by the QA Manager based on urgency of corrective action
All Others	1 to 30 calendar days, as designated by the QA Manager based on urgency of corrective action

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SECTION 13

PREVENTIVE ACTION / IMPROVEMENT

13.1 OVERVIEW

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

Dedicating resources to an effective preventive action system emphasizes the laboratory's commitment to its Quality Program. It is beneficial to identify and address negative trends before they develop into complaints, problems, and corrective actions. Additionally, the laboratory continually strives to improve customer service and client satisfaction through continuous improvements to laboratory systems.

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

The monthly Management Systems Metrics Report shows performance indicators in all areas of the laboratory and Quality System. These areas include revised reports, corrective actions, audit findings, internal auditing and data authenticity audits, client complaints, PT samples, holding time violations, SOPs, ethics training, etc. The metrics report is reviewed monthly by the laboratory management, Corporate QA, and TestAmerica's Executive Committee. These metrics are used in evaluating the management and quality system performance on an ongoing basis and provide a tool for identifying areas for improvement.

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 nonconformance event. Historical review of corrective actions 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:

- <u>Identification</u> of an opportunity for preventive action or process improvement.
- Process for the preventive action or improvement.
- <u>Define the measurements</u> of the effectiveness of the process once undertaken.
- <u>Execution</u> of the preventive action or improvement.
- Evaluation of the plan using the defined measurements.
- <u>Verification</u> of the effectiveness of the preventive action or improvement.
- <u>Close-out</u> 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. Some of the types of changes covered under this system include facility changes, major accreditation changes, addition or deletion to capabilities or instrumentation, key personnel changes, and LIMS changes. TestAmerica Irvine has not implemented the Management of Change process at the time of the effective date of this QAM.

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SECTION 14

CONTROL OF RECORDS

14.1 OVERVIEW

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

The laboratory has established procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records. A record index is listed in Table 14-1. Records are of two types, either electronic or hardcopy paper formats, depending on whether the record is computer- or hand-generated (some records may be in both formats). Quality records are maintained by the QA department in the laboratory's local server, which is backed up as part of the regular laboratory backup. Technical records are maintained by the laboratory department responsible for generating the specific technical record. When archived, they are maintained by the individual Department Managers.

	Record Types ¹ :	Retention Time:
Technical Records	 Raw data Logbooks² Certificates of Analysis for standard materials Analytical records 	5 years from the date the laboratory report was mailed to the client ³
Official Documents	- QAM - Work Instructions - Policies - SOPs - Policy memoranda - Manuals	5 years from document retirement date ³

Table 14-1. Record Index¹

¹ Record types encompass hardcopy and electronic records.

² Examples of logbook types: Maintenance, Instrument Run/Analysis/Injection, Preparation (standard and samples), Standard and Reagent Receipt, Archiving, Temperature Monitoring (hardcopy or electronic records).

³ See exceptions under Section 14.1.2.

	Record Types ¹ :	Retention Time:
QA Records	 Data investigation⁴ Internal and External audits / responses Laboratory certifications / permits Corrective / Preventive actions Management reviews Method and software validation/ verification data MDLs, IDLs, RLs, QC limits DOCs Storage blank reports PT reports 	5 years from archival ³
Project Records	 Sample receipt and COC documentation Contracts and Amendments Correspondence QAPPs SAPs Telephone logbooks Laboratory reports 	5 years from the date the laboratory report was mailed to the client ³
Administrative Records	 Finance and Accounting Employee Handbook Personnel files, employee signature and initials, training records (administrative and technical) Administrative Policies EHS Manual Disposal records and permits 	10 years Indefinitely Refer to HR Manual 7 years 7 years Indefinitely

14.1.1 All records are stored and retained in such a way that they are secure and readily retrievable at the laboratory facility or from an off-site location that provides a suitable environment to prevent damage, deterioration, and loss. All records shall be protected against fire, theft, loss, environmental deterioration, and vermin. In the case of electronic records, electronic or magnetic sources, storage media are protected from deterioration caused by magnetic fields and/or electronic deterioration.

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

• For records stored in file boxes or file cabinets on-site, a sign-out sheet, available from the laboratory's designated Record Organizers (either PMAs or the EHS Coordinator), is completed to document who pulled out the record, what record was pulled out, when the record was pulled out, who returned the record, and when the record was returned. The signout sheet replaces the same spot where the original record was filed inside the file box or cabinet. The sign-out sheet is pulled out and

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

completed when the record is returned. This procedure ensures that the chronological order the record was originally filed is not disturbed, remains consistent, and facilitates tracking.

- For records stored off-site, the manifest of the records transferred off-site is consulted to determine which file boxes (that contain the record in question) have to be requested for retrieval:
 - Report Organizers are notified of the request to retrieve a particular record.
 - Report Organizers consult the manifest to determine the barcode assigned to the file box that contained the requested record.
 - Report Organizers transmit the request information to the off-site storage facility and the file box is delivered to the laboratory.
 - Report Organizers maintain records of all transfer of records (in and out) from the off-site storage facility.

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

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

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

Program	¹ Retention Requirement
Drinking Water – All States	5 years (project records)
Drinking Water Lead and Copper Rule	12 years (project records)
FIFRA – 40 CFR Part 160	Retain for life of research or marketing permit for pesticides regulated by EPA
TSCA - 40 CFR Part 792	10 years after publication of final test rule or negotiated test agreement

Table 14-2. Example: Special Record Retention Requirements

¹Note: 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 backup records stored electronically and to prevent unauthorized access to or amendment of these records. All analytical data are maintained as hardcopy or in a secure readable electronic format. For analytical reports that are maintained as copies in PDF format, refer to Section 19.14.1 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. The history of the sample from when the laboratory took possession of the samples must be readily understood through the documentation. This shall include inter-laboratory transfers of samples and/or extracts.
 - The records include the identity of personnel involved in sampling, sample receipt, preparation, and testing. All analytical work contains the initials (at least) of the personnel involved. The laboratory's copy of the COC is stored in the LIMS server. During sample login, the COC is scanned and this copy is stored in the PDF/COC folder in the LIMS server. If a correction was made to a COC at any time before final report is issued, the corrected COC is scanned and is stored with the first scanned copy in the same folder location in the LIMS server. The COC would indicate the name of the sampler. 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). PDF copies of final reports are automatically designated by the LIMS as "Final" and include the job number (e.g., "440-

12345 Final Report.pdf"). The final report package would include the following information in the following order:

- Cover page
- o Table of Contents
- Definitions/Glossary
- Case Narrative (with NCMs, if applicable)
- Detection Summary
- o Client Sample Results
- o QC Sample Results
- o QC Association Summary
- o Lab Chronicle
- o Certification Summary
- o Method Summary
- o Sample Summary
- **COC**
- Receipt Checklists
- o Sampling equipment field data sheets and certification, if applicable
- o Subcontract report, if applicable
- o Raw data, if requested
- Instrument data are stored and identified sequentially by instrument. A given day's analyses are maintained in the order of the analysis. Injection logbooks are maintained for each instrument or method; a copy of each day's injection log or instrument sequence is stored with the data to aid in reconstructing an analytical sequence. Where an analysis is performed without an instrument, bound logbooks or bench sheets are used to record and file data. Standard and reagent information is recorded in logbooks and/or entered into the LIMS for each method.
- Changes to hardcopy records shall follow the procedures outlined in Sections 12 and 19. Changes to electronic records in LIMS or instrument data are recorded in audit trails.
- The reason for a signature or initials on a document is clearly indicated in the records such as "Sampled by," "Received by," "Prepared by,"
 "Reviewed by," "Analyzed by," or Approved by."
- All generated data, except those that are generated by automated data collection systems, are recorded directly, promptly, and legibly in permanent dark ink.
- Hardcopy data may be scanned into PDF for record storage as long as the scanning process can be verified in order to ensure that no data is lost and the data files and storage media must be tested to verify the

laboratory's ability to retrieve the information prior to the destruction of the hardcopy that was scanned.

• Also refer to Section 19.14.1 (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 of results.
- **14.2.2** Observations, data, and calculations are recorded real-time and are identifiable to the specific task.
- **14.2.3** Changes to hardcopy records shall follow the procedures outlined in Section 12 and 19. Changes to electronic records in LIMS or instrument data are recorded in audit trails.

The essential information to be associated with analysis, such as strip charts, tabular printouts, computer data files, analytical notebooks, and injection logs, include:

- Laboratory sample ID code
- Date of analysis, time of analysis is also required if the holding time is 72 hours or less, or when time critical steps are included in the analysis (e.g., drying, incubation, etc.); instrumental analyses have the date and time of analysis recorded as part of their general operations. Where a time critical step exists in an analysis, location for such a time is included as part of the documentation in a specific logbook or on a benchsheet.
- Instrumentation identification and instrument operating conditions/parameters. Operating conditions/parameters are typically recorded in the instrument maintenance logbook.
- Analysis type
- All manual calculations and manual integrations
- Analyst's or operator's initials/signature
- Sample preparation including, but not limited to, cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents
- Test results
- Standard and reagent origin, receipt, preparation, and use

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- Calibration criteria, frequency, and acceptance criteria
- Data and statistical calculations, review, confirmation, interpretation, assessment, and reporting conventions
- QC protocols and assessment
- Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries
- Method performance criteria including expected QC requirements. These are indicated both in the LIMS and in specific analytical report formats.
- **14.2.4** 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 of the above-mentioned activities, the following are retained QA records and project records (previous discussions in this section relate where and how these data are stored):

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

14.3.1 Sample Handling Records

Records of all procedures to which a sample is subjected while in the possession of the laboratory are maintained. These include, but are not limited to, records pertaining to:

- Sample preservation, including appropriateness of sample container and compliance with holding time requirement
- Sample identification, receipt, acceptance or rejection, and login
- Sample storage and tracking, including shipping receipts, sample transmittal/COC forms

 Procedures for the receipt and retention of samples, including all provisions necessary to protect the integrity of samples

14.4 ADMINISTRATIVE RECORDS

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

14.5 RECORDS MANAGEMENT, STORAGE, AND DISPOSAL

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 hardcopy, 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 issued by the QA department are numbered sequentially. No more than one notebook or logbook is active at a time for a given analysis, instrument, or task, so all data are recorded sequentially within a series of sequential notebooks or logbooks. Records are considered archived when noted as such in the records management system.

14.5.1 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 <u>Records Disposal</u>

Records are removed from the archive and destroyed after five years, unless otherwise specified by a client or regulatory requirement. On a projectspecific 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 laboratory's quality system and with the external quality programs under which the laboratory operates. Audits are planned and organized by the QA Manager. Personnel conducting the audits should be independent of the area being evaluated. Auditors will have sufficient authority, access to work areas, and organizational freedom necessary to observe all activities affecting quality and to report the assessments to laboratory management and, when requested, to Corporate management.

Audits are conducted and documented, as described in Corporate Quality SOP No. 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 Manager.

Description	Performed by	Frequency
Quality Systems Audits	QA Department, QA- approved designee, or Corporate Quality	All areas of the laboratory, annually
Quality Technical Audits	 Joint responsibility: a) QA Manager or designee b) Technical Manager or designee (Refer to Corporate Quality SOP CW-Q- S-003) 	50% of methods annually
SOP Method Compliance	 Joint responsibility: a) QA Manager or designee b) Technical Manager or designee (Refer to Corporate Quality SOP CW-Q- S-003) 	Every 2 years, except for all SOPs affecting Drinking Water analyses (including QA and administrative SOPs)
Special Audits	QA Department or designee	Surveillance or spot checks performed as needed (e.g., to confirm corrective actions from other audits)

Table 15-1. Types of Internal Audits and Frequency

Description	Performed by	Frequency
PT	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, QCs, preventive action, and corrective action. The completeness of earlier corrective actions is assessed for effectiveness and sustainability. The audit is divided into sections for each operating or support area of the laboratory, and each section is comprehensive for a given area. The area audits may be performed on a rotating schedule throughout the year to ensure adequate coverage of all areas. This schedule may change as situations in the laboratory warrant.

15.1.2 QA Technical Audits

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

15.1.3 SOP Method Compliance

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

15.1.4 Special Audits

Special audits are conducted on an as needed basis, generally as a follow-up to specific issues such as client complaints, corrective actions, PT results, data audits, system audits, validation comments, regulatory audits, or suspected ethical improprieties. Special audits are focused on a specific

issue, and report format, distribution, and timeframes are designed to address the nature of the issue.

15.1.5 <u>Performance Testing</u>

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

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

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

15.2 EXTERNAL AUDITS

External audits are performed when certifying agencies or clients conduct on-site inspections or submit performance testing samples for analysis. It is TestAmerica's policy to cooperate fully with regulatory authorities and clients. The laboratory makes every effort to provide the auditors with access to personnel, documentation, and assistance. Department Managers are responsible for providing corrective actions to the QA Manager who coordinates the response for any deficiencies discovered during an external audit. Audit responses are due in the time allotted by the client or agency performing the audit. When requested, a copy of the audit report and the laboratory's corrective action plan will be forwarded to Corporate Quality.

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

15.2.1 <u>Confidential Business Information Considerations</u>

During on-site audits, on-site auditors may come into possession of information claimed as business confidential. A business confidentiality claim is defined as "a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality or a request for

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

15.3 AUDIT FINDINGS

Audit findings are documented using the iCAT. The laboratory's corrective action responses for both types of audits (internal or external) may include action plans that could not be completed within a pre-defined timeframe. In these instances, a completion date must be set and agreed to by Operations Management and the QA Manager.

Developing and implementing corrective actions to findings is the responsibility of the Department Manager where the finding originated. Findings that are not corrected by specified due dates are reported monthly to management in the QA monthly report. . When requested, a copy of the audit report and the laboratory's corrective action plan will be forwarded to Corporate Quality.

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

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

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SECTION 16

MANAGEMENT REVIEWS

16.1 QUALITY ASSURANCE REPORT

A comprehensive QA report shall be prepared each month by the laboratory's QA department and forwarded to the Laboratory Director, Operations Manager, their Corporate Quality Director as well as their 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 Quality may request that additional information be added to the report.

On a monthly basis, Corporate Quality compiles information from all the monthly laboratory reports. The Corporate Quality Directors prepare a report that includes a compilation of all metrics and notable information and concerns regarding the QA programs within the laboratories. The report also includes a listing of new regulations that may potentially impact the laboratories. This report is presented to the Senior Management Team and VPs of Operations.

16.2 ANNUAL MANAGEMENT SYSTEMS REVIEW

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

This management systems review (Corporate Quality SOP No. 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 re-issue requests
- Review of client feedback and complaints

- Issues arising from any prior management or staff meetings
- Minutes from prior senior laboratory management team meetings. Issues that may be raised from these meetings include:
 - o Adequacy of staff, equipment, and facility resources
 - o Adequacy of policies and procedures
 - o Future plans for resources and testing capability and capacity
- The annual internal double blind PT program sample performance (if performed)
- Compliance to the Ethics Policy and Data Integrity Plan. Include any evidence/incidents of inappropriate actions or vulnerabilities related to data integrity.

A report is generated by the QA Manager and management. The report is distributed to the appropriate VP of Operations and the Corporate Quality Director. The report includes, but is not limited to:

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

Changes to the quality systems requiring update to the QAM shall be included in the next revision of the QAM.

16.3 POTENTIAL INTEGRITY-RELATED MANAGERIAL REVIEWS

Potential integrity issues (data- or business-related) must be handled and reviewed in a confidential manner until such time as a follow-up evaluation, full investigation, or other appropriate actions have been completed and issues clarified. Corporate Legal SOP No. CW-L-S-002 shall be followed. All investigations that result in finding of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notification of clients.

TestAmerica's CEO, Executive VP of Operations, VP of Client & Technical Services, VPs of Operations, and Corporate Quality Directors receive a monthly report from the Exec. Director of Quality & 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 laboratories.

SECTION 17

PERSONNEL

17.1 OVERVIEW

The laboratory's management believes that its highly qualified and professional staff is the single most important aspect in assuring a high level of data quality and service. The staff consists of professionals and support personnel as outlined in the organization charts in Figure 4-1.

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

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

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

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

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

17.2 EDUCATION AND EXPERIENCE REQUIREMENTS FOR TECHNICAL PERSONNEL

The laboratory makes every effort to hire analytical staff that possesses a college degree (AA, BA, and BS) in an applied science with some chemistry in the curriculum. Selection of qualified candidates for laboratory employment begins with documentation of minimum education, training, and experience prerequisites needed to perform the prescribed task. Minimum education and training requirements for TestAmerica employees are outlined in job descriptions and are generally summarized for analytical staff in the table below. Where specific education and experience requirements are dictated by regulatory programs or States, these requirements must be met.

The laboratory maintains job descriptions for all personnel who manage, perform, or verify work affecting the quality of the environmental testing the laboratory performs. Job descriptions are located in the TestAmerica Intranet's Human Resources webpage.

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, Dissolved Oxygen, Redox, etc.), or Titrimetric and Gravimetric Analyses	H.S. Diploma	On the job training	
GFAA, CVAA, FLAA, Single component or short list chromatography (e.g., Fuels, BTEX-GC, IC)	A college degree in an applied science or 2 years of college and at least 1 year of college chemistry, or	2 years prior analytical experience is required	
ICP, ICPMS, Long list or complex chromatography (e.g., Pesticides, PCB, Herbicides, etc.), HPLC, GCMS	A college degree in an applied science or 2 years of college chemistry, or	5 years of prior analytical experience is required	
Spectra interpretation	A college degree in an applied science or 2 years of college chemistry, and	2 years relevant experience or 5 years of prior analytical experience	
Technical Managers/Department Managers	Bachelor degree in an applied science or engineering with 24 semester hours in chemistry (or 16 semester hours in general microbiology and biology for Microbiology), and	2 years experience in environmental analysis of representative analytes for which they will oversee An advanced (MS, PhD) degree may substitute for one year of experience	

Table 17-1. Education and Experience Guidelines

When an analyst does not meet these requirements, they can perform a task under the direct supervision of a qualified (with approved DOC) personnel (analyst, peer reviewer, Department Manager, 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 required employee training:

Required Training	Time Frame	Employee Type
EHS	Prior to laboratory	All
	work	
Ethics – New Hires	1 week of hire	All
Ethics – Comprehensive	90 days of hire	All
Data Integrity	30 days of hire	Technical and PMs
QAM	30 days of hire	All
Ethics – Refresher	Quarterly	All
IDOC	Prior to unsupervised	Technical
	method performance	
	or analysis of client	
	samples	

Table 17-2. Required Employee Training

The laboratory maintains records of relevant authorization/competence, education, professional qualifications, training, skills, and experience of technical personnel (including contracted personnel) as well as the date that approval/authorization was given. These records are kept on file at the laboratory. Also refer to Section 19.4.2.

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

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

Evidence of successful training could include such items as:

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

technical training for individual technologies, and particularly for people crosstrained.

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

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

17.4 DATA INTEGRITY AND ETHICS TRAINING PROGRAM

Establishing and maintaining a high ethical standard is an important element of a quality system. Ethics and data integrity training is integral to the success of TestAmerica and is provided for each employee at TestAmerica. It is a formal part of the initial employee orientation within one week of hire followed by technical data integrity training within 30 days, comprehensive training within 90 days, and quarterly refresher for all employees. The Laboratory Director or the QA Manager at each facility typically performs the ethics training for their staff.

In order to ensure that all personnel understand the importance TestAmerica places on maintaining high ethical standards at all times, TestAmerica has established an Ethics Policy (Corporate Legal Document No. CW-L-P-004) and an Ethics Statement. All initial and 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, 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 PM with respect to those cases where the data may still be usable but are in one sense or another partially deficient

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

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SECTION 18

ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS

18.1 OVERVIEW

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

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

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

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

18.2 ENVIRONMENT

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

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

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

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

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

18.3 WORK AREAS

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

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

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

Adequate measures are taken to ensure good housekeeping in the laboratory and to ensure that any contamination does not adversely affect data quality. These measures include regular cleaning to control dirt and dust within the laboratory. Work areas are available to ensure an unencumbered work environment. Work areas include:

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

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

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

18.4 FLOOR PLAN

A floor plan can be found in Appendix 1.

18.5 BUILDING SECURITY

Building keys and alarm codes are distributed to employees, as necessary.

Visitors to the laboratory sign in and out in a visitor's logbook. A visitor is defined as any person who visits the laboratory who is not an employee of that laboratory. In addition to signing into the laboratory, the EHS Manual (Corporate EHS Document No. CW-E-M-

001) contains requirements for visitors and vendors. There are specific safety forms that must be reviewed and signed.

Visitors (with the exception of company employees) are escorted by laboratory personnel at all times, or the location of the visitor is noted in the visitor's logbook. Signs are posted in the laboratory designating employee-only areas: "Authorized employees beyond this point."

SECTION 19

TEST METHODS AND METHOD VALIDATION

19.1 OVERVIEW

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

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

19.2 STANDARD OPERATING PROCEDURES

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

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

19.3 LABORATORY METHODS MANUAL

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

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

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

19.4.1 <u>Sources of Methods</u>

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

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

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

- <u>Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the</u>
 <u>Clean Water Act; Analysis and Sampling Procedures;</u> 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 <u>Samples</u>, EPA-600/R-93/100, August 1993.

- <u>Methods for the Determination of Metals in Environmental Samples</u>, EPA/600/4-91/010, June 1991. Supplement I: EPA-600/R-94/111, May 1994.
- <u>Methods for the Determination of Organic Compounds in Drinking Water</u>, 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. <u>Supplement III EPA/600/R-95/131 August 1995 (EPA 500 Series)</u> (EPA 500 Series methods)
- Technical Notes on Drinking Water Methods, EPA-600/R94-173, October 1994
- <u>Standard Methods for the Examination of Water and Wastewater</u>, 20th and online editions; Eaton, A.D. Clesceri, L.S. Greenberg, A.E. Eds; American Water

Works Association, Water Pollution Control Federation, American Public Health Association: Washington, D.C.

- <u>Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW846)</u>, 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.
- <u>Annual Book of ASTM Standards</u>, American Society for Testing & Materials (ASTM), Philadelphia, PA.
- <u>Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-R-05-004, January 2005)</u>
- <u>Code of Federal Regulations (CFR) 40, Parts 136, 141, 172, 173, 178, 179 and 261</u>

The laboratory reviews updated versions to all the aforementioned references for adaptation based upon capabilities, instrumentation, etc., and implements them as appropriate. As such, the laboratory strives to perform only the latest versions of each approved method as regulations allow or require.

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

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

19.4.2 Demonstration of Capability

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

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

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.



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

Ongoing DOCs for analysts may include all analytes that the laboratory performs or only those analytes that are routinely analyzed as long as all analytes that the laboratory performs are included in at least one analyst's DOC (initial or ongoing) every two years. Ongoing DOCs are approved by the QA Manager annually or a new IDOC is performed, in order to continue or resume analyzing client samples or reviewing data (first- or second-level reviews). All associated documentation must be retained in accordance with the laboratory's archiving procedures.

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

- **Note:** In some instances, a situation may arise where a client requests that an unusual analyte be reported using a method where this analyte is not normally reported. If the analyte is being reported for regulatory purposes, the method must meet all procedures outlined within this QAM (SOP, MDL, and DOC). If the client states that the information is not for regulatory purposes, the result may be reported as long as the following criteria are met:
 - The instrument is calibrated for the analyte to be reported using the criteria for the method and ICV/CCV criteria are met (unless an ICV/CCV is not required by the method or criteria are per project DQOs).
 - The laboratory's nominal or default RL is equal to the QL, must be at or above the lowest non-zero standard in the calibration curve, and must be reliably determined. Project RLs are client-specified reporting levels, which may be higher than the QL. Results reported below the QL must be qualified as estimated values. Also see Section 19.6.1.3.
 - The client request is documented and the laboratory informs the client of its procedure for working with unusual compounds. The final report must be footnoted or qualified, as applicable: *Reporting Limit based on the low standard of the calibration curve.*

19.4.3 IDOC and Ongoing DOC Procedures

- **19.4.3.1** The spiking standard used must be prepared independently from those used in instrument calibration.
- **19.4.3.2** The analyte(s) shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at one to four times the RL (for

IDOCs) or at the concentration specified by a method or the laboratory SOP (for Ongoing DOCs).

- **19.4.3.3** Four aliquots shall be prepared and analyzed according to the test method. The four aliquots shall be analyzed consecutively on the same day or consecutively over a period of consecutive days, meaning one replicate per day for four days or two consecutive aliquots per day for two days, or three consecutive aliquots in one day and one replicate the next day, however preferred, as long as the aliquots are analyzed in consecutive order in consecutive days.
- **19.4.3.4** Using all of the results, calculate the mean recovery in the appropriate reporting units and the standard deviations for each parameter of interest.
- **19.4.3.5** When it is not possible to determine the mean and standard deviations, such as for presence, absence, and logarithmic values, the laboratory will assess performance against criteria described in the laboratory SOP.
- **19.4.3.6** Compare the information obtained above to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or to the laboratory-generated acceptance criteria (or interim criteria) for the LCS, if there is no mandatory criteria established. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.
- **19.4.3.7** When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst must proceed according to either option listed below:
 - Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with Section 19.4.3.3 above.
 - Beginning with Section 19.4.3.3 above, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, will confirm a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with Section 19.4.3.1 above.
- **Note:** Results of successive LCS analyses can be used to fulfill the DOC requirement. All analytes that the laboratory can possibly report (i.e., those analytes with approved ICAL and MDL studies) must be included in the analyst IDOC. Routine LCS or LCSD analytes may be used for ongoing DOCs.

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

19.5 LABORATORY-DEVELOPED METHODS AND NON-STANDARD METHODS

Any new method developed by the laboratory must be fully defined in an SOP and validated by qualified personnel with adequate resources to perform the method. Method specifications and the relation to client requirements must be clearly conveyed to the client if the method is a non-standard method (not a published or routinely accepted method). The client must also be in agreement to the use of the non-standard method.

19.6 VALIDATION OF METHODS

Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

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

19.6.1 Method Validation and Verification Activities for All New Methods

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

19.6.1.1 Determination of Method Selectivity

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

19.6.1.2 Determination of Method Sensitivity

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

19.6.1.3 Relationship of Limit of Detection to the Quantitation Limit

An important characteristic of expression of sensitivity is the difference in the LOD and the QL. The LOD is the minimum level at which the presence of an analyte can be reliably concluded. The QL is the minimum concentration of analyte that can be 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.

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

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

19.6.1.4 Determination of Interferences

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

19.6.1.5 Determination of Range

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

19.6.1.6 Determination of Accuracy and Precision

Accuracy and precision studies are generally performed using

replicate analyses, with a resulting percent recovery and measure of reproducibility (standard deviation, relative standard deviation) calculated and measured against a set of target criteria.

19.6.1.7 Documentation of Method

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

19.6.1.8 Continued Demonstration of Method Performance

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

19.7 METHOD DETECTION LIMITS / LIMITS OF DETECTION

MDLs are initially determined in accordance with 40 CFR Part 136, Appendix B or, alternatively, by other technically acceptable practices that have been accepted by regulators. MDL is also sometimes referred to as LOD. The MDL theoretically represents the concentration level for each analyte within a method at which the analyst is 99% confident that the true value is not zero. The MDL is determined for each analyte initially during the method validation process and updated as required in the analytical methods, whenever there is a significant change in the procedure or equipment, or based on project-specific requirements. Generally, the analyst prepares at least 7 replicates of standard spiked at one to five times the estimated MDL (most often at the lowest standard in the calibration curve) into the applicable matrix with all the analytes of interest. Each of these aliquots is analyzed over two to four days to provide a more realistic MDL.

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

19.8 INSTRUMENT DETECTION LIMITS

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

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

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

19.9 VERIFICATION OF DETECTION AND REPORTING LIMITS

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

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

19.10 **RETENTION TIME WINDOWS**

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

19.11 EVALUATION OF SELECTIVITY

The laboratory evaluates selectivity by following the checks within the applicable analytical methods, which include mass spectral tuning, second column confirmation, ICP interelement interference checks, chromatography RT windows, sample blanks, spectrochemical, atomic absorption, or fluorescence profiles, co-precipitation evaluations, and specific electrode response factors.

19.12 ESTIMATION OF UNCERTAINTY OF MEASUREMENT

19.12.1 Uncertainty is "a parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand" (as defined by the International Vocabulary of Basic and General Terms in Metrology, ISO Geneva, 1993, ISBN 9610171).

Knowledge of the uncertainty of a measurement provides additional confidence in a result's validity. Its value accounts for all the factors which could possibly affect the result, such as adequacy of analyte definition, sampling, matrix effects and interferences, climatic conditions, variances in weights, volumes, standards, analytical procedure, and random variation. Some national accreditation organizations require the use of an "expanded uncertainty": the range within which the value of the measurand is believed to lie within at least a 95% confidence level with the coverage factor k=2.

- **19.12.2** Uncertainty is not error. Error is a single value, the difference between the true result and the measured result. In environmental samples, the true result is never known. The measurement is the sum of the unknown true value and the unknown error. Unknown error is a combination of systematic error, or bias, and random error. Bias varies predictably, constantly, and independently from the number of measurements. Random error is unpredictable, assumed to be Gaussian in distribution, and reducible by increasing the number of measurements.
- **19.12.3** The minimum uncertainty associated with results generated by the laboratory can be determined by using the LCS accuracy range for a given analyte. The LCS limits are used to assess the performance of the measurement system since they take into consideration all of the laboratory variables associated with a given test over time (except for variability associated with the sampling and the variability due to matrix effects). The percent recovery of the LCS is compared either to the method-required LCS accuracy limits or to the statistical, historical, in-house LCS accuracy limits.
- **19.12.4** To calculate the uncertainty for the specific result reported, multiply the result by the decimal of the lower end of the LCS range percent value for the lower end of the uncertainty range, and multiply the result by the decimal of the upper end of the LCS range percent value for the upper end of the uncertainty range. These calculated values represent uncertainties at approximately the 99% confidence level with a coverage factor of k = 3. As an example, for a reported result of 1.0 mg/L with an LCS recovery range of 50 to 150%, the estimated uncertainty in the result would be 1.0 ± 0.5 mg/L.
- **19.12.5** In the case where a well-recognized test method specifies limits to the values of major sources of uncertainty of measurement (e.g., EPA 524.2, EPA 525, etc.) and specifies the form of presentation of calculated results, no further discussion of uncertainty is required.

19.13 SAMPLE RE-ANALYSIS GUIDELINES

Because there is a certain level of uncertainty with any analytical measurement, a sample re-preparation (where appropriate) and subsequent analysis (hereafter referred to as 're-analysis") may result in either a higher or lower value from an initial sample analysis. There are also variables that may be present that may affect the results of a re-analysis. Based on the above comments, the laboratory will re-analyze samples at a

client's request with the following caveats. Client-specific Contractual Terms & Conditions for re-analysis protocols may supersede the following items:

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

19.14 CONTROL OF DATA

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

19.14.1 Computer- and Electronic Data-Related Requirements

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

- **19.14.1.1** <u>Maintain the Database Integrity:</u> Assurance that data is reliable and accurate through data verification (review) procedures, password-protecting access, anti-virus protection, data change requirements, as well as an internal LIMS permissions procedure.
 - LIMS Database Integrity is achieved through data input validation, internal user controls, and data change requirements.
 - Spreadsheets and other software developed in-house must be verified with documentation through hand calculations prior to use. QA approval must be received prior to use. Cells containing calculations must be lock-protected and controlled.
 - Instrument hardware and software adjustments are safeguarded through maintenance logs, audit trails, and controlled access.

- **19.14.1.2** <u>Ensure Information Availability:</u> Protection against loss of information or service is ensured through scheduled backups, stable file server network architecture, secure storage of media, line filter, Uninterruptible Power Supply, and maintaining older versions of software as revisions are implemented.
- **19.14.1.3** <u>Maintain Confidentiality:</u> 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, the data is reduced by the analyst and then verified by the Department Manager, or alternate analyst, prior to updating the data into LIMS. The spreadsheets, or any other type of applicable documents, are signed by both the analyst and the Department Manager (or alternate analyst) to confirm the accuracy of the manual entry.

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

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

- **19.14.2.1** All raw data must be retained in the worklist or project folder, computer file (if appropriate), and/or injection/run log. All criteria pertinent to the method must be recorded. The documentation is recorded at the time observations or calculations are made and must be signed or initialed/dated (month/day/year). It must be easily identifiable who performed which tasks, if multiple employees were involved.
- **19.14.2.2** In general, concentration results are reported in milligrams per liter (mg/l) or micrograms per liter (μg/l) for liquids and milligrams per kilogram (mg/kg) or micrograms per kilogram (μg/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 lab 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 into LIMS with at least three significant figures. In general, results are reported to two significant figures in the final report.
- **19.14.2.4** For those methods that do not have an instrument printout or an instrumental output compatible with the LIMS, the raw results and dilution factors are entered directly into LIMS by the analyst, and the software calculates the final result for the analytical report. LIMS has a defined significant figure criterion for each analyte.
- **19.14.2.5** The laboratory strives to import data directly from instruments or calculation spreadsheets to ensure that the reported data are free from transcription and calculation errors. For those analyses with an instrument output compatible with the LIMS, the raw results and dilution factors are transferred into LIMS electronically after reviewing the quantitation report, and removing not needed/not requested or poor spectrally-matched compounds. The analyst prints a copy, if applicable, of what has been entered to check for errors. Otherwise, the instrument's record of calibrations, concentrations, RTs, chromatograms, and mass spectra, if applicable, are retained with the data file. The data file is stored in a folder in the instrument computer. Periodically, this file is transferred to the server and, eventually, to a tape file.

19.14.3 Logbook / 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, temperature 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 laboratory.
- Unused portions of pages must be Z'd out, initialed/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.
- Logbooks are reviewed monthly by the Department Manager of the department where the logbook resides. The name of the reviewer and date of review is documented on each page of the logbook. Once reviewed, the Department Manager updates the laboratory's Logbook

Tracking Database to mark the latest review performed on a particular logbook. QA uses the same database to track missing or overdue logbook reviews.

19.14.4 <u>Review / Verification Procedures</u>

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

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

- **19.14.4.1** <u>Log-In Review</u> The data review process starts at the sample receipt stage. Sample control personnel review COC 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** <u>First Level Data Review</u> 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. To ensure data compliance, the Department Manager or another analyst (different from that who

performed the first level data review) performs the second level review.

Issues that deem further review include, but not limited to, 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 re-analysis of the samples. Any problems are brought to the attention of the Laboratory Director, PM, QA Manager, Technical Manager, or Department Manager 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 PM reviews the results for appropriateness and completeness. This review and approval ensures that client requirements have been met and that the final report has been properly completed. The process includes, but is not limited to, verifying that chemical relationships are evaluated, COC is followed, cover letters/narratives are present, flags are appropriate, and project-specific requirements are met.
- **19.14.4.7** Any project that requires a data package is subject to a tertiary data review for transcription errors and acceptable QC requirements. The PM 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.

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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.

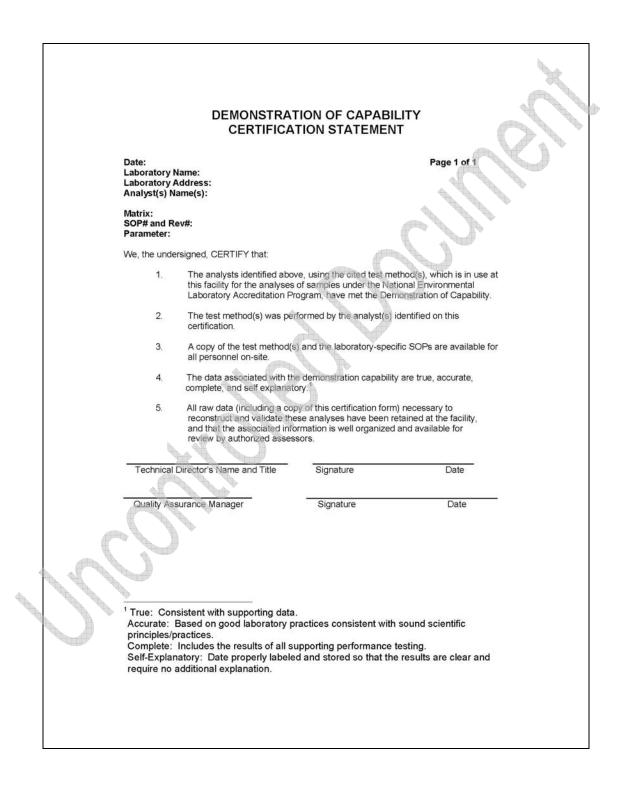
19.14.5 Manual Integrations

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 QC acceptance limits. Improper re-integrations lead to legally indefensible data, a poor reputation, or possible laboratory decertification. Because guidelines for re-integration of data are not provided in the methods and most methods were written prior to widespread implementation of computerized data systems, the laboratory trains all analytical staff on proper manual integration techniques using Corporate Quality Document No. CA-Q-S-002 as guideline.

- **19.14.5.1** The analyst must adjust baseline or the area of a peak in some situations, for example, when two compounds are not adequately resolved or when a peak shoulder needs to be separated from the peak of interest. The analyst must use professional judgment and common sense to determine when manual integration is required. Analysts are encouraged to ask for assistance from a senior analyst or Department Manager when in doubt.
- **19.14.5.2** Analysts shall not increase or decrease peak areas for the sole purpose of achieving acceptable QC recoveries that would have otherwise been unacceptable. The intentional recording or reporting of incorrect information (or the intentional omission of correct information) is against company principles and policy and is ground for immediate termination.
- **19.14.5.3** Client samples, performance evaluation samples, and QC samples are all treated equally when determining whether or not a peak area or baseline should be manually adjusted.
- **19.14.5.4** All manual integrations require a second-level review. Manual integrations must be indicated on an expanded scale "after" chromatograms such that the integration performed can be easily evaluated during data review. Expanded scale "before" chromatograms are also required for all manual integrations on QC parameters (calibrations, calibration verifications, LCS, internal standards, surrogates, etc.) unless the laboratory has another documented Corporate-approved procedure in place that can demonstrate an active process for detection and deterrence of improper integration practices.

Figure 19-1.

Example - Demonstration of Capability Documentation



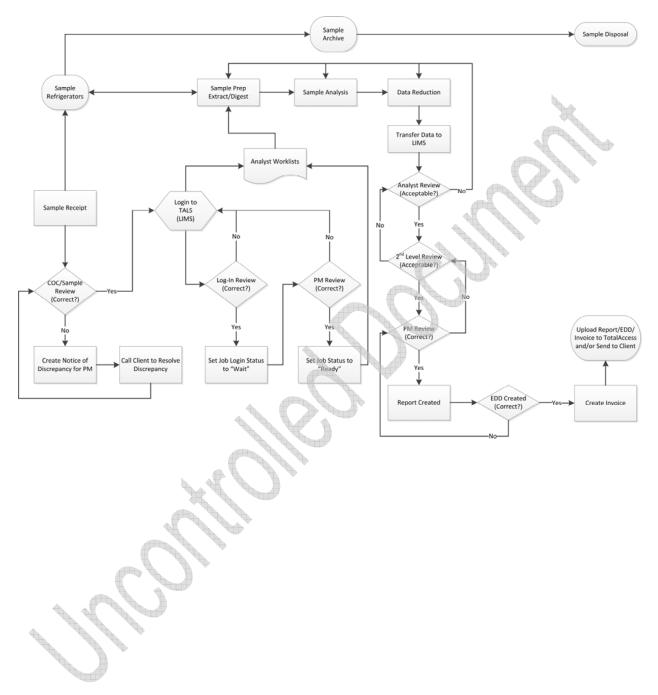


Figure 19-2. TestAmerica Irvine Workflow

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SECTION 20

EQUIPMENT AND CALIBRATIONS

20.1 OVERVIEW

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

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

20.2 PREVENTIVE MAINTENANCE

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 QC criteria.

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

Instrument maintenance logbooks are controlled and are used to document instrument problems, instrument repair, and maintenance activities. Maintenance logbooks shall be kept for all major pieces of equipment. Instrument maintenance logbooks 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 maintenance logbook includes the analyst's initials, the date, a detailed description of the problem (or maintenance needed/scheduled), a detailed explanation of the solution or maintenance performed, and a verification that the equipment is functioning properly (state what was used to determine a return to control, e.g., "CCV run on 'date' was acceptable" or "Instrument recalibrated on 'date' with acceptable verification," etc.) must also be documented in the instrument maintenance records.
- When maintenance or repair is performed by an outside agency, service receipts
 detailing the service performed shall be affixed into the logbooks adjacent to pages
 describing the maintenance performed. The service receipt that is taped or stapled
 into the logbook must be initialed and dated on the edge, with initials and date
 overlapping the attached receipt and the page where attached, so it is clear that a
 page is missing if only half a signature is found in the logbook.

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

- When an instrument or support equipment must be tagged as out-of-service, the same laboratory personnel who affixed the tag-out form must be the same laboratory personnel to remove the tag-out form, after the repair/maintenance has been completed and after documentation of such repair/maintenance has been examined to be complete. The same procedure must be followed when the repair/maintenance is performed by an outside vendor.
 - **Note:** If the repair/maintenance can be started and completed, and 'return to control' demonstrated and documented, within the same work shift, it is not necessary to tag-out the instrument or support equipment.
- For the repair/maintenance to be considered complete, 'return to control' must be demonstrated and documented.

The repair/maintenance must be documented in the designated maintenance logbooks.

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

At a minimum, if an instrument is sent out for service or transferred to another facility, it must be recalibrated and verified (including new initial MDL study) prior to return to laboratory operations.

20.3 SUPPORT EQUIPMENT

This section applies to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include, but are not limited to, balances, ovens, refrigerators, freezers, incubators, water baths, field sampling devices, temperature measuring devices, thermal/pressure sample preparation devices, and volumetric dispensing devices, if quantitative results are dependent on their accuracy, as in standard preparation and sample dilution into a specified volume. All raw data records associated with the support equipment are retained to document instrument performance.

20.3.1 Weights and Balances

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

Each balance is checked prior to initial serviceable use with at least two certified ASTM Type 1 weights spanning its range of use (weights that have been calibrated to ASTM Type 1 weights may also be used for daily verification). ASTM Type 1 weights used only for calibration of other weights (and no other purpose) are inspected for corrosion, damage, or nicks, at least annually, and if no damage is observed, they are calibrated at least every five years by an outside calibration laboratory. Any weights (including ASTM Type 1) used for daily balance checks or other purposes are recalibrated/recertified annually to NIST standards (this may be done internally if laboratory maintains "calibration only" ASTM Type 1 weights). All balances are serviced annually by a qualified service representative, who supplies the laboratory with a certificate that identifies traceability of the calibration to the NIST standards.

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

20.3.2

pH, Conductivity, and Turbidity Meters

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

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

µmhos/cm.

Turbidity meters are also calibrated before each use.

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

20.3.3 <u>Thermometers</u>

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

The mercury NIST thermometer is recalibrated every three years (unless thermometer has been exposed to temperature extremes or apparent separation of internal liquid) by an approved outside service and the provided certificate of traceability is kept on file. The NIST thermometers have increments of no more than 1°C (or 0.5°C or less increments for drinking water microbiological laboratories) and have ranges applicable to method and certification requirements. The NIST-traceable thermometer is used for no other purpose than to calibrate other thermometers.

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

20.3.4 <u>Refrigerators/Freezer Units, Waterbaths, Ovens, and Incubators</u>

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

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

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

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

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

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

20.3.5 Autopipettors, Dilutors, and Syringes

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

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

Glass micro-syringes with volumes of $\geq 20 \ \mu$ L are checked for accuracy every six months. Glass micro-syringes with volumes < 20μ 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 <u>Autoclaves</u>

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

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

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

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

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

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

20.3.7 Field Sampling Devices (Isco Auto Samplers)

Each Auto Sampler (ISCO) is assigned a unique identification number and is

recorded on the sampling documentation.

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

20.4 INSTRUMENT CALIBRATIONS

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

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

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

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

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

20.4.1 Calibration Standards

Calibration standards are prepared using the procedures indicated in the Reagents and Standards section of the determinative laboratory SOP. If a reference method does not specify the number of calibration points, a minimum of three calibration points (exception being ICP and ICP/MS methods) will be used.

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

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

The other concentrations define the working range of the instrument/method or correspond to the expected range of concentrations found in actual samples that are also within the working range of the instrument/method. Results of samples not bracketed by the ICAL standards (within calibration range to at least the same number of significant figures used to report the data) must be reported as having less certainty (e.g., use defined qualifiers or flags and report in an NCM using the NCM program in the LIMS). The exception to these rules is ICP methods or other methods where the referenced method does not specify two or more standards.

All ICALs are verified with a standard obtained from a second source and traceable to a national standard, when available (or vendor-certified different lot, if a second source is not available). Any claim of unavailability of second-source standards must be accompanied by supporting documentation (e.g., e-mails from several prospective vendors where they state that the standard being sought is unavailable). The ICAL verification must occur immediately after the calibration curve has been analyzed, and before the analysis of any samples.

20.4.2 <u>Calibration Verification</u>

The calibration relationship established during the ICAL must be verified at least daily, as specified in the laboratory SOPs in accordance with the referenced analytical methods and in the 2009 TNI Standard. The process of calibration verification applies to both external standard and internal standard calibration techniques, as well as to linear and non-linear calibration models. The ICAL is verified with a standard source secondary (second source standard) to the ICAL standards, but CCVs may use the same source standards as the calibration curve.

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

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

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

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

CCV and the RT criteria (if applicable).

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

A CCV must be repeated at the beginning and, for methods that have quantitation by external calibration models, at the end of each analytical batch. Some methods may have more frequent CCV requirements. Most inorganic methods require the CCV to be analyzed after every 10 samples or injections, including matrix or batch QC samples.

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

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

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

when the acceptance criteria for the CCV are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit/decision level, if known. Otherwise the samples affected by the unacceptable CCV shall be re-analyzed after a new calibration curve has been established, evaluated and accepted.

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

20.4.2.1 Verification of Linear and Non-Linear Calibrations

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

Regardless of whether a linear or non-linear calibration model is used, if initial verification criterion is not met, then no sample analyses may take place until the calibration has been verified or a new ICAL that meets the specifications listed in the laboratory SOPs is performed.

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

When the acceptance criteria for the calibration verification are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit/decision level, if known. Otherwise, the samples affected by the unacceptable calibration verification shall be re-analyzed after a new ICAL has been established, evaluated, and accepted.

20.5 TENTATIVELY IDENTIFIED COMPOUNDS - GC/MS ANALYSIS

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

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

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

20.6 GC/MS TUNING

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

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

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
Ammonia Probe	Orion	96-12		1/1/2005	SM4500 NH3 D
Auto Sampler	Varian	Archon	14635	1/1/2005	EPA 8015 (GRO)
Auto Sampler	Varian	Archon	14169	1/1/2005	
Auto Sampler	O.I. Analytical	4552	14407	1/1/2006	EPA 8260B-SIM
Auto Sampler	O.I. Analytical	4552	14417	1/1/2006	screening
Auto Sampler	Dionex	AS40	03080145		EPA 300.1
Auto Sampler	Dionex	AS 40	04110044		EPA 300.0/9056
Auto Sampler	Dionex	AS40	06110242	1/1/2002	EPA 300.0/9056
Auto Sampler	Dionex	AS40-1	98050117	10/1/2008	EPA 300.0/9056
Auto Sampler	ManTech	PC-Titrate PC1000-102	MS-9K8-210	1/1/2009	pH (Water samples only) and Conductivity
Auto Sampler	Metrohm	838	1838001005147	3/29/2010	EPA 7199/218.6
Auto Sampler	O.I. Analytical	4552	14217	1/1/2011	EPA 8021
Auto Sampler	Dionex	AS40	98050116	1/1/2007	EPA 300.1
Auto Sampler	Dionex	AS 40	04110044	6/1/2015	
Auto Sampler	Metrohm	9191C	1919002002153	10/3/2013	EPA 300.0/9056
Auto Sampler	Dionex	ICS-AS-DV	10120363	10/3/2013	EPA 7199/218.6
Auto Sampler	Metrohm	838	1838002006220	1/1/2012	EPA 332, 6860
Auto Sampler	Metrohm	838	1838002009651	1/1/2004	EPA 332, 6860
Auto Sampler	Dionex	AS40	06110242	1/1/2007	EPA 300.0/9056
Auto Sampler	Dionex	AS 40	94090145	6/1/2015	EPA 300.0/9056
Auto Sampler	Metrohm	838	1838001009124	6/1/2015	EPA 300.0/9056
Auto Sampler	Metrohm	838	1838001005147	6/1/2015	EPA 7199/218.6
Auto Sampler	Metrohm	838		6/1/2015	EPA 7199/218.6
Auto Sampler	Dionex	AS40	0411072	10/1/2008	EPA 314.0
Auto Sampler	Metrohm	858	1858002003286	5/2/2011	EPA 218.7
Auto Sampler	Dionex	068888	14071159	1/1/2015	EPA 314.1
Auto Sampler (Archon)	Varian	Archon DY505220-16	12731	1/1/2001	
Auto Sampler (Archon)	Varian	Archon	14636	1/1/2004	
Auto Sampler (Archon)	Varian	Archon	14633	1/1/2006	
Auto Sampler (Archon) Auto Sampler	Varian	Archon	14634	1/1/2006	
(Archon)	Varian	Archon	14662	1/1/2006	
Auto Sampler (Archon)	Varian	Archon	13171	1/1/2006	
Auto Sampler (Archon)	Varian	Archon	14638	1/1/2006	
Auto Sampler (Archon)	Varian	Archon	14418	1/1/2006	
Auto Sampler (Archon)	Varian	Archon	14195	1/1/2006	
Auto Sampler (Archon)	Varian	Archon	13388	1/1/2006	

Table 20-1. Example: Instrumentation List

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
Auto Sampler (Archon)	Varian	Archon	14411	1/1/2006	EPA 8015
Auto Sampler (Archon)	Varian	Archon	14492	1/1/2006	
Auto Sampler (Archon)	Varian	Archon	14639	1/1/2006	
Auto Sampler (Archon)	Varian	Archon	14637	1/1/2006	
Auto Sampler (Archon)	Varian	Archon	13389	1/1/2006	
Auto Sampler (Archon)	O.I. Analytical	4552	12221	1/1/2009	EPA 524.2, EPA 524.2-SIM
Auto Sampler (Archon)	O.I. Analytical	4552	14420	1/1/2009	EPA 524.2, EPA 524.2-SIM
Auto Sampler (Archon)	EST	Archon	14653	1/1/2009	EPA 524.2, EPA 524.2-SIM
Auto Sampler (Archon)	Varian	Archon	13520	1/1/2009	EPA 524.2, EPA 524.2-SIM
Auto Sampler (DPM)	Varian	Archon	14654	1/1/2005	
Auto Sampler (DPM)	O.I. Analytical	MPM16/DPM16	H308369/89049B	1/1/1993	
Auto Sampler (DPM)	O.I. Analytical	MPM/DPM 16	91349/D12241664 6	1/1/1993	
Auto Sampler (DPM)	O.I. Analytical	MPM16/DPM16	H303322/C420411 196	1/1/1993	
Auto Sampler (DPM)	O.I. Analytical	DPM 16	B704411427	1/1/2003	
Auto Sampler (DPM)	O.I. Analytical	MPM 16		1/1/2011	Diesel
Auto Sampler for GC	Hewlett Packard	18596A	2718A09693	1/1/2005	
Auto Sampler for GC	Hewlett Packard	18596A	2718A08776	1/1/2006	
Auto Sampler for GC	Hewlett Packard	18596B	3445A17015	1/1/2006	
Auto Sampler for GC	Agilent	G2614A	US20914533	1/1/2006	
Auto Sampler for GC	Hewlett Packard	18596B	3206A27724	1/1/2006	
Auto Sampler for GC	Agilent	G2614A	CN24322262	1/1/2006	
Auto Sampler for GC	Hewlett Packard	7673B		1/1/1993	
Auto Sampler for GC	Hewlett Packard	7673B		1/1/1995	
Auto Sampler for GC	Agilent	G2614A	US12812101	1/1/2003	
Auto Sampler for	Agilent	G2614A	CN33826431	1/1/2005	
GC Auto Sampler for	Hewlett Packard	7673B		1/1/1993	
GC Auto Sampler for	Agilent	G2614A	CN63340749	1/1/2006	PAH low-level
GC Auto Sampler for	Hewlett Packard	18593B	3120A26939	1/1/1992	1,4-Dioxane
GC Auto Sampler for	Agilent	G2614A	CN55237971	1/1/2006	8081
GC Auto Sampler for	Agilent	G2614A	CN55237964	1/1/2007	

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Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
GC					
Auto Sampler for GC	Agilent	G2614A	CN42629414	1/1/2006	EPA 8270/625
Auto Sampler for GC	Hewlett Packard			1/1/2008	
Auto Sampler for GC	Agilent	18596B	3202A27470	1/1/2008	
Auto Sampler for GC	Agilent	G2614A	US10510643	1/1/2009	EPA 525.2
Auto Sampler for GC	Agilent	7683	CN42729496	1/18/2013	
Auto Sampler for Hg	Perkin Elmer	AS 91	6060	1/1/1995	
Auto Sampler for ICP	Perkin Elmer	AS 93 Plus	1075	1/1/2002	\bigcirc
Auto Sampler for ICPMS	Perkin Elmer	CETAC	060019ASX	1/1/2001	
Auto Sampler for Mercury	Perkin Elmer	AS 90	3380	1/1/1995	
Auto Sampler for Metals	Perkin Elmer	AS 93 Plus	3023	1/1/2006	
Autoclave	Tuttnaur/Brinkman	3870E	2903420	1/1/2009	
Autoclave	Market Forge	STM-E Type C	3Y0521	1/1/2009	
Automated	Horizon Technology	SPE-DEX 4790	03-0360	1/1/2003	EPA 1664A
Extractor Automated Extractor	Horizon Technology	SPE-DEX 4790	Various	3/25/2014	525.2 (SN: 06-0726, 0729, 0730, 0728, 0731,0711)
Automated Extractor	Horizon Technology	SPE-DEX 4790	09- 1208,1209,1210,12 07, 06-0718,06- 0727 (SPE17-22)	4/21/2014	14Diox, NDMA
Autosampler	Agilent	CETAC ASX 520	120916A520	1/1/2010	EPA 200.8 DW
Autosampler	ESI	SL-4AXF95T3	X4DXS-HS-TDP- 16-120401	1/1/2010	EPA 200.8 / 6020 /6020_LL
Autosampler	Metrohm	919	1919002002190	11/5/2012	EPA 7199/218.6
Autosampler	EST	Arcon	12116	4/1/2013	EPA 8260B
Autotitration with autosampler	ManTech	Tetra Rinse/Autosampler	MS-9K9-108	1/1/2002	
Balance, Analytical	Denver	P-214	27150173	6/1/2015	
Balance, Analytical	Denver	P-214	27150174	6/1/2015	
Balance, Analytical	Denver	P-214	27150172	6/1/2015	
Balance, Analytical	Denver	P-214	26850013	1/1/2012	
Balance, Top Loader	Ohaus	C11P9	0605016JHP	1/1/2006	
Balance, Top Loader	Denver	P-602	27050794	6/1/2015	
Balance, Top Loader	Denver	P-602	27150188	6/1/2015	
Balance, Top	Denver	P-602	27150187	6/1/2015	

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Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
Loader					
Balance, Top Loader	Denver	P-602	27150186	6/1/2015	
Balance, Top Loader	Denver	P-602	27150184	6/1/2015	
Balance, Top Loader	Denver	P-602	27150183	6/1/2015	
Balance, Top Loader	Denver	P-602	27150182	6/1/2015	- A - A - A - A - A - A - A - A - A - A
Balance, Top Loader	Sartorius	12000S	40040045	6/1/2015	
Block Digestor	Bioscience	163-466T		1/1/1997	EPA 410.4
Block Digestor	Bioscience	2091B1		1/1/1997	EPA 410.4
BOD Meter	Accumet	25	C0021582	1/1/2006	BOD
BOD probe	Jenco			1/1/2006	BOD
Centrifuge	Fisher Scientific	AccuSpin 300	40327924	1/1/2003	
Centrifuge	Precision	Durafuge 100	40317924	1/1/2003	
Chiller	Thermoneslab	M75	101226011	1/1/1999	
Chiller	VWR	1177PD	G42546	1/1/2004	
Chiller	VWR	1177PD	106A00879	1/1/2005	
Chiller	VWR	1173PD	106600242	1/1/2005	
Chiller for ICP	Polyscience	N0772026	G36430	1/1/2005	
Chiller for ICP	VWR	1173PD	106800421	1/1/2006	
Chiller for ICP	Polyscience	N0772026	106A00726	1/1/2006	
Chiller for ICPMS	Neslab	CFT-75	199064010	1/1/1999	
COD Reactor	Bioscience Inc.	2091B1	34613302	1/1/2006	
COD Reactor	Bioscience Inc.	163-466T	COD-T349	1/1/2006	
Compound Microscope (10x100)	VWR	ВВ-Р/ТВ-Р	V167531	1/1/2009	
Concentrator	O.I. Analytical	4560	N228460103	1/1/2009	EPA 8260B
Concentrator	O.I. Analytical	4560	M012460798	1/1/2009	EPA 524.2, EPA 524.2-SIM
Concentrator	O.I. Analytical	4560	D306030	1/1/2009	EPA 524.2, EPA 524.2-SIM
Concentrator	O.I. Analytical	4560	N114460213	1/1/2009	EPA 524.2, EPA 524.2-SIM
Concentrator	0	4660	B425466658P	4/1/2013	EPA 8260B
Conductivity Detector	Dionex	CD25A	03070269	1/1/2007	EPA 300.0/9056
Conductivity Detector	Dionex	CD20	98040309	6/1/2015	EPA 300.0/9056
Conductivity Meter	VWR	21800-012	Q022545	1/1/2009	EPA 120.1, 2510B, 9050A, 2520B
Conductivity Probe	Yellow Springs	32	COD0031	1/1/2006	EPA 120.1, 2510B, 9050A, 2520B
Conductivity/TDS Probe	Corning	M90	001253	1/1/2006	EPA 360.1
Conductivity/TDS Probe	Acument	AP75	943318	1/1/2013	2510B
Cyanide Distillation	Andrew Glass Co	110-10-R	A780509	1/1/1999	

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
Cyanide Distillation	Andrew Glass Co	110-10-R	A8X0309	1/1/1999	
Cyanide Distillation	Andrew Glass Co	110-10-R		1/1/1999	
Cyanide Distillation Unit	Andrew Glass Co	MIDI System	MCVA13908221	1/1/2006	
Cyanide Distillation Unit	Andrew Glass Co	MIDI System	33212579	1/1/2006	
Detector	Metrohm	887 UV / 800 Dosino	1887001006158	11/5/2012	EPA 7199/218.6
Digestion Unit	Lachat	BD-46	100700000985	10/10/2012	TKN/Ammonia
Dispenser with Adapter	Fisher Scientific	NA	W2838	1/1/2009	
Drying Oven	Fisher		40200001	1/1/2006	
Drying Oven	Fisher	630G	800121	1/1/2006	
Drying Oven	Scientific Products	DX-61	194002	1/1/2006	
Drying Oven	Fisher	Isotemp Standard OB602G	2032100355237	1/1/2010	TSS, VS, %Solids, %Moisture
Drying Oven	Fisher	Isotemp Standard OB702F	2153100457536	1/1/2010	TDS, TS (Water)
Drying Oven					
Drying Oven	Quincy Lab Inc	30GC	G3-008043	1/1/2006	
Drying Oven	Fisher	Isotemp Standard	613226-529	5/15/2013	TDS, TS (Water)
Drying Oven	Fisher	750F	305N0072	6/8/2015	TDS, TS (Water)
Eluent Generator	Dionex	EG50	03080261	1/1/2007	EPA 300.0/9056
Evaporator	Buchi	Q-101	1000170194	7/24/2014	3510, 3546, 3520
Flashpoint Tester	Koehler	K-162	10A/Y-2	1/1/1992	EPA 1010
Fluoride Probe	Orion	96-09	9609BN	1/1/2006	SM4500F
Gas Chromatograph	Agilent	6890N/1530N	CN10551059	1/1/2007	EPA 8081/608
Gas Chromatograph (Dual ECD)	Hewlett Packard	5890 Series II	3223A43015	1/1/2005	EPA 8081/608
Gas Chromatograph (Dual ECD)	Hewlett Packard	5890 Series II	336A51142	1/1/2005	EPA 8082/608
Gas Chromatograph (Dual ECD)	Agilent	6890N	US10215019	1/1/2002	EPA 608, 8082
Gas Chromatograph (Dual ECD)	Agilent	6890N/G1530N	US10250081	1/1/2005	EPA 8081/608
Gas Chromatograph (Dual ECD)	Agilent	6890N/G1540N	US10423015	1/1/2008	EPA 8081/608
Gas Chromatograph (Dual ECD)	Agilent	6890N/G1540N	US10423014	1/1/2008	EPA 8081/8082
Gas Chromatograph (Dual ECD)	Agilent	7890A/G3440A	CN10741034	1/1/2007	EPA 504.1

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
Gas Chromatograph (Dual ECD)	Agilent	6890N/G1530N	US10322076	1/1/2007	EPA 8081, 8082
Gas Chromatograph (Dual ECD)	Agilent	6890N	US10212094	1/1/2009	EPA 508.1
Gas Chromatograph (Dual ECD)	Agilent	6890N	US10402034	1/1/2009	EPA 552.2, EPA 504.1
Gas Chromatograph (Dual ECD)	Agilent	6890N	US10244151	1/1/2010	EPA 505
Gas Chromatograph (Dual ECD)	Hewlett Packard	5890 Series II	3336A56851	1/1/2010	EPA 8082
Gas Chromatograph (Dual FID)	Hewlett Packard	5890 Series II	3126A36534	1/1/2005	EPA 8015 Diesel
Gas Chromatograph (Dual FID)	Agilent	6890N/G1540N	US10546009	1/1/2007	EPA 8015B Diesel
Gas Chromatograph (Dual FID)	Agilent	6890N/G1540N	US10546010	1/1/2007	EPA 8015B Diesel
Gas Chromatograph (FID)	Agilent	6890N	CN10505005	1/18/2013	EPA 8015 Diesel
Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3133A37156	1/1/1992	EPA 8021
Gas Chromatograph (FID/PID)	Hewlett Packard	5890A	S/N2750A15898	1/1/1997	EPA 8021
Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3223A2733	1/1/1993	EPA 8015
Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3336A60064	1/1/1993	EPA 8015
Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3033A33301	1/1/1998	EPA 8015
Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	2921A23920	1/1/2011	EPA 8015B Diesel
Gas Chromatograph (FID/PID)	Agilent	5890 Series II	S/N3133A37568	1/1/2008	EPA 8015M Methanol/Ethanol
Gas Chromatograph (FID/TCD)	Varian	CP-3800	05262	5/20/2013	RSK-175
Gas Chromatograph (FID/TCD)	Varian	CP-3800	11827	5/20/2013	EPA 25C
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	6890/5973A	US00007750/US70 810354	1/1/2000	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	6890/5973A	US00022931/US82 311546	1/1/2000	EPA 8260B

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973N	US00001207/US01 140222	1/1/2001	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973	US00001206/US01 140215	1/1/2001	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973N	US0001947/US103 40261	1/1/2002	EPA 8260B SIM
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973N	US00002140/US10 440793	1/1/2002	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973N	US00002860/US21 843317	1/1/2003	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890/5973	US00034262/US01 112246	1/1/2004	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973	CN10318006/US3 0945515	1/1/2004	EPA 8260B (screener)
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973	CN10318007/US3 0945517	1/1/2004	EPA 8260B SIM
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973	CN0523048/US43 146864	1/1/2006	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973	CN01521014/US4 4647184	1/1/2005	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	6890/5973A	US00020097/US72 810389	1/1/1999	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	5890Ser.II/5971	3140A39653	1/1/1993	Screening
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973/G2578A	US10341048/US33 210028	1/1/2005	EPA 8270/625-Low level
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	5890Ser.II/5971	3033A30488/3133 A37717	1/1/1993	1,4-Dioxane
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973	US10206070/US10 462145	1/1/2006	EPA 8260B (screener)
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973N	US10222064/US10 462085	1/1/2006	EPA 8260B

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5975B/G3171A	CN10636107/US6 2724086	1/1/2006	PAH low-level
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973	US00001682/US92 522712	1/1/2001	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	5890IIB/5971A	2921A24077/3188 A02848	1/1/1992	1,4-Dioxane
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973 Inert	CN10349032/US3 3220240	1/30/2008	EPA 625 and EPA 8270C
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973 inert	CN10339005/US3 5120285	1/1/2007	EPA 8260B and TPH by GCMS
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N / 5973 Inert	CN10345035 / US33220184	1/1/2009	EPA 524.2, EPA 524.2-SIM
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N / 5973	CN10521030 / US40620627	1/1/2009	EPA 524.2, EPA 524.2-SIM
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N / 5973	CN10503040 / US10461983	1/1/2009	EPA 524.2, EPA 524.2-SIM
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N / 5973	US00002015 / US10440578	1/1/2009	EPA 524.2, EPA 524.2-SIM
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973N	US10232062/US21 863660	1/1/2009	EPA 525.2
Gas Chromatograph/ Mass Spectrometer	Agilent	6890/G1530N	US10243060	1/1/2010	EPA 525.2
Gas Chromatograph/ Mass Spectrometer	Agilent	6890/5973	US10226108/US21 843299	1/1/2010	EPA 8270C PAH SIM
Gas Chromatograph/ Mass Spectrometer	Agilent	7890/5975	CN10752039/US8 0148288	1/1/2010	EPA 8270C
Gas Chromatograph/ Mass Spectrometer	Agilent	7890/5975	CN10824037/US8 3140433	1/1/2010	Pyrethroid by EPA 8270C
Gas Chromatograph/ Mass Spectrometer	Hewlett Packerd	5890/5970	3336A60053/3307 A00396	1/1/2011	EPA 8270C Screener
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard/O.I.	6890/5973	US00029799	1/1/2011	EPA 8260B

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Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
GFAA	Perkin Elmer	AA600	601S3110501	9/19/2013	HML 939-M Organic Lead
Heat block (analog)	VWR	949312	110705008	1/1/2006	
Heat block (standard)	VWR	949031	4066	1/1/2006	
Hg FIAS Mercury Analyzer	Perkin Elmer	FIMS 400	4167	1/1/1995	EPA 245.1/7470/7471
Hg FIAS Mercury Analyzer	Perkin Elmer	FIMS 400	401510021001	1/1/2010	EPA 245.1/7470/7471
High volume stir plate	VWR	986920	090915011	1/1/2009	Metals Prep
High volume stir plate with heating	VWR	986663	090930001	1/1/2009	Metals Prep
Hot Block 36 Place	Environmental Express	SC154	1763CEC1138	1/1/2006	Hg digestion
Hot Block 36 Place	Environmental Express	SC154	31577	1/1/2006	Metals soil digestion
Hot Block 36 Place	Environmental Express	SC154	31576	1/1/2011	Metals soil digestion
Hot Block 36 Place	Environmental Express	SC154	8031CECW3359	5/26/2015	Metals soil digestion
Hot Block 36 Place	Environmental Express	SC154		1/1/2011	Metals soil digestion
Hot Block 54 Place	Environmental Express	SC154	3098CEC1491	1/1/2006	Metals water digestion
Hot Block 54 Place	Environmental Express	SC154	424CEC0641	1/1/2006	Hg digestion
Hot Block 54 Place	Environmental Express	SC154	4186CEC1997	1/1/2006	Metals water digestion
Hot Block 54 Place	Environmental Express	SC154	4186CEC1998	1/1/2006	Metals water digestion
Hot Block 54 Place	Environmental Express	SC154	8031CECW3355	5/26/2015	Metals soil digestion
Hotplate with Stirrer	VWR	800 Series	58849-001	1/1/2009	
HPLC (DAD) 🐁	Agilent	1100	DE14914766	1/1/2009	EPA 549.2
HPLC (DAD)	Hewlet Packard	G1316A	US54000547	1/1/2009	EPA 549.2
HPLC (FLD)	Agilent	1100	DE14903835	1/1/2009	EPA 547
HPLC (FLD)	Agilent	1100	DE14903629	1/1/2009	EPA 531.1, EPA 547
IC Pump/Lamp	Metrohm	818/1010	1818011013123/11 53001013131	3/29/2010	EPA 7199/218.6
Ice Machine	Microban	XAC830	63K0426BL075	1/1/2004	None
Incubator for BOD	Fisher	307C	00037-090-00	1/1/2002	
Incubator for BOD	VWR	2020	6003205	1/1/2002	
Incubator for Micro	Fisher Scientific			1/1/2009	

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
Incubator for Micro (35C)	VWR	1915	800902	1/1/2009	For MTF and QC
Incubator for Micro (35C)	VWR	1915	1102003	1/1/2009	For P/A, HOC-SIM, HPC- PP, Q-Tray
Incubator for Micro (55C)	Fisher Scientific	516D	502N0034	1/1/2009	
Incubator, small				1/1/2009	
Inductively Coupled Plasma Spectrophotomet er	Perkin Elmer	Optima 4300 DV	077N1100901	1/1/2002	EPA 200.7/6010B
Inductively Coupled Plasma Spectrophotomet er	Perkin Elmer	Optima 5300DV	077N5112802	1/1/2006	EPA 200.7/6010B
Inductively Coupled Plasma Spectrophotomet er	Perkin Elmer	Optima 8300	078N1051001	1/1/2011	EPA 200.7/6010B
Inductively Coupled Plasma Spectrophotomet er/MS	Agilent	7700 series G3281A	JP09480189	1/1/2010	EPA 200.8 DW
Inductively Coupled Plasma Spectrophotomet er/MS	Agilent	7700 series G3281A	JP12091608	1/1/2012	EPA 200.8 / 6020 / 6020_LL
Injector	Hewlett Packard	7673	NA	1/1/2011	Diesel
Injector for GC	Agilent	7673 series (18593B)	3120A27934	1/1/2008	
Injector Tower	Hewlett Packard	18593B	3120A27153	1/1/2006	
Injector Tower	Agilent	G2913A	CN55130059	1/1/2007	
Injector Tower	Agilent	7683	CN54859595/US9 1907180	1/18/2013	8015B-DRO
Integrated Sample Introduction System (ISIS)	Agilent	G4911A	JP09300004	1/1/2010	EPA 200.8 DW
lon Chromatograph	Dionex	ICS-1000	03110585	1/1/2002	EPA 300.0/9056
lon Chromatograph	Dionex	LC25	02050420	1/1/2005	EPA 300.1
lon Chromatograph	Dionex	LC 30	97040546	1/1/2002	EPA 300.0/9056
lon Chromatograph	Dionex	LC20	94010215	9/1/2006	EPA 300.0/9056
lon Chromatograph	Dionex	LC25	03080195	1/1/2007	EPA 300.0/9056
lon Chromatograph	Metrohm	861/838	1861004003159/18 38001009124	3/29/2010	EPA 300.0/9056
lon Chromatograph	Metrohm	881	1881000007119	3/29/2010	EPA 7199/218.6
lon Chromatograph	Metrohm	881	1881000123101	11/5/2012	EPA 7199/218.6
lon Chromatograph	Metrohm	861	1861002008105	10/3/2013	EPA 300.0
lon Chromatograph	Dionex	ICS-2000-TC	08010736	10/3/2013	EPA 7199 / 218.6
lon	Dionex	ICS-2000	04100753	10/28/2013	314.0

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Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
Chromatograph					
lon Chromatograph	Dionex	ICS-2100	11021089	1/24/2014	314.0
lon Chromatograph	Dionex	ICS-2100	13071408	1/1/2015	314.0
lon Chromatograph (with UV/VIS detector)	Metrohm	881/887	15105/03140	5/2/2011	EPA 218.7
lon Chromatograph/ Mass Spectrometer	Metrohm (IC) / Agilent (MS)	LC30-1/LC110/IC800	1820023004102/U S34800214	1/1/2005	EPA 332, 6860
lon Chromatograph/ Mass Spectrometer	Metrohm/Agilent	G1956B	US34800214	1/1/2004	Perchlorate EPA 332.0, EPA 6860
lon Chromatograph/ Mass Spectrometer	Metrohm (IC) / Agilent (MS)	761-SL / G1956B	1830002008183 / US42500764	1/1/2012	EPA 332, 6860
ISCO Sampler	GLS Teledyne	60-2954-00		1/1/2006	Field Sampling
ISCO Sampler	GLS Teledyne	60-2954-00		1/1/2006	Field Sampling
ISCO Sampler	GLS Teledyne	60-2954-00		1/1/2006	Field Sampling
ISCO Sampler	GLS Teledyne	60-2954-00		1/1/2006	Field Sampling
ISCO Sampler	GLS Teledyne	60-2954-00		1/1/2006	Field Sampling
ISCO Sampler	GLS Teledyne	60-2954-00		1/1/2006	Field Sampling
ISCO Sampler	603714001	3710		1/1/2006	Field Sampling
ISCO Sampler	603714001	3710		1/1/2006	Field Sampling
Kiln	Cress Electric Klin	E2418	0503DD	1/1/2005	
Kone Lab	Lab Medics	Aquakem 250	E2319629	1/1/2004	
Lachat auto- analyzer	Lachat	QuickChem 8500 series 2	140100001626	1/28/2014	Ammonia, Cyanide, Phenol, Nitrate-Nitrite
Lachat auto- dilutor	Lachat	PDS-200	14010000704	1/28/2014	Ammonia, Cyanide, Phenol, Nitrate-Nitrite
Lachat auto- sampler	Lachat	ASX-520 Series	14100002230	1/28/2014	Ammonia, Cyanide, Phenol, Nitrate-Nitrite
Lachat in-line sample prep (ammonia)	Lachat	A30113	140100002217	1/28/2014	Ammonia, Cyanide, Phenol, Nitrate-Nitrite
Lachat in-line sample prep (cyanide)	Lachat	A303113	140100002218	1/28/2014	Ammonia, Cyanide, Phenol, Nitrate-Nitrite
Mercury Analyzer	Leeman	Hydra AF Gold+	AFG+ 3010	1/1/2010	EPA 245.7
Microwave	СЕМ	MARS5	MD3165	1/1/2010	EPA 3546
Microwave	СЕМ	MARS XPRESS	MD8441	1/1/2010	EPA 3546

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
Muffle Furnace	Fisher	Isotemp 630G	801N0001	1/1/2006	
mV Meter	Denver Instrument	Basic	13036	1/1/2006	pH for BOD
mV Meter	Accumet	Model 25	C0021582	1/1/2006	BOD
Orbital Shaker	Heathrow Scientific	EF9796	ADA00973	12/22/2014	
Oven	Fisher Scientific	Isotemp Oven		1/1/2012	
pH Meter	Mettler Toledo	SevenEasy	1227116127	1/1/2006	Redox
pH Meter	Fisher Scientific	Accumet AB15 Plus	AB92334024	1/1/2010	Microbiology
pH Meter	Thermo Scientific	Orion 3Star 1219000	A11235	7/1/2010	Field Sampling
pH Meter	Hach	Sens10N™+pH1	321113	7/15/2013	Field Sampling
pH Meter	Beckman	Φ 255	2227	1/1/2006	Field Sampling
pH Meter	Denver Instruments	UB-10	UB10107126	1/2/2008	pH for alkalinity
pH Meter	Accumet	AB15	AB92338994	1/1/2006	Fluoride
pH Meter	Thermo	OrionStarA111	J00943	1/1/2006	pH for TCLP
pH Meter	Mettler Toledo	SevenEasy	1231105377	1/1/2006	рН
pH Meter	Thermo Scientific	Orion Star AllI	J0791	4/7/2014	рН
pH Meter	Sartorius	Basic Meter PB-11	31350114	10/14/2014	рН
pH probe	Thermo	9107BNMD	PV1-30483	7/1/2011	Field Sampling
pH probe	Hach	50.50TpHelectrode	LZW5050T.97.002	7/15/2013	Field Sampling
Pipet-Aid Pipettor	Drummond	Pipet-Aid XP	68640	1/1/2009	
Plastic Shredder	Prodeva	315-S	11090	1/1/2001	None
Post-Column Derivatizer	Pickering	1102202	PCX5200	1/1/2009	EPA 547
Post-Column Derivatizer	Pickering	Pinnacle PCX	1007302	1/1/2009	EPA 531.1, EPA 547
Pump	Metrohm	818	1818011014106	11/5/2012	EPA 7199/218.6
Pump	Dionex	IC25	01030292	1/1/2007	EPA 300.0/9056
Pump	Dionex	IS20	98060397	6/1/2015	EPA 300.0/9056
Pump	Dionex	ICS-2000-DP	09080225	10/3/2013	EPA 7199/218.6
Purge & Trap Concentrator	O.I. Analytical	4460A	12584-1027	1/1/1992	
Purge & Trap Concentrator	O.I. Analytical	4460A	123811014	1/1/1993	
Purge & Trap Concentrator	O.I. Analytical	4460A	108061863	1/1/1997	
Purge & Trap Concentrator	O.I. Analytical	4560	N111460835	1/1/1993	
Purge & Trap Concentrator	O.I. Analytical	4560	A229100	1/1/1992	
Purge & Trap Concentrator	O.I. Analytical	4460A	M214048	1/1/1993	
Purge & Trap Concentrator	O.I. Analytical	4560	N222460463	1/1/1998	
Purge & Trap Concentrator	O.I. Analytical	4560	K728460713	1/1/1999	
Purge & Trap Concentrator	O.I. Analytical	4560	J513460474	1/1/1997	

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Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
Purge & Trap Concentrator	O.I. Analytical	4560	K841460440	1/1/2001	
Purge & Trap Concentrator	O.I. Analytical	4560	M946460833	1/1/2001	
Purge & Trap Concentrator	O.I. Analytical	4560	K82946045	1/1/2002	
Purge & Trap Concentrator	O.I. Analytical	4560	J431460443	1/1/2002	
Purge & Trap Concentrator	O.I. Analytical	4560	N228460103	1/1/2003	
Purge & Trap Concentrator	O.I. Analytical	4560	K907460143	1/1/2004	A P A
Purge & Trap Concentrator	O.I. Analytical	4560	J624460525	1/1/2004	
Purge & Trap Concentrator	O.I. Analytical	4560	J513460468	1/1/2004	
Purge & Trap Concentrator	O.I. Analytical	4560	A229108	1/1/2006	
Purge & Trap Concentrator	O.I. Analytical	4560	L924460239	1/1/2005	
Purge & Trap Concentrator	O.I. Analytical	4560	C301264	1/1/1997	
Purge & Trap Concentrator	O.I. Analytical	4560	K810460876	1/1/1999	
Purge & Trap Concentrator	O.I. Analytical	4560	H351460339	1/1/2006	
Purge & Trap Concentrator	O.I. Analytical	4560	E324406	1/1/2006	
Purge & Trap Concentrator	O.I. Analytical	4560	L930460194	1/1/2000	
Purge & Trap Concentrator	O.I. Analytical	4560	E324406	1/1/2001	
Quanti Tray Sealer	ldexx	89-10894-04	6345	1/1/2009	
Quebec Colony Counter	Reichert	3325	02561-1009	1/1/2009	
Rapid Vap	Labconco	Rapidvap	705319	1/1/1999	
Rapid Vap	Labconco	Rapidvap	21098412F	1/1/2002	
Rapid Vap	Labconco	Rapidvap	010194458E	1/1/2002	
Rapid Vap	Labconco	Rapidvap	040824527F	1/1/2006	
Rapid Vap	Labconco	Rapidvap	100931761	1/1/2010	
Rapid Vap	Labconco	Rapidvap	266894	1/1/2010	Drinking Water
Rapid Vap	Labconco	Rapidvap	990391288C	1/1/2010	Drinking Water
Reciprocal Shaker	Lab-Line	3506	0590-1753	1/1/2012	
Rotator, 10-place	Environmental Express	5K939C	V00212AY10	1/1/2006	
Rotator, 12-place	Environmental Express		GFMG060J1	1/1/2002	
Rotator, 20-place	Ed W. Smith Machine Works	NA	NA	1/1/1999	
Rotator, 8-place	Environmental Express	F057	E512-TMP	1/1/2002	
Rotator/ Shaker	Thermolyne "Big Bill"	M49235	49	1/1/2012	

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Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
SPE	Horizon	SPE-3000XL PLUS	1006	1/1/2008	EPA 1664A HEM & SGT- HEM
SPE-Controller	Horizon Technology	SPE-DEX	020357	1/1/2003	EPA 1664A
SpeedVapII	Horizon	SpeedVap 9000	00-248	1/1/2005	EPA 1664 and EPA 413.1
SpeedVapII	Horizon	SpeedVap 9000	99-216	1/1/2007	EPA 1664 and EPA 413.1
SpeedVapIII	Horizon	SpeedVap III	04-2019	1/1/2007	EPA 1664 and EPA 413.1
SpeedVapIII	Horizon	SpeedVap 9000	04-2032	1/1/2007	EPA 1664 and EPA 413.1
Stereo Microscope with Fluorescence source	VWR	HF-745	V167693	1/1/2009	
Thermolyne 48000 Furnace	Thermolyne	F48015	1205001206827	1/1/2015	TVS
TOC Analyzer	Shimadzu	5000A	33N01036A	1/1/1998	EPA 415.1, SW9060, SM5310B
TOC Analyzer	Tekmar-Dohrmann	Phoenix 8000	US02106006	1/1/2002	SM5310C
TOC Analyzer	O.I. Analytical	Solids	C905776109	1/1/2009	EPA 415.1, SW9060 (Soil Only)
TOC Analyzer	Shimadzu	VCSH	HS1104535257CS	1/1/2011	SW9060, SM5310B
TOC Analyzer	Shimadzu	ASI-V	H52104502349SA	1/1/2011	SW9060, SM5310B
TOC Analyzer	O.I. Analytical	Solids	C532776280	1/6/2015	SW9060 (Soil Only)
TOC Autosampler	Shimadzu 🧥	ASI-500A-H-P	33212579	1/1/1998	TOC
TOC Autosampler	Tekmar-Dohrmann	223	CAN 001 768 396	1/1/2002	SM5310C
Tower	Agilent	G2613A	CN22425747	1/1/2009	EPA 525.2
Tower	Hewlett Packard	18593B	3239A32438	1/1/2009	
Turbidity Meter	Orbeco-Hellige	965-10A	4389	1/1/2007	Turbidity
Turbidity Meter	Orbeco-Hellige	965-10A	5187	1/1/2009	EPA 180.1Turbidity
Turbo Vap II	Zymark	TurboVap II	TV0239N11193	1/1/2002	
TurboVap II	Zymark	TurboVap II	04427	1/1/2008	1664, 418.1/413.2, 3510C
TurboVap II	Zymark	TurboVap II	04429	1/1/2008	1664, 418.1/413.2, 3510C
TurboVap II	Zymark	TurboVap II	TV0635N13234	6/1/2015	1664, 418.1/413.2, 3510C, CALuft
TurboVap II	Zymark	TurboVap II	TV0634N13224	6/1/2015	1664, 418.1/413.2, 3510C, CALuft
TurboVap II	Zymark	TurboVap II	TV0635N13233	6/1/2015	1664, 418.1/413.2, 3510C, CALuft

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year put into Service	Methods Performed
TurboVap II	Zymark	46368/A	TV9424N4100	12/8/2014	1664, 3510C
UV Lamp (big)	UVP	C-65	95025701	1/1/2009	
UV Lamp (small)	UVP	CC-10	95007201	1/1/2009	
UV Viewing Cabinet (big)	UVP	UVLMS	95025201	1/1/2009	
UV Viewing Cabinet (small)	UVP	UVGL58	9500705	1/1/2009	
UV/VIS Detector	Dionex	ICS-VWD	08040042	10/3/2013	EPA 7199/218.6
UV/VS Spectrometer	Thermo Spectronic	Genesys20	3SGG06B0117	1/1/2002	SM4500-CN
UV/VS Spectrometer	Thermo Spectronic	Genesys20	3SGQ068003	1/1/2012	SM4500-CN
UV/VS Spectrometer	Thermo Spectronic	Genesys20	3SGS260009	10/6/2014	SM4500CN, SM5520, SM5220
Water Bath	Precision	185	N/A	1/1/2010	Odor
Water Bath	Fisher	IsoTemp 228	1608090911951	1/1/2009	Odor
Water Bath, circulating (44.5C)	Precision	2866	205648-295	1/1/2010	For MTFs
Water Bath, circulating (44.5C)	Precision	2862	200035	1/1/2009	For P/As

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

Table 20-2. Example: Schedule of Routine Maintenance

Instrument	Procedure	Frequency
lon 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 KCI calibration Conductivity cell cleaning	Daily As required
Turbidimeter	Check light bulb Clean sample holder	Daily, when used Daily, when used
Deionized/Distilled Water	Daily conductivity check Check deionizer light Monitor for VOA's System cleaning Replace cartridge & large mixed bed resins	Daily Daily As required As required As required
Drying Ovens	Temperature monitoring Temperature adjustments	When used As required
Refrigerators/ Freezers	Temperature monitoring Temperature adjustment Defrosting/cleaning	Daily As required As required
pH/Specific Ion Meter	Calibration/check slope Clean electrode	Daily As required
BOD Incubator	Temperature monitoring Incubator cleaning	Daily As required
Centrifuge	Check brushes and bearings	As needed
Water baths	Temperature monitoring Water replaced	Daily Monthly or as needed
Automated Solvent Extraction units (ASE)	Check solvent reservoirs Check tubing	Daily Daily
TurboVaps	Check gas lines Check water level Calibrate temperature	Daily Daily Annually
Total Organic Carbon Analyzer	Check gas flow Check reagent reservoir levels Replace o-rings Check autosampler needle Replace scrubbers Replace catalyst	Daily Daily As needed Daily Annually As needed
Automated Analyzer	Clean sampler Check all tubing Clean detector Clean optics and cells	Daily Daily Daily Daily

Instrument	Procedure	Frequency
Infrared Spectrophotometer (IR)	Clean lens/optimize	As needed
Flashpoint Apparatus	Check gas line for leaks	Daily
	Check stirrer speed	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, and Deionized and Reverse Osmosis water systems, automatic pipettes and other volumetric measuring devices. (Refer to Section 20.3.) With the exception of Class A Glassware and Glass microliter syringes, monthly accuracy checks are performed for all mechanical volumetric devices. Microsyringes are verified at least semi-annually or disposed after 6 months of use. Wherever possible, subsidiary or peripheral equipment is checked against standard equipment or standards that are traceable to national or international standards. Class A Glassware and Glass microliter syringes should be routinely inspected for chips, acid etching, or deformity (e.g., bent needle). If the Class A glassware or syringe is suspect, the accuracy of the glassware will be assessed prior to use.

21.2 NIST-TRACEABLE WEIGHTS AND THERMOMETERS

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

For NIST-traceable weights and thermometers, the laboratory requires that all calibrations be conducted by a calibration laboratory accredited by A2LA, NVLAP, or another accreditation organization that is a signatory to an MRA of one or more of the following cooperations: ILAC or APLAC. A calibration certificate and scope of accreditation is kept on file at the laboratory. Refer to Section 20 for calibration of weights and thermometers.

21.3 REFERENCE STANDARDS / MATERIALS

Reference standards/materials, where commercially available, are traceable to certified reference materials. Commercially prepared 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. The appropriate QC criteria for specific standards are defined in laboratory SOPs. In most cases, the analysis of an ICV or LCS, where there is no sample preparation, is used as the second source confirmation. These checks are generally performed as an integral part of the analysis method (e.g., calibration checks, LCS).

All standards and reference materials must be stored and handled according to manufacturer's recommendations in order to prevent contamination or deterioration. Refer to Corporate EHS Document No. CW-E-M-001 or laboratory SOPs. For safety requirements, refer to method SOPs and the laboratory EHS Manual.

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

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

Reagents must be at a minimum the purity required in the test method. The date of reagent receipt and the expiration date are documented. The lots for most of the common solvents and acids are tested for acceptability prior to company-wide purchase. Refer to Corporate Quality Document No. CA-Q-S-001.

All manufacturer- or vendor-supplied Certificate of Analysis or Purity must be retained, stored appropriately, and readily available for use and inspection. These records are maintained in the LIMS 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 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 value 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 LIMS and are assigned a unique identification number. The following information is typically recorded in the electronic database within the LIMS:
 - Standard ID
 - Description of standard
 - Department
 - Preparer's name
 - · Final volume and number of vials prepared
 - Solvent type and lot number
 - Preparation date
 - Expiration date
 - Standard source type (stock or daughter)
 - Standard type (spike, surrogate, other)
 - Parent standard ID (if applicable)
 - Parent standard analyte concentration (if applicable)
 - Parent standard amount used (if applicable)
 - Component analytes
 - Final concentration of each analyte
 - Comments (e.g., recommended storage conditions)

Records are maintained electronically 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 labeled with a minimum of the following information:

- Expiration date (include prep date for reagents)
- Standard ID (specified from LIMS)
- 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 LIMS.

- **21.4.3** In addition, the following information may be helpful:
 - Date opened (for multi-use containers, if applicable)
 - Description of standard (if prepared at the laboratory)
 - Recommended storage conditions
 - Expiration date (include prep date for reagents)
 - 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 laboratory SOP No. IR-SC-FIELD. The laboratory also supplies samplers with the necessary coolers, sample containers, sample labels, custody seals, COC forms, and packing materials required to properly pack and ship samples to the laboratory.

22.2 SAMPLING CONTAINERS

The laboratory offers clean sampling containers for use by clients. These containers are either obtained from reputable container manufacturers and meet EPA specifications as required. 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 time expressed in "hours" (e.g., 6 hours, 24 hours, etc.) is measured from date and time zero. Holding times for analysis include any necessary re-analysis.

22.4 SAMPLING CONTAINERS, PRESERVATION REQUIREMENTS, HOLDING TIMES

The preservation and holding time criteria specified in the laboratory SOPs are derived from the source documents for the methods. If method-required holding time or preservation requirements are not met, the results 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 / SUB-SAMPLING

Taking a representative sub-sample from a container is necessary to ensure that the analytical results are representative of the sample collected in the field. The size of the sample container, 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 sub-sample 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 and sub-sampling are defined in laboratory SOP No. IR-QA-SUBSAMP.

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SECTION 23

HANDLING OF SAMPLES

23.1 CHAIN OF CUSTODY

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

- Sample identification
- Date and time of sampling
- Preservative

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

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

available

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

When the sampling personnel delivers the samples directly to TestAmerica personnel, the samples are stored in a cooler with ice, as applicable, and remain solely in the possession of the client's field technician (or sampler) until the samples are delivered to the laboratory personnel. The sample collector must assure that each container is in his/her physical possession or in his/her view at all times, or stored in such a place and manner to preclude tampering. The field technician relinquishes the samples in writing on the COC form to the Sample Control personnel at the laboratory or to a TestAmerica courier.

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

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

23.1.2 Legal / Evidentiary COC

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

23.2 SAMPLE RECEIPT

Samples are received at the laboratory by designated sample receiving personnel and a unique laboratory project identification number is assigned. Each sample container shall be assigned a unique sample identification number that is cross-referenced to the client identification number such that traceability of test samples is unambiguous and documented. Each sample container is affixed with a durable sample identification label. Sample acceptance, receipt, tracking, and storage procedures are summarized in the following sections and are discussed in detail in laboratory SOP No. IR-SC-LOGIN.

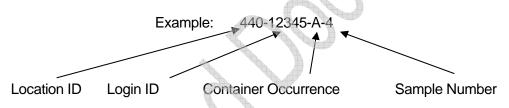
23.2.1 Laboratory Receipt

When samples arrive at the laboratory, sample receiving personnel inspect the coolers and samples. The integrity of each sample must be determined by comparing sample labels or tags with the COC and by visual checks of the container for possible damage. Any nonconformance, irregularity, or compromised sample receipt must be documented in the NCM program in the LIMS and brought to the immediate attention of the client. The COC, shipping documents, documentation of any nonconformance, irregularity, or compromised sample receipt, record of client contact, and resulting instructions become part of the project record.

23.2.1.1 Unique Sample Identification

All samples that are processed through the laboratory receive a unique sample identification to ensure that there can be no confusion regarding the identity of such samples at any time. This system includes identification for all samples, subsamples, and subsequent extracts and/or digestates.

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



The above example is a login at TestAmerica Irvine Laboratory (Location 440). Login ID is 12345 (unique to a particular client/job occurrence). The container code indicates it is the first container ("A") of Sample #4.

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: 440-12345-A-4-A **Secondary Container Occurrence**

Example 440-12345-A-4-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 be tracked throughout the laboratory in every step from receipt to disposal.

23.3 SAMPLE ACCEPTANCE POLICY

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

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

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

Data from samples that do not meet these criteria are flagged and the nature of the variation from policy is defined. Sample Control personnel shall include this copy with the sample container shipment to the client or the PM may e-mail the client a copy during project setup (prior to shipment of samples to the laboratory).

- **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 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 or freezers 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, analyze the sample, and return the remaining sample or empty container to the refrigerator from which it originally came. All unused portions of samples, including empty sample containers, are returned to the Sample Control area. All samples are kept in the refrigerators for two to four weeks after analysis, which meets or exceeds most sample holding times. After two to four weeks, the samples are moved to dry room temperature Sample Archive area, where they are stored for an additional two to four weeks before they are disposed. This four to eight week holding period allows samples to be checked if a discrepancy or question arises. Special arrangements may be made to store samples for longer periods of time. This extended holding period allows additional metal analyses to be performed on the archived sample and assists clients in dealing with legal matters or regulatory issues.

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

23.5 HAZARDOUS SAMPLES AND FOREIGN SOILS

To minimize exposure to personnel and to avoid potential accidents, hazardous and foreign soil samples are stored in an isolated area designated for hazardous waste only. For any sample that is known to be hazardous at the time of receipt, the Sample Control personnel handling wastes clearly marks the sample with a red stamp, stamped on the sample label reading "HAZARDOUS" or "FOREIGN SOIL," and places it in a colored and/or marked bag for easy identification. The Sample Control personnel handling wastes must completely fill out the Hazardous & Quarantine/Foreign Soil – Drum for Incineration Sample Notice (see Figure 23-3) and include a copy with the original COC and other sample receipt records that will be submitted to the PM. The original is retained by the Sample Control personnel handling wastes.

If after completion of analysis the analyst has determined a sample to be hazardous (based on action limits that are exceeded, as set up in the LIMS), the analyst will notify the Sample Control personnel handling wastes and submit to that personnel the original of the completed notification form (Figure 23-3) and a copy to the PM for archiving with the job records.

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

23.6 SAMPLE SHIPPING

In the event that the laboratory needs to ship samples, the samples are placed in coolers with enough ice to ensure the samples remain just above freezing and at or below 6.0°C

during transit. The samples are carefully surrounded by packing material to avoid breakage (yet maintain appropriate temperature). A trip blank is enclosed for those samples requiring water/solid volatile organic analyses (see Note). The COC form is signed by Sample Control and is attached to the shipping paperwork. Samples are generally shipped overnight express or hand-delivered by a TestAmerica courier to maintain sample integrity. All personnel involved with shipping and receiving samples must be trained to maintain the proper COC documentation and to keep the samples intact and on ice, if needed. Corporate EHS Document No. CW-E-M-001 contains additional shipping requirements.

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

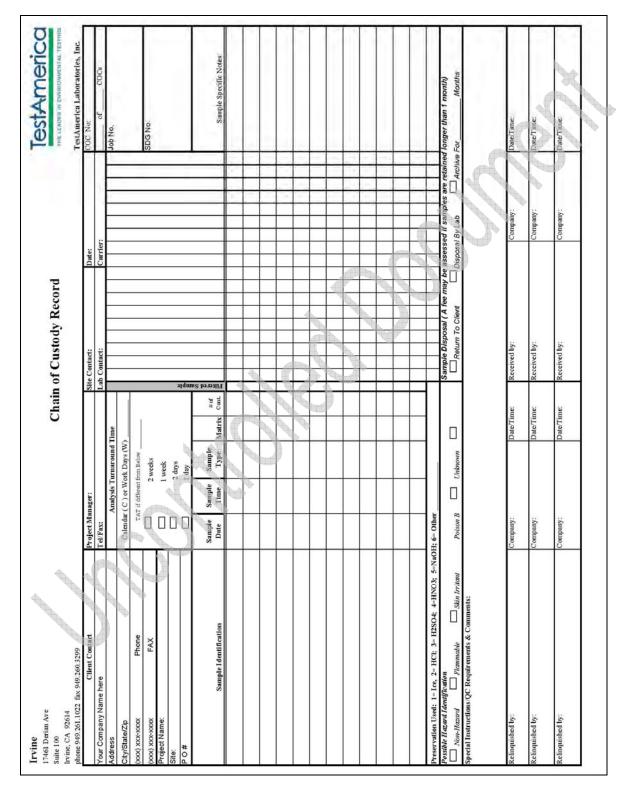
23.7 SAMPLE DISPOSAL

Samples should be retained for a minimum of 30 days after the project report is sent, however, provisions may be made for earlier disposal of samples once the holding time is exceeded. Some samples are required to be held for longer periods based on regulatory or client requirements (e.g., 60 days after project report is sent). The laboratory must follow the longer sample retention requirements, where required by regulation or client agreement. Several possibilities for sample disposal exist: the sample may be used up completely during analysis, the sample may be returned to the customer or location of sampling for disposal, or the sample may be disposed of in accordance with laboratory SOP No. IR-EHS-WASTE. All procedures in the laboratory EHS 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, and return to client), and names of individuals who conducted the arrangements and physically completed the task. The laboratory will remove or deface sample labels prior to disposal, unless this is accomplished through the disposal method (e.g., samples are incinerated). A waste disposal record should be completed.

Figure 23-1.

Example - Chain of Custody



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Figure 23-2.

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Example - Sample Acceptance Policy

TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING
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).
 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 store stime used
 Include preservative used. Use indelible ink
Information must be legible
 Proper sample containers with adequate volume for the analysis and necessary QC are required for each analysis requested. See TA Sample Container Guide.
 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.
17461 Derian Ave Suite 100, Irvine, CA 92606 (949) 261-1022 FAX (949) 261-1228

5)	 to 4°C (other than water samples for metals analysis and samples for air analysis). For these methods, the criteria are met if the samples are chilled to below 6°C and above freezing (0°C), for methods with other temperature criteria (e.g. some bacteriological methods require < 10°C), the samples must arrive within ± 2° C of the required temperature or within the method specified range. Note: Samples that are hand-delivered to the laboratory immediately after collection may not have had time to cool sufficiently. In this case the samples will be considered acceptable as long as there is evidence that the chilling process has begun (arrival on ice). 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. 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
	samples should be filtered in the field within 15 minutes. Dissolved Sunde 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.
	G:\FORMS\SampleControl\Sample Acceptance Policy 6-20-2014.doc
	Updated June 20, 2014

Figure 23-3.

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

HAZARDOU	S & QUARAN	ITINE/FOREIGN	
	RUM FOR INC		
· · · ·		Date:	
CLIENT:		LOG NO:	
PROJECT ID NO:		MATRIX	
Sample Potentially Ha	azardous	C.V.	
Sample Hazardous			
	n Soil (Mexico, Canada, Hav	HAZARD (Compound &	
		Result)	
DATE ARCHIVED: (Sample placed on hazardous shelves)		Initials	
DATE DISPOSED: (On the date samples are removed for I	hazardous sample disposal, please	Initials a date & return this form to Sample Control)
	G:\D	epts\QUALITY\FORMS\SampleControl\Haz	
		(2	/02/09)

SECTION 24

ASSURING THE QUALITY OF TEST RESULTS

24.1 OVERVIEW

In order to assure our clients of the validity of their data, the laboratory continuously evaluates the quality of the analytical process. The analytical process is controlled not only by instrument calibration as discussed in Section 20, but also by routine process QC measurements (e.g., blanks, LCS, MS, sample duplicates, surrogates, and internal standards). These QC checks are performed as required by the method or regulations to assess precision and accuracy. QC samples are to be treated in the exact same manner as the associated field samples being tested. In addition to the routine process QC samples, PT samples (concentrations unknown to laboratory) are analyzed to help ensure laboratory performance.

24.2 CONTROLS

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

24.3 NEGATIVE CONTROLS

Control Type	Details
	are used to assess preparation and analysis for possible contamination during the preparation and processing steps.
	The specific frequency of use for method blanks during the analytical sequence is defined in the specific SOP for each analysis. Generally, it is one for each batch of samples; not to exceed 20 environmental samples.
2/	The method blank is prepared from a clean matrix similar to that of the associated samples that is free from target analytes (e.g., reagent water, Ottawa sand, glass beads, etc.) and is processed along with and under the same conditions as the associated samples.
	The method blank goes through all of the steps of the process (including as necessary: filtration, clean-ups, etc.).
	Re-analyze or qualify associated sample results when the concentration of a targeted analyte in the method blank is at or above the RL (or at or above 1/2, as established by the method or by regulation, AND is greater than 1/10 of the amount measured in the sample.
Blanks	are prepared and analyzed along with calibration standards, where applicable. They are prepared using the same reagents that are used to prepare the standards. In some analyses, the calibration blank may be included in the calibration curve.

Table 24-1. Example – Negative Controls

Control Type	Details
Instrument Blanks	are blank reagents or reagent water that may be processed during an analytical sequence in order to assess contamination in the analytical system. In general, instrument blanks are used to differentiate between contamination caused by the analytical system and that caused by the sample handling or sample preparation process. Instrument blanks may also be inserted throughout the analytical sequence to minimize the effect of carryover from samples with high analyte content.
Trip Blanks 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 is prepared in the field by filling a clean container with pure reagent water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA OSWER)
Equipment Blanks ¹	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	are also referred to as refrigerator blanks or storage blanks and are used to monitor the sample storage units for volatile organic compounds during the storage of VOA samples in the laboratory.

¹ When known, these field QC samples should not be selected for matrix QC as it does not provide information on the behavior of the target compounds in the field samples. Usually, the client sample ID will provide information to identify the field blanks, equipment blanks, or trip blanks with labels such as "FB", "EB", or "TB."

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

24.3.1 Negative Controls for Microbiological Methods

Microbiological methods utilize a variety of negative controls throughout the process to ensure that false positive results are not obtained. These controls are critical to the validity of the microbiological analyses. Some of these negative controls are:

Table 24-2. Negative Controls for Microbiology

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Control Type	Details
	are analyzed for each lot of pre-prepared media, ready-to-use media, and for each batch of medium prepared by the laboratory.
	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.
(Sample	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.
	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.

Negative culture controls demonstrate that a media does not support the growth of non-target organisms and ensures that there is not an atypical positive reaction from the target organisms. Prior to the first use of the media, each lot of pre-prepared selective media or batch of laboratory prepared selective media is analyzed with at least one known negative culture control. as appropriate to the method.

24.4 POSITIVE CONTROLS

Control samples (e.g., QC indicators) are analyzed with each batch of samples to evaluate data based upon (1) Method Performance (LCS or Blank Spike), which entails both the preparation and measurement steps; and (2) Matrix Effects (MS or sample duplicates), which evaluates field sampling accuracy, precision, representativeness, interferences, and the effect of the matrix on the method performed. Each regulatory program and each method within those programs specify the control samples that are prepared and/or analyzed with a specific batch.

Note that frequency of control samples vary with specific regulatory, methodology, and project-specific criteria. Complete details on method control samples are as listed in the laboratory SOPs.

24.4.1 <u>Method Performance Control – LCS</u>

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

The LCS is prepared from a clean matrix similar to that of the associated samples that is free from target analytes (e.g., reagent water, Ottawa sand, glass beads, etc.) and is processed along with and under the same conditions as the associated samples. The LCS is spiked with verified known amounts of analytes or is made of a material containing known and verified amounts of analytes, taken through all preparation and analysis steps along with the field samples. Where there is no preparation taken for an analysis (such as in aqueous volatiles), or when all samples and standards undergo the same preparation and analysis process (such as Phosphorus), a calibration verification standard is reported as the LCS. In some instances where there is no practical clean solid matrix available, aqueous LCSs may be processed for solid matrices; final results may be calculated as mg/kg or ug/kg, assuming 100% solids and a weight equivalent to the aliquot used for the corresponding field samples, to facilitate comparison with the field samples.

Certified pre-made reference material purchased from a NIST/A2LAaccredited 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 SOP for each analysis. It is generally one for each batch of samples, not to exceed 20 environmental samples.

If the mandated or requested test method or project requirements do not specify the spiking components, the laboratory shall spike all reportable components to be reported in the LCS (and MS), where applicable (e.g. no spike of pH). However, in cases where the components interfere with accurate assessment (such as simultaneously spiking chlordane, toxaphene and PCBs in Method 608), the test method has an extremely long list of components or components are incompatible, at a minimum, a representative number of the listed components (see below) shall be used to control the test method. The selected components of each spiking mix shall represent all chemistries, elution patterns and masses, permit specified analytes, and other client-requested components. However, the laboratory shall ensure that all reported components are used in the spike mixture within a two-year time period.

- For methods that have 1-10 target analytes, spike all components.
- For methods that include 11-20 target analytes, spike at least 10 or 80%, whichever is greater.
- For methods with more than 20 target analytes, spike at least 16 components.
- Exception: Due to analyte incompatibility in pesticides, Toxaphene and Chlordane are only spiked at client request based on specific project needs.
- Exception: Due to analyte incompatibility between the various PCB aroclors, aroclors 1016 and 1260 are used for spiking as they cover the range of all of the aroclors. Specific aroclors may be used by request on a project specific basis.

24.4.2 Positive Controls for Microbiological Methods

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

24.5 SAMPLE MATRIX CONTROLS

Table 24-3. Sample Matrix Control

Control Type		Details
MS	Use	used to assess the effect that the sample matrix of the spiked sample has on the precision and accuracy of the results generated by the method used.
	Typical Frequency ¹	At a minimum, with each matrix-specific batch of samples processed, an MS is carried through the complete analytical procedure. Unless specified by the client, samples used for spiking are randomly selected and rotated between different client projects. If the mandated or requested test method does not specify the spiking components, the laboratory shall spike all reportable components to be reported in the LCS and MS. Refer to the laboratory SOP for complete details.
	Description	essentially, a sample fortified with a known amount of the test analyte(s).
Surrogate	Use	Measures method performance to sample matrix (organics only).
	Typical Frequency ¹	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.
	Description	are similar to MS except the analytes are compounds with properties that mimic the analyte of interest and are unlikely to be found in environmental samples.
Duplicates ² Use For a measure		For a measure of analytical precision, with each matrix-specific batch of samples processed, a sample duplicate or LCSD is carried through the complete analytical procedure.
	Typical Frequency ¹	Duplicate samples are usually analyzed with methods that do not require MS analysis.
	Description	Performed by analyzing two aliquots of the same field sample independently or an additional LCS.
Internal Standard	Use	are spiked into all environmental and QC samples (including the ICAL 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 laboratory SOP for type and frequency of sample matrix control samples.

² 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 RPD. Poor precision between duplicates (except LCS/LCSD) may indicate non-homogeneous matrix or sampling.

24.6 ACCEPTANCE CRITERIA (CONTROL LIMITS)

As mandated by the test method and regulation, the individual analyte in the LCS, MS, or Surrogate Spike is evaluated against the control limits published in the test method. Where there are no established acceptance criteria, the laboratory calculates in-house control limits with the use of control charts or, in some cases, utilizes client project-specific control limits. 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 percent recovery acceptance (control) limits are generally established by taking ± 3 standard deviations (99% confidence level) from the average recovery of a minimum of 20-30 data points (more points are preferred).

- Regardless of the calculated limit, the control limit should be no tighter than those used in the Calibration Verification (ICV/CCV), unless the analytical method specifies a tighter limit.
- In-house limits cannot be any wider than those mandated in a regulated analytical method. Client- or contract-required control limits are evaluated against the laboratory's statistically derived control limits to determine if the DQOs can be achieved. If laboratory control limits are not consistent with DQOs, then alternatives must be considered, such as method improvements or use of an alternate analytical method.
- The lowest acceptable recovery limit will be 10% (the analyte must be detectable and identifiable). Exception: The lowest acceptable recovery limit for Benzidine will be 5% and the analyte must be detectable and identifiable.
- The maximum acceptable recovery limit will be 150%. The QA Manager may grant exceptions, as warranted.
- The maximum acceptable RPD limit will be 35% for waters and 40% for soils. The minimum RPD limit will be 10%.
- If either the high or low end of the control limit changes by <5% from previous, the control chart is visually inspected and, using professional judgment, the control limits may be left unchanged if there is no effect on the laboratory's ability to meet the existing limits.
- **24.6.1** The laboratory must be able to generate a current listing of their control limits and track when the updates are performed. In addition, the laboratory must be able to recreate historical control limits. Refer to laboratory SOP No. IR-QA-CNTRLLIM.
 - The QA Department e-mails the appropriate laboratory staff a table that contains the accuracy and precision limits for the spiked analytes for each method performed at the laboratory. Unless otherwise noted, the control limits within these tables are laboratory-generated. The table includes an effective date. The control limits are stored in the LIMS.
 - When control limits are updated, the LIMS maintains in its database the previous control limits, so that historical control limits in effect for a specific time period may be retrieved for reference.
- **24.6.2** An LCS that is within the acceptance criteria establishes that the analytical system is in control and is used to validate the process. Samples that are analyzed with an LCS with recoveries outside of the acceptance limits may be determined to be out of control and should be re-analyzed, if possible. If re-analysis is not possible, then the results for all affected analytes for samples within the same batch must be qualified when reported. The internal corrective action process (see Section 12) is also initiated if an LCS exceeds

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

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

<11 analytes	0 marginal exceedences are allowed.
11 – 30 Analytes	1 marginal exceedence is allowed
31-50 Analytes	2 marginal exceedences are allowed
51-70 Analytes	3 marginal exceedences are allowed
71-90 Analytes	4 marginal exceedences are allowed
> 90 Analytes	5 marginal exceedences are allowed

- Marginal exceedences are recovery exceedences between 3 SD and 4 SD from the mean recovery limit (TNI).
- Marginal exceedences 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 exceedences to ensure that they are random.

Though marginal exceedences 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 acceptance limits. If obvious preparation errors are suspected, or if requested by the client, unacceptable MS/MSDs are reprocessed and re-analyzed to prove matrix interference. A more detailed discussion of acceptance criteria and corrective action can be found in the laboratory SOPs and in Section 12.
 - If a surrogate standard falls outside the acceptance limits, if there is not obvious chromatographic matrix interference, re-analyze the sample to confirm a possible matrix effect. If the recoveries confirm or there was obvious chromatographic interference, results are reported from the original analysis and a qualifier is added. If the re-analysis meets surrogate recovery criteria, the second run is reported (or both are reported if requested by the client). Under certain circumstances, where all of the samples are from the same location and share similar chromatography, the re-analysis may be performed on a single sample rather than all of the samples, and if the surrogate meets the recovery criteria in the re-analysis, all of the affected samples would require re-analysis.

24.7 ADDITIONAL PROCEDURES TO ASSURE QUALITY CONTROL

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

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

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

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

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

Constant and consistent test conditions are discussed in Section 18.

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

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 requirements are paramount, and the laboratory will work with the client during project setup to develop an acceptable solution. Refer to Section 7.

A variety of report formats are available to meet specific needs.

In cases where a client asks for simplified reports, there must be a written request from the client. There still must be enough information that would show any analyses that were out of conformance (e.g., QC out of limits) and there should be a reference to a full report that is made available to the client. Review of reported data is included in Section 19.

25.2 TEST REPORTS

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

- **25.2.1** A report title (e.g., Analytical Report) with headers for the different information associated with a sample result (e.g., analyte name, data qualifiers, units, MDL, RL, dilution, date analyzed, instrument, analyst, and QC batch).
- **25.2.2** Each report cover page printed on company letterhead, which includes the laboratory name, address, and telephone number.
- **25.2.3** A unique identification of the report (e.g., job number) and on each page an identification to ensure the page is recognized as part of the report and a clear identification of the end.
 - **Note:** Page numbers of report are represented as Page # of ##, where the first number is the page number and the second is the total number of pages.
- **25.2.4** A copy of the 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 PM or other contact
- **25.2.7** Description and unambiguous identification of the tested sample(s) including the client identification code
- **25.2.8** Date of receipt of sample, date and time of collection, and date(s) of test preparation and performance, and time of preparation or analysis if the required holding time for either activity is less than or equal to 72 hours.
- **25.2.9** Date reported or date of revision, if applicable.
- **25.2.10** Method of analysis including method code (EPA, Standard Methods, etc.)
- 25.2.11 RLs
- 25.2.12 MDLs, if requested
- 25.2.13 Definition of data qualifiers and reporting acronyms, e.g., ND
- **25.2.14** Sample results
- **25.2.15** QC data consisting of method blank, surrogate (if applicable), LCS, and MS/MSD recoveries and control limits
- **25.2.16** Condition of samples at receipt, including temperature (if applicable).
- **25.2.17** A statement expressing the validity of the results, that the source methodology was followed, and that all results were reviewed for error.
- **25.2.18** A statement to the effect that the results relate only to the items tested and the sample, as received by the laboratory.
- **25.2.19** A statement that the report shall not be reproduced except in full, without prior express written approval by the laboratory.
- **25.2.20** A signature and title of the person(s) accepting responsibility for the content of the report and date of issue. Signatories are appointed by the Laboratory Director.
- **25.2.21** When TNI accreditation is required, the laboratory 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 Corporate Information Technology SOP No. CA-I-P-002 for details on internally applying electronic signatures of approval.

25.3 REPORTING LEVEL OR REPORT TYPE

The laboratory offers four levels of report packages. Each level, in addition to its own specific requirements, contains all the information provided in the preceding level. The packages provide the following information in addition to the information described above. Note that raw data presented in Level III and Level IV reports are in CLP-like format:

- Level I is a report with the features described in Section 25.2 above.
- Level II is a Level I report plus summary information, including results for the method blank reported to the laboratory MDL (if required or applicable), percent recovery for LCS and MS samples, and the RPD values for all LCS/LCSD, MS/MSD, and sample duplicate analyses.
- Level III contains all the information supplied in Level II, but presented on the CLPlike summary forms, and relevant calibration information. A Level II report is not included, unless specifically requested. No raw data are provided.
- Level IV is the same as Level III with the addition of all raw supporting data.

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

followed by hardcopy, when requested. Procedures used to ensure client confidentiality are outlined in Section 25.6.

25.3.1 <u>Electronic Data Deliverables</u>

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 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 Corporate IT staff coding the EDD.

EDDs shall be subject to a review to ensure their accuracy and completeness. If EDD generation is automated, review may be reduced to periodic screening if the laboratory can demonstrate that it can routinely generate that EDD without errors. Any revisions to the EDD format must be reviewed until it is demonstrated that it can routinely be generated without errors. If the EDD can be reproduced accurately and if all subsequent EDDs can be produced error-free, each EDD does not necessarily require a review.

25.4 SUPPLEMENTAL INFORMATION FOR TEST

The laboratory identifies any unacceptable QC analyses or any other unusual circumstances or observations such as environmental conditions and any non-standard conditions that may have affected the quality of a result. This is typically in the form of a 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/noncompliance 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 – In general, the test report contains objective

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

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

25.5 ENVIRONMENTAL TESTING OBTAINED FROM SUBCONTRACTORS

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

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

25.6 CLIENT CONFIDENTIALITY

In situations involving the transmission of environmental test results by telephone, facsimile, or other electronic means, client confidentiality must be maintained.

TestAmerica will not intentionally divulge to any person (other than the client or any other person designated by the client in writing) any information regarding the services provided by TestAmerica or any information disclosed to TestAmerica by the client. Furthermore, information <u>known</u> to be potentially endangering to national security or an entity's proprietary rights will not be released.

- **Note:** This shall not apply to the extent that the information is required to be disclosed by TestAmerica under the compulsion of legal process. TestAmerica will, to the extent feasible, provide reasonable notice to the client before disclosing the information.
- **Note:** Authorized representatives of an accreditation body are permitted to make copies of any analyses or records relevant to the accreditation process, and copies may be removed from the laboratory for purposes of assessment.
- **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:

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

25.7 FORMAT OF REPORTS

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

25.8 AMENDMENTS TO TEST REPORTS

Corrections, additions, or deletions to reports are only made when justification arises through supplemental documentation. Justification is documented using the laboratory's corrective action system (refer to Section 12).

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

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

25.9 POLICIES ON CLIENT REQUESTS FOR AMENDMENTS

25.9.1 Policy on Data Omissions or RL Increases

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

- Laboratory error
- Sample identification is indeterminate (confusion between COC and sample labels).
- An incorrect analysis (not analyte) was requested (e.g., COC lists 8315 but client wanted 8310). A written request for the change is required.
- Incorrect limits reported based on regulatory requirements

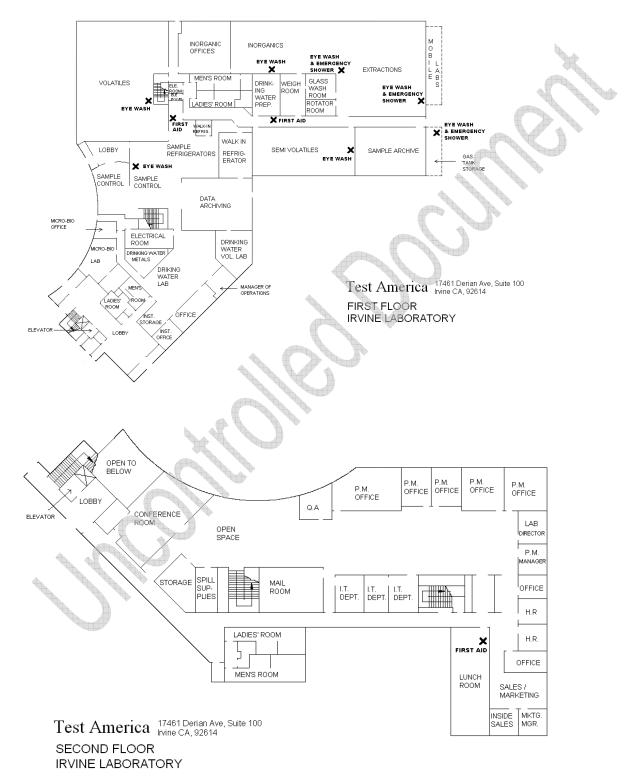
 The requested change has absolutely <u>no possible</u> impact on the interpretation of the analytical results and there is <u>no possibility</u> of the change being interpreted as misrepresentation by anyone inside or outside of our company.

25.9.2 Multiple Reports

TestAmerica does not issue multiple reports for the same job where there is different information on each report (this does not refer to copies of the same report) unless required to meet regulatory needs and approved by the QA Manager.

Appendix 1.

Laboratory Floor Plan



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. (ASQ)

Accreditation:

The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory.

Accuracy:

The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator.

Analyst:

The designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent QC to meet the required level of guality.

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:

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

A preparation batch is composed of one to 20 environmental samples of the same quality systems matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours.

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

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

A set of up to 20 environmental samples (reportable or not) of the same matrix processed using the same procedures and the same lot(s) of reagents within the same time period. A preparation batch is composed of one to 20 environmental samples of the same quality systems matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch is composed of prepared environmental samples (extracts, digestates, or concentrates) and/or those samples not requiring preparation, which are analyzed together as a group using the same calibration curve or calibration factor. The batch must be analyzed sequentially using the same instrument and instrument configuration within the same calibration event (i.e., the same calibration curve, calibration factors, or RFs must be in effect throughout the analysis). QC samples do not count towards the 20 samples in a batch. Rerun of the same environmental sample is counted as part of the 20 in a batch. Field QC samples are included in the batch count.

Bias:

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

Blank:

A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage, or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. (ASQ)

Calibration:

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

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

Calibration Curve:

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

Calibration Standard:

A substance or reference material used to calibrate an instrument.

Certified Reference Material:

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

Chain of Custody:

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

Compromised Samples:

Those samples, which are improperly sampled, insufficiently documented (COC and other sample records and/or labels), improperly preserved, collected in improper containers, or exceeding holding times when delivered to a laboratory. Under normal conditions, compromised samples are not analyzed. If emergency situation requires analysis, the results must be appropriately qualified.

Confidential Business Information:

Information that an organization designates as having the potential of providing a competitor with inappropriate insight into its management, operation, or products. TNI and its representatives agree to safeguard identified CBI and to maintain all information identified as such in full confidentiality.

Confirmation:

Verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to, second-column confirmation, alternate wavelength, derivatization, mass spectral interpretation, alternative detectors, or additional clean-up procedures. (TNI)

Conformance:

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

Correction:

Action necessary to correct or repair analysis-specific nonconformances. The acceptance criteria for method-specific QC and protocols as well as the associated corrective actions. The analyst will most frequently be the one to identify the need for this action as a result of calibration checks and QC sample analysis. No significant action is taken to change behavior, process, or procedure.

Corrective Action:

The action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence. (ISO 8402)

Data Audit:

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

Data Reduction:

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

Deficiency:

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

Duplicate Analyses:

The analyses or measurements of the variable of interest performed identically on two sub-samples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement

precision but not the precision of sampling, preservation, or storage internal to the laboratory. (EPA-QAD)

Equipment Blank:

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

External Standard Calibration:

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

Field Blank:

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

Field of Accreditation:

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

Holding Times:

The maximum times that samples may be held prior to analyses and still be considered valid or not compromised. (40 CFR Part 136)

Internal Standard:

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

Internal Standard Calibration:

Calibrations for methods that utilize internal standards to compensate for changes in instrument conditions.

Instrument Blank:

A clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD)

Instrument Detection Limit:

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

Laboratory Control Sample (or however named, such as laboratory fortified blank, spiked blank, or QC check sample):

A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes, taken through all preparation and analysis steps of the procedure, unless otherwise noted in a reference method. It is generally used to establish intra-laboratory or analyst-specific precision and bias or to assess the performance of all or a portion of the measurement system.

An LCS shall be prepared at a minimum of 1 per batch of 20 or less samples per matrix type per sample extraction or preparation method except for analytes for which spiking solutions are not available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen, or turbidity. The results of these samples shall be used to determine batch acceptance.

Least Squares Regression (1st Order Curve):

The least squares regression is a mathematical calculation of a straight line over two axes. The y-axis represents the instrument response (or Response ratio) of a standard or sample and the x-axis represents the concentration. The regression calculation will generate a correlation coefficient (r) that is a measure of the "goodness of fit" of the regression line to the data. A value of 1.00 indicates a perfect fit. In order to be used for quantitative purposes, r must be greater than or equal to 0.99 for analysis of organic compounds and 0.995 for analysis of inorganic compounds.

Limit(s) of Detection (LOD) [a.k.a., Method Detection Limit (MDL)]:

A laboratory's estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect in their facility. (TNI)

LOD Verification [a.k.a., MDL Verification]:

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

Limit(s) of Quantitation (LOQ) [a.k.a., Reporting Limit]:

The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence. (TNI)

Matrix Spike (spiked sample or fortified sample):

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

Matrix Spike Duplicate (spiked sample or fortified sample duplicate):

MS prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

Method Blank:

A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

Method Detection Limit:

The minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. (40 CFR Part 136, Appendix B)

Negative Control:

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

Non-conformance:

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

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

Proficiency Testing:

A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. (TNI)

Proficiency Testing Program:

The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results, and the collective demographics and results summary of all participating laboratories. (TNI)

Proficiency Testing Sample:

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

Quality Assurance:

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

Quality Assurance [Project] Plan:

A formal document describing the detailed QC procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EAP-QAD)

Quality Control:

The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions, and ensuring that the results are of acceptable quality. (TNI)

Quality Control Sample:

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

Quality Manual:

A document stating the management policies, objectives, principles, organizational structure, authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users. (TNI)

Quality System:

A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC activities. (TNI)

Quality System Matrix:

The component or substrate that contains the analyte of interest. For purposes of batch and QC requirement determinations, the following matrix distinctions shall be used:

- Aqueous: Any aqueous sample excluded from the definition of Drinking Water or Saline/Estuarine. Includes surface water, groundwater, effluents, and TCLP or other extracts.
- Drinking Water: Any aqueous sample that has been designated as a potable or potential potable water source.
- Saline/Estuarine: Any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

Non-aqueous Liquid: Any organic liquid with <15% settleable solids.

- *Biological Tissue:* Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.
- Solids: Includes soils, sediments, sludges, and other matrices with >15% settleable solids.
- Chemical Waste: A product or by-product of an industrial process that results in a matrix not previously defined.
- Air & Emissions: Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbant tube, impinger solution, filter, or other device. (TNI)

Range:

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

Raw Data:

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

Record Retention:

The systematic collection, indexing, and storing of documented information under secure conditions.

Reference Material:

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

Reference Standard:

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

Sampling:

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

Second-Order Polynomial Curve (Quadratic):

The second-order order curves are a mathematical calculation of a slightly curved line over two axes. The y-axis represents the instrument response (or Response ratio) of a standard or sample and the x-axis represents the concentration. The second-order regression will generate a coefficient of determination (r^2) that is a measure of the "goodness of fit" of the quadratic curvature of the data. A value of 1.00 indicates a perfect fit. In order to be used for quantitative purposes, r^2 must be greater than or equal to 0.99.

Selectivity:

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

Sensitivity:

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

Spike:

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

Standard:

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

Standard Operating Procedures:

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

Storage Blank:

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

Surrogate:

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

Surrogate compounds must be added to all samples, standards, and blanks, for all organic chromatography methods except when the matrix precludes its use or when a surrogate is not available. Poor surrogate recovery may indicate a problem with sample composition and shall be reported to the client whose sample produced poor recovery.

Systems Audit (also Technical Systems Audit):

A thorough, systematic, qualitative on-site assessment of the facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system. (EPA-QAD)

Technical Manager (or Technical Director):

A member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results.

Technology:

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

Traceability:

The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project. (TNI)

Trip Blank:

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

Uncertainty:

A parameter associated with the result of a measurement that characterizes the dispersion of the value that could reasonably be attributed to the measured value.

Acronyms:

A2LA – American Association for Laboratory Accreditation

AE - Account Executive

ANSI – American National Standards Institute

APLAC – Asia-Pacific Laboratory Accreditation Cooperation

ASQ - American Society for Quality

ASTM – American Society for Testing and Materials

CBI – Confidential Business Information

- CCV Continuing Calibration Verification
- CEO Chief Executive Officer
- CF Calibration Factor
- CFR Code of Federal Regulations

CHP – Chemical Hygiene Plan

- CIO Chief Information Officer
- COC Chain of Custody
- CQMP Corporate Quality Management Plan
- CRM Client Relations Manager
- CSO Client Service Organization
- DOC Demonstration of Capability
- DOT Department of Transportation
- DQO Data Quality Objectives
- DW Drinking Water
- ECO Ethics and Compliance Officer
- EDD Electronic Data Deliverable
- EHS Environmental Health and Safety

EPA-OSWER – Environmental Protection Agency–Office of Solid Waste and Emergency Response

EPA-QAD – Environmental Protection Agency–Quality Assurance Division

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FID – Flame Ionization Detector GC – Gas Chromatography GC/MS - Gas Chromatography/Mass Spectrometry GFAA – Graphite Furnace Atomic Absorption HPLC – High Performance Liquid Chromatography HVAC – Heating, Ventilation, and Air Conditioning ICAL – Initial Calibration iCAT - Incident/Complaint Activity Tracker ICP – Inductively Coupled Plasma Atomic Emission Spectroscopy ICP/MS – Inductively Coupled Plasma Mass Spectrometry ICV – Initial Calibration Verification **IDL** – Instrument Detection Limit IDOC – Initial Demonstration of Capability IEC – International Electrotechnical Commission ILAC – International Laboratory Accreditation Cooperation IR – Infrared ISO - International Standards Organization IT – Information Technology LCS – Laboratory Control Sample LCSD - Laboratory Control Sample Duplicate LIMS – Laboratory Information Management System LOD – Limit of Detection LOQ - Limit of Quantitation MDL – Method Detection Limit MDLV – Method Detection Limit Verification MRA - Mutual Recognition Arrangement MS – Matrix Spike MSD - Matrix Spike Duplicate NCM – Nonconformance Memo ND – Not Detected NELAC - National Environmental Laboratory Accreditation Conference NELAP – National Environmental Laboratory Accreditation Program NIST – National Institute of Standards and Technology NVLAP – National Voluntary Laboratory Accreditation OSHA – Occupational Safety and Health Administration PDF – Portable Document Format PID – Photo Ionization Detector PM - Project Manager PMA - Project Manager Assistant PT – Proficiency or Performance Testing QA/QC – Quality Assurance/Quality Control QAM – Quality Assurance Manual QAS – Quality Assurance Summaries QAPP – Quality Assurance Project Plan QIM – Quality Information Manager QL – Quantitation Limit QS - Quality System R&U - Read and Understand **RF** – Response Factor RFP - Request for Proposal **RL** – Reporting Limit **RPD** – Relative Percent Difference **RT** – Retention Time SAP – Sampling and Analysis Plan SDS – Safety Data Sheet SOP – Standard Operating Procedure

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TAT – Turnaround Time TCLP - Toxicity Characteristic Leaching Procedure TDS – Total Dissolved Solids TIC – Tentatively Identified Compound TNI – The NELAC Institute USDA – U.S. Department of Agriculture VOA – Volatile Organic Analytes VOC – Volatile Organic Compound VP – Vice-President VPO – Vice-President of Operations

Appendix 3.

Laboratory Certifications, Accreditations, Validations

TestAmerica Irvine maintains certifications, accreditations, and approvals with numerous state and national entities. Programs vary but may include on-site audits, reciprocal agreements with another entity, performance testing evaluations, review of the QAM, SOPs, MDLs, training records, etc. At the time of this QAM revision, the laboratory has accreditation/certification/licensing with the following organizations:

State	Agency	Program	License Number	Expiration Date
СА	ELAP	DW, WW, HW	2706	06/30/16
AK	DEC	DW	CA01531	06/30/16
AZ	DHS	DW, WW, HW	AZ0671	10/31/15
NV	DEP	DW, WW, HW	CA01531	07/31/16
н	DOH	DW		01/29/16
Northern Mariana Islands	DEQ	DW	MP0002	01/29/16
Guam	EPA	DW	15-001r	01/23/16
NM	DWB	DW	CA01531	01/29/16
OR	ORELAP	DW, WW, HW	4028	01/29/16
KS	KDHE	WW, HW	E-10420	07/31/16
WA	Dept Of Ecology	DW, WW, HW	C900	09/03/16
CA	County Sanitation District Los Angeles County	WW	10256	n/a
	USDA	Foreign Soil	P330-15-00184	07/08/18

CERTIFICATION / ACCREDITATION STATUS IRVINE LABORATORY (EPA ID CA01531)

The certificates and accredited parameter lists are available for each State/Program at www.testamericainc.com under Analytical Services Search – Certifications.

EQuIS Formats

Overview

The project will utilize EQuIS 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.

EQuIS 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 EQuIS sample loader file, butcontain information that is generally not provided to the laboratory. For consistency with theimport utility, these fields must remain in the EDD; however, population of these fields is notexpected.

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	Ν	Time of sample collection in 24-hr (military) HH:MM format.
10	sys_Joe_code	Text(20)	Ν	Sample collection location.
11	start_depth	Double	Ν	Beginning depth (top) of soil sample.
12	end_depth	Double	Ν	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(I5)	N	Chain of custody identifier. A single sample may be assigned to only one chain of custody. Ifthe 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_na mem	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)	Ν	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(I5)	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	qcJevel	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_rnoisture	i		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 theirsource (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)		Unique sample identifier. Each sample must havea 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		Date of sample analysis in MM/DD/YYYY format.
4	analysis_time	Text(5)		Time of sample analysis in 24-hr (military) HH:MM format.

Pos#	Field Name	Data Type	Required	Comments
5	Total_or_dissolved	Text (1)		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 theirsource (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#		Data Type	Required	Comments							
5	Total_or_dissolved	Text(1)	Y	of analysis. Valid values include: "T"=Total analysis; "D"=Dissolved or Filtered analysis;							
				"N"=constituents for which neither ¹¹ 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 uniqueidentifier.							
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_valu e	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/rnethod/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(I5)	Y	Units of measurement for the result.							
21	detection_limit_unit	Text(I5)	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(l4)	N	The concentration of the analyte in the original (unspiked) sample.							
25	qc_spike_added	Text(l4)	N	The concentration of the analyte added to the original sample.							

Pos#	Field Name	Data Type	Required	Comments							
26	qc_spike_rneasured	Text(l4)	N	The measured concentration of the analyte. Use zero for spiked compounds that were not detected in the sample.							
27	qc_spikerecovery	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_ cone	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_measur ed	Text(14)	N	The measured concentration of the analyte in the duplicate.							
31	qc_dup_spike_recover y	Text(14)	N	The duplicate percent recovery calculated as specified by the laboratory QC program. Report as							
32	qc_rpd	Text(8)	N	percentage value (e.g., report ⁰ 120%" 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 aspercentage 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 <i>was</i> 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 <i>was</i> within control limits. Use the "*" character to indicate failure, otherwise leave blank. Required for any duplicated sample.

Appendix B

Example Chain-of-Custody Forms



□ 3638 E. Sunset Rd., Ste. 100, Las Vegas, NV 89120 Phone: (702) 873-4478 Fax: (702) 873-7967 (EPA #: NV0930)

CHAIN-OF-CUSTODY-RECORD

(Project Work Order)

www.ssalabs.com

4587 Longley Lane, No 2, **Reno**, NV 89502 Phone: (775) 825-1127 Fax: (775) 825-1167 (EPA #: NV0931)

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Project or PO # or SSAL Client Job #: Payment Method: Quote #:							ΤÖ	Name: Phone:													
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Authorization is required to process samples. This obligates your organization for service fees. SSAL Standard T & C's or other written agreement applies. If collections or legal services are required to recover said fees. your organization will be responsible for all fees and costs in addition to service fees.			Note: Sa	mples are d	liscarded	30 days	after res	sults are	e report	ed. Sar	nples d	eemed	hazaro	dous are	e returne	ed to the	client up	pon completion of analysis.			

>>>	Select	a Laboi	ratory <<<
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Chain of Custody Record

#N/A

#N/Δ

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#N/A	

#N/A	Regu	latory Pro	ogram: [DW [NPDE	ES [RCRA		Other:									TestAmerica Labora	atories, Inc
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TestAmerica

THE LEADER IN ENVIRONMENTAL TESTING