Division of Waste Management and Radiation Control
Quality Assurance Program Plan

Revision 4
January 2023

Disclaimer

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A1. Approval Page

Kimberly D. Shelley, Executive Director
Utah Department of Environmental Quality

Kimberly Shelley
_____ Date: 02/13/2023

Douglas J. Hansen, Director
Division of Waste Management and Radiation Control

_____ Date: 02/13/2023

Stevie Norcross, PhD, Assistant Director
Division of Waste Management and Radiation Control

Stevie Norcross
_____ Date: 02/05/2023

Jalynn Knudsen, Assistant Director
Division of Waste Management and Radiation Control

Jalynn Knudsen
_____ Date: 02/09/2023

Deborah Ng, QA/QC Manager/Officer
Division of Waste Management and Radiation Control

Deborah Ng
_____ Date: 02/03/2023

Eleanor Divver, Quality Assurance Committee Coordinator
Utah Department of Environmental Quality

Eleanor Divver
_____ Date: 02/14/2023

A2. Table of Contents

List of Abbreviations and Acronyms

CFR	Code of Federal Regulations
CLP	Contract Laboratory Program
COC	Chain of Custody
DQO	Data Quality Objectives
DWMRC	Division of Waste Management and Radiation Control
EPA	Environmental Protection Agency
FD	Field Duplicate
HSWA	Hazardous and Solid Waste Amendments
LCS/LCSD	Laboratory Control Spike/Laboratory Control Spike Duplicate
LIMS	Laboratory Information Management System
MDL	Method Detection Limit
MS/MSD	Matrix Spike/Matrix Spike Duplicate
NELAP	National Environmental Laboratory Accreditation Program
NRC	Nuclear Regulatory Commission
OSHA	Occupational, Safety, and Health Administration
QA	Quality Assurance
QC	Quality Control
QAO	Quality Assurance Officer
QA/QC	Quality Assurance/Quality Control
QAPP	Quality Assurance Program Plan
QAPjP	Quality Assurance Project Plan
Qs	Quantity of Added Spike
Qss	Quantity of Analyte Found in the Spike Sample
Qus	Quantity of Analyte Found in the Unspoked Sample
QKC	Known Concentration of the Spiked LCS
QLCS	Quantity of Analyte Found in the Lab Spiked Sample
RCRA	Resource Conservation and Recovery Act
%R	Percent Recovery
RPD	Relative Percent Difference
RSD	Relative Standard Deviation
SAP	Sampling and Analysis Plan
UAC	Utah Administrative Code
UDEQ	Utah Department of Environmental Quality
UPHL	Utah Public Health Laboratory
UST	Underground Storage Tank

A3. Distribution List

The following is a distribution list of personnel that will receive a copy of the Quality Assurance Program Plan (QAPP). Individuals listed in the Distribution List will be updated annually, if applicable.

Kimberly D. Shelley, Executive Director
Utah Department of Environmental Quality

Douglas J. Hansen, Director
Division of Waste Management and Radiation Control

Stevie Norcross, PhD, Assistant Director
Division of Waste Management and Radiation Control

Jalynn Knudsen, Assistant Director
Division of Waste Management and Radiation Control

Deborah Ng, Hazardous Waste & Used Oil Program Manager/Quality Assurance Officer
Division of Waste Management and Radiation Control

Paige Walton, Corrective Action Program Manager
Division of Waste Management and Radiation Control

Brian Speer, Solid Waste Program Manager
Division of Waste Management and Radiation Control

Otis Willoughby, Low Level Radioactive Waste Program Manager
Division of Waste Management and Radiation Control

Phillip Goble, Radioactive Materials and Uranium Mill Program Manager
Division of Waste Management and Radiation Control

Tom Ball, Planning and Technical Support Program Manager
Division of Waste Management and Radiation Control

Eleanor Divver, Utah DEQ Quality Assurance Committee Coordinator
Utah Department of Environmental Quality

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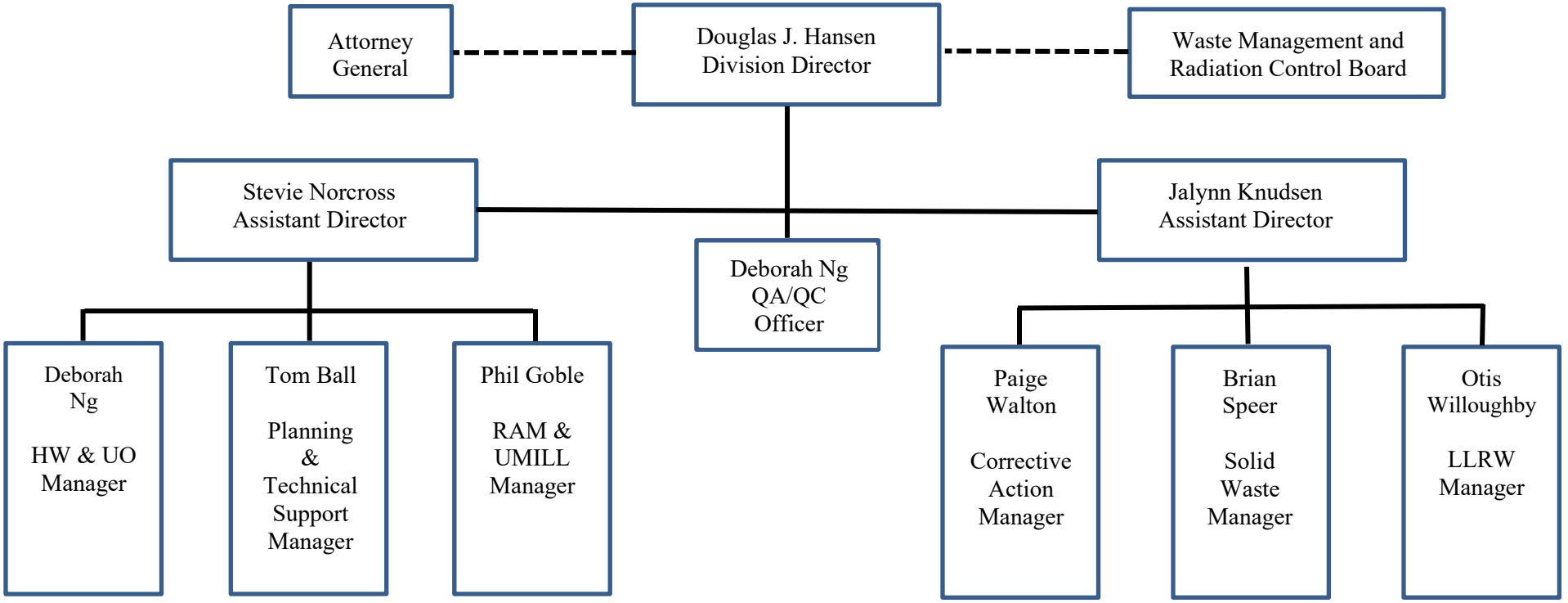
Figure 1 – DWMRC Organizational Chart



A4. Key Individuals and Responsibilities

The Division of Waste Management and Radiation Control (the Division) administers solid and hazardous waste, low level radioactive waste, and radioactive materials programs for the State of Utah. (See Figure 1). The Division Director is Douglas J. Hansen. The Executive Director of the Utah Department of Environmental Quality is Kimberly Shelley. The Division is a part of the Utah Department of Environmental Quality (UDEQ).

The Environmental Protection Agency (EPA) and Nuclear Regulatory Commission (NRC) oversee the Division's programs, and the EPA and NRC monitor and advise the Division on Quality Assurance (QA) issues.

The Utah Attorney General's office provides advice on legal issues for the Division's programs, including but not limited to contractual, enforcement, and policy matters.

The Utah Waste Management and Radiation Control Board (Board) is the statutory authority through which the Division administers the solid and hazardous waste and radioactive materials programs in the State of Utah.

The Division's QA/QC Plan officer (QAO) is responsible for generating, maintaining, and distributing the QAPP. The QAO reports directly to the Director and Assistant Directors regarding any issues that arise with the QAPP implementation. The QAO is independent of the entity generating the data.

A secure, current copy of the Division's QAPP will be maintained in the Division's Document Management System and on the Division's website by the Planning and Technical Support Section.

Division staff are assigned as project leads by Division program managers, as applicable. A Project Lead provides technical review of the sampling and analysis plan (SAP) and quality assurance project plan (QAPjP). Once approved, the Project Lead provides oversight of these plans.

The Division utilizes contractors for technical support when necessary. The contractor will review the Division's QAPP and the QAPjP's prior to starting a project.

The Utah Public Health Laboratory (UPHL) or a Utah-certified laboratory (UAC R444-14, Rules for Certification) performs sample analyses. Quality requirements for physical and chemical analyses performed by the UPHL are delineated in the UPHL, Environmental Chemistry Program Quality Manual (Appendix 3) or project SAP and QAPjP plan requirements.

Test procedures and methods performed by laboratories are described in:

1. Test Methods for Evaluating Solid Waste (SW-846), current edition.
2. Standard Methods for the Examination of Water and Wastewater, current edition.
3. Guidelines Establishing Test Procedures for the Analysis of Pollutants under the Clean Water Act.
4. Guidelines Establishing Test Procedures for the Analysis of Contaminates under the Safe Drinking Water Act.
5. RCRA Waste Sampling Draft Technical Guidance Planning, Implementation, and Assessment https://www.epa.gov/sites/default/files/2015-10/documents/rwsdtg_0.pdf
6. Other methods approved by the Director in accordance with the Utah Administrative Code (Rules).

The Division technical staff's focus is to review SAPs and QAPjPs provided by the regulated community to determine if they meet regulatory or risk requirements. The technical staff, including the Division's contractors, will verify that the minimum requirements of this QAPP have been met. The Division does not write project specific

plans, that is the responsibility of the regulated entity. The minimum quality requirements for all laboratory analyses are specified in this document. The quality requirements for sampling are specified in the Sampling Protocol and Chain-of-Custody Procedures provided in Appendix 1. Project Leads and technical staff, including contractors, review and implement the QAPjP. The QAO provides guidance to project leads for any issues that may arise during the plan development and throughout the project lifetime.

A5. Program Definition and Background

The Division is authorized by EPA to administer solid and hazardous waste regulatory programs. The Division is also authorized by the NRC to administer the radioactive materials program. The QAPP provides requirements for implementing SAPs, data management, and validation to ensure compliance with the Resource Conservation and Recovery Act (RCRA) and NRC compatible state regulations.

RCRA is the law governing the disposal of solid and hazardous waste. Congress passed RCRA on October 21, 1976. RCRA, which amended the Solid Waste Disposal Act of 1965, set national goals for:

- Protecting human health and the environment from the potential hazards of waste disposal.
- Conserving energy and natural resources.
- Reducing the amount of waste generated.
- Ensuring that wastes are managed in an environmentally and sound manner.

To achieve these goals, RCRA established three distinct, yet interrelated, programs:

1. The solid waste program is governed under RCRA Subtitle D, to develop comprehensive plans for managing nonhazardous industrial solid waste and municipal solid waste, sets criteria for municipal solid waste landfills and other solid waste disposal facilities, and to prohibit the open dumping of solid waste.
2. The hazardous waste program, under RCRA Subtitle C, establishes a system for controlling hazardous waste from the time it is generated until its ultimate disposal; in effect, from "cradle to grave".
3. The underground storage tank (UST) program is governed under RCRA Subtitle I to develop comprehensive plans for the management of underground storage tanks. This program is not regulated by the Division.

The first RCRA regulations, "Hazardous Waste and Consolidated Permit Regulations," published in the Federal Register on May 19, 1980 (45 FR 33066; May 19, 1980), established the basic "cradle to grave" approach to hazardous waste management that exists today.

Congress amended RCRA in November 1984 with the passing of the Federal Hazardous and Solid Waste Amendments (HSWA).

Utah's solid and hazardous waste programs are governed by Utah Administrative Code (UAC), the Solid and Hazardous Waste Act, the Used Oil Management Act, and the Waste Tire Recycling Act.

A6. Program Description

This QAPP has been prepared in accordance with EPA's Requirements for Quality Assurance Project Plans QA/R-5 (EPA, 2001), Guidance for Quality Assurance Project Plans QA/G-5 (EPA, 2002b), and Guidance on Systematic Planning Using the Data Quality Objectives Process QA/G-4 (EPA, 2006). This QAPP is designed to guide collection and chemical analysis of environmental media samples, including field Quality Assurance/Quality Control (QA/QC) samples to verify compliance of the regulated community.

A7. Data Quality Objectives and Criteria

The objective of the QAPP is to develop and implement procedures for field sampling, chain- of-custody, laboratory analyses and reporting that are technically and legally defensible. Specific procedures to be used for sampling, chain-of-custody, calibration, laboratory analyses, reporting, internal quality control, audits, preventative maintenance, and corrective actions are described in other sections of this QAPP. For example, the quality requirements for sampling are provided in Appendix 1, *Sampling Chain of Custody Procedures.*

Quality control measures are described in this section of the QAPP and are required to prevent, identify, and correct errors that may occur at any point in a process. The generated data is intended to support monitoring, investigation, and enforcement activities associated with regulated activities. Both physical and chemical analyses are performed.

The purpose of this section is to define goals for precision, accuracy, representativeness, completeness, comparability, and detection limit. The EPA's User's Guide to the Contract Laboratory Program, (EPA 540-R-08-01, June 2008 and EPA 540-R-04-004, October 2004, EPA 540-R-10-011, January 2010)) Organic and Inorganic Validation Functional Guidelines may be used for determining data usability.

This plan incorporates parts of the UPHL Quality Assurance Plan (Appendix 3) specific to solid and hazardous waste programs and groundwater monitoring. This plan provides guidance for l.) review of facilities' QAPjP and 2.) sampling activities performed by the Division's technical staff.

Specific sampling processes and data objectives will be detailed in the individual site's QAPjP.

Data Precision

Precision is defined as the degree of agreement among individual measurements made under prescribed conditions. Precision will use two different measurements depending on the number of data points being considered. Two data points will have the relative percent difference (RPD) calculated. Three or more data points will use the relative standard deviation (RSD) as a measure of the precision. External precision audits may be conducted by submitting blind duplicates to the laboratory and comparing the results with the acceptance criteria. The number of blind duplicates required will usually be 20 percent of all samples taken. Precision will be calculated for laboratory control spiked duplicates (LCSD1, LCSD2) and field duplicate samples (FD1, FD2) or the use of matrix spiked duplicates (MSD1, MSD2) using the following equations:

$$RPD = \{(X_1 - X_2) / [(X_1 + X_2)*0.5]\} \times 100$$

Where:
RPD = Relative Percent Difference
X_1 = Highest Analytical Sample Result
X_2 = Duplicate Analytical Sample Result

RSD = (standard deviation/average value) x 100
Where: RSD = Relative Standard Deviation

Calculation of the precision for each analysis will be based on different criteria as discussed in the project plan and the analytical methods. The default values for water and soil are < 20%, < 40%, respectively. Project specific requirements may vary due to other considerations.

Data Bias

Bias is a measure of systematic error. When a sample of known concentration is tested repeatedly, the bias is determined by how close the average test value is to the actual, known value.

Data Accuracy

Accuracy is the degree of agreement between a measurement and an accepted reference or true value. The accuracy is determined from analyses of samples spiked with a known concentration. The number of spiked samples and the spiking levels will be taken from the respective methods. A project specific matrix spike/matrix spike duplicates (MS/MSD) must be analyzed for every 20 samples of the same matrix.

The formula used to assess the accuracy of a laboratory control spike (LCS) is:

$$\%R = (QLCS/QKC) \times 100$$

Where:
%R = Percent Recovery
QLCS = Quantity of Analyte Found in the Lab Spike Sample
QKC = Known Concentration of the Spiked LCS

The formula used to assess the accuracy of the MS/MSD samples is:

$$\%R = ((Qss-Qus)/Qs) \times 100$$

Where:
%R = Percent Recovery
Qss = Quantity of Analyte Found in the Spike Sample
Qus= Quantity of Analyte Found in the Unspiked Sample
Qs = Quantity of Added Spike

Calculation of the accuracy for each analysis will be based on different criteria as discussed in the QAPjP and the analytical methods. The default values for water and soil are 75-125% and 60-140%, respectively. Project specific requirements may vary from the default values due to other considerations. The Division Project Lead will review if project goals and data quality have been met, if not, the Project Lead may discuss the impact to the data and if data is useable with the QAO.

Data Representativeness

Data representativeness is assessing the sample design to determine whether samples collected were representative of the environmental conditions and extent of physical boundaries of a universe or whole (e.g., waste pile, lagoon, groundwater). It is especially important to assess if the sampling design was based on judgmental sampling and not on statistical means. To assure representativeness, all samples should be taken following protocols as set forth in Standard Operating Procedures for field samplers, or other procedures approved by the Project Lead. Additionally, site descriptions, site photo documentation, sampling conditions and techniques should be documented in bound field notebooks.

Data Completeness

Completeness is defined as the amount of valid data obtained from a measurement system compared to the amount that is expected to be obtained. A goal of at least 95% completeness should be obtained.

Comparability

Comparability is a quantitative characteristic, which may be considered in planning sampling activities. The Project Lead should work closely with the Utah Public Health Laboratory or the Utah-certified laboratory to ensure all data generated are consistent with and expressed in the same units as the data generated by other laboratories reporting similar analyses. This will allow comparison of data among organizations.

Similarly, the Project Lead should work closely with the field team to ensure that all data generated by field measurements are expressed in units that are consistent with standard practices. In addition to units, comparability should be assured in terms of sampling plans, analytical methodology, quality control and data reporting.

Proper preservatives, appropriate containers, and holding times for samples and analyses are given in Appendix 2.

Unless specifically outlined in the project plan, all soil/solids/sludge data will be reported on a dry weight basis.

Sensitivity and Method Detection Limit

Sensitivity refers to the capability of a method or instrument to detect a given analyte at a given concentration and reliably quantitate the analyte at that concentration in a given matrix. Method detection limit (MDL) is defined as the minimum concentration of a substance 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.

Each project plan will specify the regulatory or site-specific requirements (e.g., risk levels) and the method sensitivity and MDL for each specific sample set. The method specified must meet or exceed the specified requirements or a new method must be selected for evaluation. Questions related to method sensitivity and MDL: Are the field and/or laboratory methods able to "see" or quantify project parameters of concern at or below the regulatory thresholds or the project action levels (e.g., risk levels)? Are the quality limits and MDLs low enough to answer the question(s) you are asking? How low can the method measure while still providing confidence in the results?

A8. Special Training/Certifications

Field personnel are required to obtain OSHA hazardous waste operations and emergency response (HAZWOPER) training per 29 CFR 1910.120. The initial 40-hour HAZWOPER training is performed offsite or virtually, while the Division provides the subsequent 8-hour refresher course annually, which includes inhouse, division specific training. Division managers ensure training and certifications are complete and up to date. Documentation of training is maintained by the individual and copies are provided to the Division's Managers. The official list is maintained by the Planning and Technical Support Manager in our document management system.

A9. Documentation and Records

The Division receives data packages from both our own sampling and analyses and from client projects to verify compliance with permit conditions or the Utah Administrative Code. Project leads ensure the documents are placed in the electronic document management system by submitting them to the Division staff member who oversees the electronic document management system. Documents will be maintained in facility specific files (hard copy) and electronically in the division document management system. The document management system is backed up nightly to a server in another county in Utah. Records are maintained in accordance with the Division's retention schedule.

The QAPP is maintained in the document management system as a Word document and in a protected pdf format. The pdf document is made available on the Division's website for use by Division staff and the public. The documents have restricted/protected rights for editing by the QAO and the Planning and Technical Support Manager, and other Division staff as needed only.

B1. Sampling Responsibility and Type

The Project Lead for each project will determine the nature and extent of sampling. Types of sampling include:

- Identification of waste streams to determine whether the waste is a listed or characteristic hazardous waste.
- Closure activities to determine whether facilities are properly closing the interim status/permitted units.
- Environmental samples to determine whether the environment has been contaminated because of a spill or other activity.
- Groundwater monitoring to ensure that facilities are monitoring the aquifer properly to detect any impact on the environment by their regulated units.
- Other projects include but are not limited to trial burns, Subpart X processes, and site assessments.
- Leachate sampling to determine potential contamination and closure status.

B2. Sampling Methods/Procedures

Sampling should be conducted following the protocol established in

- *A Guide for Field Samplers* (EPA Region VIII, 2004 or current version),
- Standard Operating Procedures for Hazardous Waste Streams (EPA Document 600/80-018), Sampler's Guide:
- Contract Laboratory Program Guidance for Field Samplers (EPA 540-R-014-13, October 2014),
- Standard Methods for the Examination of Water and Wastewater (22nd Edition December 16, 2013),
- RCRA Waste Sampling Draft Technical Guidance Planning, Implementation, and Assessment https://www.epa.gov/sites/default/files/2015-10/documents/rwsdtg_0.pdf, or other applicable guidance.

  Additional information on acceptable procedures is contained in the Division's document titled *Sampling and Chain-of-Custody Procedures/Form* (Appendix 1) and the Energy*Solutions'* Ground Water Quality Discharge Permit UGW450005, Appendix B Water Monitoring Quality Assurance Plan, 2014 which was prepared following the guidance in the RCRA Groundwater Monitoring Technical Enforcement Guidance Document (TEGD) (EPA, 1986 and EPA, 1992).

Few analyses will take place at the sampling site (e.g., pH). Most samples will be preserved if applicable and returned to the designated laboratory for analysis. If waste characterization is unknown or staff personnel are unfamiliar with processes that created the wastes to be sampled and/or determine there may be a safety problem with

sample preservation, then no sample preservation will occur, and a shorter holding time will be considered. The sample label will include notes on preservation (e.g., cold preservation, chemical, or that the sample has not been preserved).

Additional container, volume, and preservation requirements are in Appendix 2. Any problems that arise during sampling will be corrected on the spot by the Project Lead before sampling is completed.

All sample containers will be obtained from the laboratory a few days or less prior to sampling. The Project Lead will notify the laboratory of type(s) of samples to be collected, number of samples, analytes, methods, reporting/detection limit requirements, and any quality control samples required for the project. The Project Lead will also use the UPHL's Chain of Custody form for proper payment of testing, as applicable. The Project Lead will include their name and contact information to receive the test results.

B3. Sample Handling and Chain-of-Custody

The Division samplers may use either a legal chain-of-custody or sample tracking form to enable tracking the possession and handling of a sample during transfer (from sample collection through laboratory analysis and final disposal) so that the samples physical possession is known at all steps in the process. All samples should be cooled to 4°-6°C unless otherwise specified. If the samples could potentially be used in an enforcement action, a chain of custody form and protocol must be utilized. Use of the UPHL's Chain of Custody Form also ensures proper payment for the testing. The Division/UPHL Chain of Custody form is in Appendix 2. Disposal of samples is the laboratories responsibility. Any field waste shall be properly managed at the sampling site. Once samples have been analyzed, UPHL or the Utah certified laboratory shall properly dispose of the remaining materials.

A sample is under legal chain-of-custody if:

1. It is in the sampler or designated representative's possession, or
2. it is always in the sampler or designated representative's view, or
3. it is locked in a secure location.

The individual sample containers or the sample cooler will have a chain of custody tag over the seal of the container with the sampler's signature and date. A photo should be taken to document the seal. At the laboratory, samples are logged in and identified as either legal chain-of-custody or sample tracking samples. The laboratory will follow the sample handling procedure appropriate to the sample (e.g., chain-of-custody procedures).

Sampling containers, required preservatives, and holding times for inorganic and organic analysis are specified in Appendix 2

Sample Identification/Labels

Sample containers should always be labeled with a permanent marker with the sample identification (ID), date and time of collection, analysis to be performed, and sampler's name or initials prior to or upon sample collection. Sample labeling is required to chronicle all sample handling for collection or creation through analysis and/or disposal.

Sample ID designation will consist of a series of letters and numbers to indicate the unique ID, which will include a sequential 3-digit number starting at -001 for the first sample collected and continue thereafter until the last sample. No samples will have the same unique ID designation. If more than one field team is simultaneously deployed, each team should be provided a block of unique IDs so that sample IDs are not duplicated. All duplicate samples will have the same sample ID (including the unique ID) as the corresponding assessment sample followed by a "-D" unless it is a blind

duplicate. If the sample duplicate is a blind duplicate for the laboratory, it will receive a new unique ID number and be tracked by the project lead.

B4. Analytical Methods/Procedures

In accordance with R444-14 of the Utah Administrative Code, a Utah certified laboratory will be used to provide an analytical data package for compliance with the Utah Solid and Hazardous Waste Rules. The Utah Public Health Lab (UPHL) is certified by the EPA. (Appendix 3). When reviewing project specific plans, the Project Lead will ensure a Utah Certified Laboratory is specified for methods that will be used for that project. Analytical method selection for samples will be based on whether the method provides comparable, representative, complete, precise, and sufficient detection limits, and accurate data for the sample matrix and the range of expected values for the constituents for which the samples are being analyzed. EPA and American Society for Testing and Materials (ASTM) analytical methods will be used for analyses when available. Laboratory reporting limits must be lower than regulatory and risk assessment limits. If EPA or ASTM does not have a method for analysis that can detect at or below the regulatory or risk limit, then the Project Lead can request a copy of the standard operating procedure and validation package for an equivalent or better method for Division approval for each specific project matrix.

If the Division splits samples with the facility/site, the same methods specified in the project specific plans will be utilized by the Division. However, the Project Lead will use a different Utah certified laboratory than the site uses for the analysis.

B5. Internal Division Quality Control Procedures

Field quality control samples will be submitted to the laboratory as appropriate and as often as practical during field investigations. Such quality control check samples may consist of:

1. One or more “blind” duplicate samples;
2. one or more field blanks;
3. one or more duplicate samples, or
4. spiked" samples prepared with known amounts of constituents or standard reference samples.

Division Project Leads will determine sampling source(s), parameters to be audited and the appropriate field quality control samples. Field quality control samples will be collected or prepared in accordance with EPA approved procedures or approved Division procedures (e.g., chemical agent procedures).

Quality control samples, as identified above, may be collected or prepared for each sample event. The Division Project Lead will determine the number and type of quality control samples to be collected prior to going to the field. The quality control samples will be handled in the same manner as all other samples being analyzed for the same parameter. Sample identification labeling will be consistent with the identification of actual samples.

Project records concerning quality control check samples and results of their analyses will be maintained by the Division in either electronic format or paper copy per the retention schedule specified at http://www.archives.state.ut.us/

B6. Instrument/Equipment Testing, Inspection, and Maintenance

The Division utilizes specific radiation equipment for field screening. These instruments are calibrated per the manufacturer or based on usage requirements both internally or externally.

B7. Calibration Procedures and Frequency

Laboratory equipment calibration procedures will be in accordance with the method and manufacturer specification. Any equipment used for field measurements will be calibrated according to manufacturer's specifications prior to use. Documentation of the calibration is required. The Project Lead will maintain documentation on all field equipment calibrations. The laboratory will maintain their calibrations and maintenance documents. Any problems associated with field equipment, will be identified, the Project Lead will be notified, and the Project Lead will implement a corrective action.

B8. Inspection/Acceptance of Supplies and Consumables and Preventative Maintenance

The Project Lead will assess field equipment for proper operation and maintenance prior to use. Records of performed preventive maintenance of the equipment will be maintained in a logbook with the equipment.

Any instrument consumables, including spare parts, will be approved for purchase through the Division Director. These items will be stored in the Division Secured Storage location on the first floor or at the Technical Support Building. Any required sample containers will be obtained from the UPHL or Utah Certified laboratory prior to field sampling. The laboratory will maintain cleanliness records of sample containers.

All contractors working for the Division will be responsible for preventative maintenance of their own equipment.

Preventive maintenance procedures for laboratory equipment are the responsibility of the laboratory.

B9. Non-Direct Data Measurements and Management

EPA approved/validated models will be used for risk assessments, groundwater, etc. and will be outlined in project specific plans.

B10. Data Management

Data summaries will be placed in the facilities' file folders by the Project Leads and into the Division’s current electronic database (e.g., Documentum). The database is backed up nightly.

Data Usage

Data collected, analyzed, and validated is used to support the Division's waste management programs. The Project Lead reviews sampling and analytical data submitted to the Division to meet the project goals and objectives. If questions arise, the Project Lead will consult with the Division’s QAO to resolve the issue appropriately.

C1. Data Assessment Procedures

Data quality will be evaluated using the precision, accuracy, representativeness, and completeness criteria specific to each project plan or use the default criteria found in this plan. The Project Lead will evaluate field quality control sample results and analytical results provided by the Utah Public Health Laboratory or other Utah-certified laboratories in accordance with R444-14 to determine if project goals were achieved. All reports will be assessed by the Project Lead to verify project objectives were met.

If the quality control samples meet the project's criteria, the reported data will be accepted. If not, the laboratory will be consulted to determine what laboratory quality control/quality assurance samples were included with the sample batch. These samples will be included with the field set and reevaluated. If the combined set meets the acceptance criteria, the reported data may be accepted. If not, the data from analyzing the sample set may be used as a basis for a data corrective action referral.

Corrective Action Procedures

If a quality control audit results in detection of unacceptable conditions or data, as defined by the criteria presented above, the Project Lead will be responsible for developing and initiating corrective action. If the unacceptable conditions indicate a program difficulty or if corrective action is likely to require expertise not immediately available to the project team, the Project Lead will be notified the QAO or Division Management. Corrective action may include:

1. Re-analysis of the sample batch.
2. Re-sampling and analysis.
3. Evaluation and amendment of sampling and analytical procedures.
4. Acceptance of data, with an acknowledgement of the level of uncertainty surrounding the analytical results.

C2. Reports to Management – Performance and System Audits of Regulated Entities

Division Performance and System Audits

The Division periodically monitors and audits the regulated facilities' QA procedures to ensure that all project activities are performed in accordance with approved quality assurance procedures. Laboratory and system audits may be conducted, including systems performance audits. System audits will be conducted prior to the start of sampling episodes to determine if the system spelled out in the site-specific quality assurance project plan and sampling plan is adequate to produce quality data.

Laboratory Performance and System Audits

The EPA subjects the Utah Public Health Laboratory to audits. External performance audits, internal performance audits, and system audits are employed by the Utah Public Health Laboratory to ensure the reliability and quality of data. The UPHL participates in the EPA’s Proficiency Testing Program also.

Quality Control Reports

A separate Division QC report is not required for the field sampling programs. Site-specific QA/QC information will be included in the Division facility files.

D1. Data Analysis, Validation, and Reporting

The primary data analysis, validation, and reporting is performed by the Utah Public Health Laboratory or the Utah-certified laboratory. Data is stored on site per the Utah Division of Archives and Records Service Retention Schedule. Internal validation is performed by the Division or by the Division's contractor. Upon completion of the sample analyses, the laboratory will submit the results to the Project Lead or QA officer for review. Laboratory reports will be filed in the Division's facility files or the Division's current electronic database. Other Utah certified laboratories will retain the sample analysis records according to UAC R444-14.

Laboratory Analysis, Validation, and Reporting

Each laboratory analyst will ascertain if the analytical data are within prescribed control limits before the data is entered into the Laboratory Information Management System (LIMS). Data is then reviewed for quality assessment by the laboratory.

At least 25% of all final analytical data will be cross-checked before the results are forwarded by the laboratory to the Division. Certified analytical data will be reported on standard report forms in both hard and searchable electronic format. Data will be reviewed by the Project Lead/QAO to verify it meets the project specific requirements, e.g., detection limits. Any data outside the project objectives will be reviewed by both the Project Lead and QAO for determination of acceptability for the project.

The reporting limit submitted by the laboratory must be below the regulatory or project specific limits or the data must be flagged to determine its useability or rejected.

D2. Verification and Validation Methods

The UPHL ((Attachment 3) and Utah Certified Laboratory's internal quality control procedures must meet EPA guidelines and National Environmental Laboratory Accreditation Program (NELAP) specifications. Internal quality control procedures include the use of duplicate analyses, spikes, calibration standards, internal standard, blanks, quality control charts, standard reference materials, reagent checks, and sample splits as described in the UPHL Quality Assurance Plan. Laboratories other than the UPHL must be Utah-certified for all parameters being reported. A Utah certified laboratory must also meet NELAP requirements.

The Project Lead is responsible for ensuring field information such as chain-of-custody forms and sample logs are accurate, and that the data package received from the laboratory meets the project objectives specified in the QAPjP. Any anomalies will be discussed with the laboratory's QAO and the Division QAO for resolution.

D3. Reconciliation with User Requirements

Any data not meeting the required Data Quality Objectives (DQOs) will be discussed with the laboratory and client and usability of the data will be determined for each project. Any qualified data will be discussed in the case narrative for project management.

References

Test Methods for Evaluating Solid Waste (SW-846, current revisions.), EPA Federal Register and online https://www.epa.gov/hw-sw846/sw-846-compendium

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United States Environmental Protection Agency, et al.,1997. Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM), Revision 1, EPA 402-R-97-016. Washington, LoD.C. August 2000 p. 4-34.

United States Environmental Protection Agency, 2020. USEPA Contract Laboratory Program National Functional Guidelines for Inorganic Data Review, EPA 542-R-20-006. Washington, D.C. November 2020

United States Environmental Protection Agency, 2020. USEPA Contract Laboratory Program National Functional Guidelines for Organic Data Review, EPA 540-R-20-005, Washington, D.C. November 202

Sampler's Guide, Contract Laboratory Program Guidance for Field Samplers, OSWER 9200.2-147, EPA -540-R-014-013, October 2014

Appendix 1 Division Sampling and Chain-of-Custody Procedures

The following are the procedures and protocols for management of sample integrity for solid and hazardous waste samples and mixed waste samples.

Safety Protection Protocols

The Project Lead will evaluate the personal protection and safety equipment to be used.

Pre-Sampling Procedures

The Project Lead will review existing information, including existing investigation files (permits, etc.), reports of previous inspections (Federal, State, etc.), correspondence files and personal communication. Care should be taken to assure that files and one-of-a-kind reports are not misplaced or inadvertently destroyed. Removal of items from the office is highly discouraged. If material is to be taken into the field, copies should be made.

Proposed Sampling Locations

The Project Lead will prepare a list of the proposed samples to be taken, sampling locations, and sample analyses to be performed. In deciding the number of samples to be taken, scheduling coordination should be conducted with the QAO and Utah Certified Contract Lab. This is to assure that the laboratory will be prepared to handle the incoming samples.

Containers and Forms

Once the number, types of samples and parameters to be analyzed are determined, the laboratory will be contacted and informed of the proposed sampling program. The laboratory will ensure that capabilities are available to complete the required work within the appropriate holding times. If the laboratory can complete the proposed work, the Project Lead will inform the laboratory of the necessary supplies needed, including:

1. Types of sample containers with preservative (if necessary) and volumes of samples to be collected. Sample containers will be prepared in accordance with the method requirements and required quality control samples needed (e.g., MS/MSD, duplicates).
2. Sample analysis request forms.
3. Sample tracking or chain-of-custody forms.
4. Sample seals and sample labels, if applicable.
5. Trip blanks, if applicable.
6. Ice chests and ice packs, if applicable.

It is recommended that extra containers and sample request forms be taken to the sampling site. This will ensure that the job will be accomplished if breakage occurs, or conditions dictate that more samples need to be taken.

Sampling Equipment Provision

The Project Lead will gather the sampling equipment. Examples of appropriate sampling equipment are contained in Table 1. Appropriate support items, such as maps, GIS markers and stakes, will be collected as needed.

Decontamination Supplies

The Project Lead will specify decontamination procedures and supplies or will use disposable equipment. Containers for the disposal of waste generated as a result of the sampling will also be supplied and properly disposed of.

Chain-of-Custody Procedures

Each person involved in the collection and the handling of samples will know chain-of- custody procedures. Samples collected may be introduced as documentation or evidence into legal proceedings. Chain-of-custody sample integrity will need to be maintained and the possession of samples be traceable from the time samples are collected until results are obtained from the lab. Chain-of-custody starts when the sampling team accepts the sampling containers. Sampling containers should be always kept in a secure manner or in the sampler's possession. The Project Lead is responsible for coordinating the chain-of-custody.

Sample Tracking Procedures

When chain-of-custody is not required, the Project Lead will follow the sample tracking procedure. At a minimum, this procedure will include:

1. Sample Identification (e.g., Division sample number).
2. Sample description (e.g., location and depth, if applicable).
3. Sample date and time.
4. Sample matrix (e.g., air, water etc.).
5. Sampler and Division employee if not sampler.
6. Analytes requested methods and special instructions if needed.
7. Contact information.

Field Sampling Procedures

The following table lists procedures which may be used in the collection of field samples.

Table 1 – Field Sample Collection Procedures

Sampling Point **Waste Type**	Drum	Sack & bags	Open Bed Truck	Closed Bed Truck	Storage Tanks or bins	Waste Piles	Ponds, Lagoons, & pits	Conveyor Belt	Pipe
Free flowing liquids & slurries	COLIWASA	N/A	N/A	COLIWASA	Weighted bottle	N/A	Dipper	N/A	Dipper
Sludges	Trier (Spoon)	Trier (Spoon)	Trier (Spoon)	Trier	Trier	N/A	NA	N/A	N/A
Moist Powders or Granules	Trier (Spoon)	Trier (Spoon)	Trier (Spoon)	Trier	Trier	Trier	Trier (Bucket*)	Shovel	
Dry Powders or Granules	Trier (Spoon)	Trier (Spoon)	Trier	Trier	Trier	Trier (spoon)	Trier (Bucket*)	Shovel	
Sand or packed powders & granules	Auger (Spoon)	Auger (Spoon)	Auger (Spoon)	Auger	NA	NA	NA	N/A	
Large grained solids	Large Trier spoon	Large Trier spoon	Large Trier spoon	Large Trier	Large Trier	Large Trier	Large Trier	Large Trier	Large Trier

Note: Quality control samples will need to be collected as called for in the Quality Assurance Project Plan (QAPjP). The Project Lead will ensure that the QAPjP is followed. Field preservation and filtering requirements should be met per the methods. A composite sample collected in the field will be mixed and placed in sample containers. Incremental sampling must be coordinated with the designated laboratory.

Sample Seals

The following procedures apply to sample seals if chain-of-custody is required:

1. The sample seals are to be completed for each sample or the entire ice chest and include the Sample Number, date and collector's signature.
2. A sample seal will be placed over the top or around the "neck" of each sample container used. The seal should be around or over the lid of the container. The seal ensures the integrity of the sample. The laboratory analyst will break the seal before analyzing the material collected.

The sample seals do not have to be used on each sample container if the samples remain in the custody of the sampler and are delivered directly to the laboratory by the sampler. One seal can be used to seal the ice chest for the trip to the laboratory. The seal should not be broken until the laboratory representative, qualified to accept chain-of-custody samples, accepts them.

Sample Tracking Forms

When samples are collected, the appropriate sample tracking forms will need to be completed. The sample tracking forms may be obtained from the laboratory. Samplers will need to notify the Division liaison prior to sampling.

Sample Identification

Sample identification is performed for every sample collected. There are two main purposes for collecting samples: 1) confirmation/environmental samples and 2) chain-of-custody samples as physical evidence from a facility or from the environment for enforcement investigations. To accomplish this, the following sample identification and chain-of-custody procedures have been established.

The method of identification of a sample depends on the type of measurement or analysis performed. When on-site measurements are made, the data are recorded directly in field logbooks, with identifying information. Samples are identified with a unique sample label. Field analysis, such as pH, are document in a field logbook. The information on the sample label includes, as applicable:

1. Field identifier
2. Date
3. Time
4. Sample location
5. Name of Sampler
6. Type of sample
7. Preservatives
8. Methods

Cleaning of Equipment

At each specific sampling point, the team should:

1. Use new or cleaned equipment, new disposable equipment is highly recommended.
2. Clean the sample equipment either in the field or laboratory, prior to use or re-use. This may be verified using "rinseate blanks." These will be collected at a minimum rate of one blank per 20 samples. The sampling team should check with the Project Lead before leaving to determine an acceptable method of "field cleaning" for the equipment to be used. Single use disposable equipment does not need to be cleaned prior to use.

Transporting Samples

The samples shall be transported either by sample personnel or by a commercial carrier with tracking ability, e.g., UPS, FEDEX to the designated laboratory.

Completion of the Sampling Event

The following are items to consider prior to leaving the sampling location:

1. Verify the number of samples taken.
2. Match the physical samples with the paperwork. The team should check for proper samples in the correct containers and that the field sample numbers on the samples correspond with the numbers on the sample request form.
3. Verify the samples are properly preserved, if applicable.
4. Clean and package all non-disposable equipment.
5. Verify time/date on sample tag, request forms.
6. Bag all disposable items that need to be discarded.
7. Ensure that all sample containers are free of any debris or residue on the outside of the container.
8. If necessary, leave a spilt sample with the facility and a receipt for samples collected.
9. Place samples in cooler with ice packs or ice.

Laboratory Check-In

During normal business hours, the following procedures apply:

1. Notify the laboratory that the sampling team is delivering samples.
2. Check in with sample receiving.

3. Verify samples are received by a chain-of-custody technician if applicable.
4. Present all sample request forms to the laboratory receiving personnel.
5. Verify samples and provide laboratory sample numbers on the forms.
6. Document personnel/location where laboratory results are sent.
7. Provide copy of the chain-of custody/sample request forms to the sampling team leader after all pertinent information is completed and signed by the laboratory personnel.
8. After-hour check-in is unavailable unless prior arrangements with laboratory personnel. If laboratory personnel are not available, then the sample team lead will keep custody of samples and place them in the Division sample refrigerator overnight located in Technical Support Building DWMRC Sample Refrigerator. An ice chest seal will be placed on the chest and place into the refrigerator. Samples will be delivered the next business day. Sampling should be scheduled to minimize storage at the Division.

Completion of Laboratory Analysis

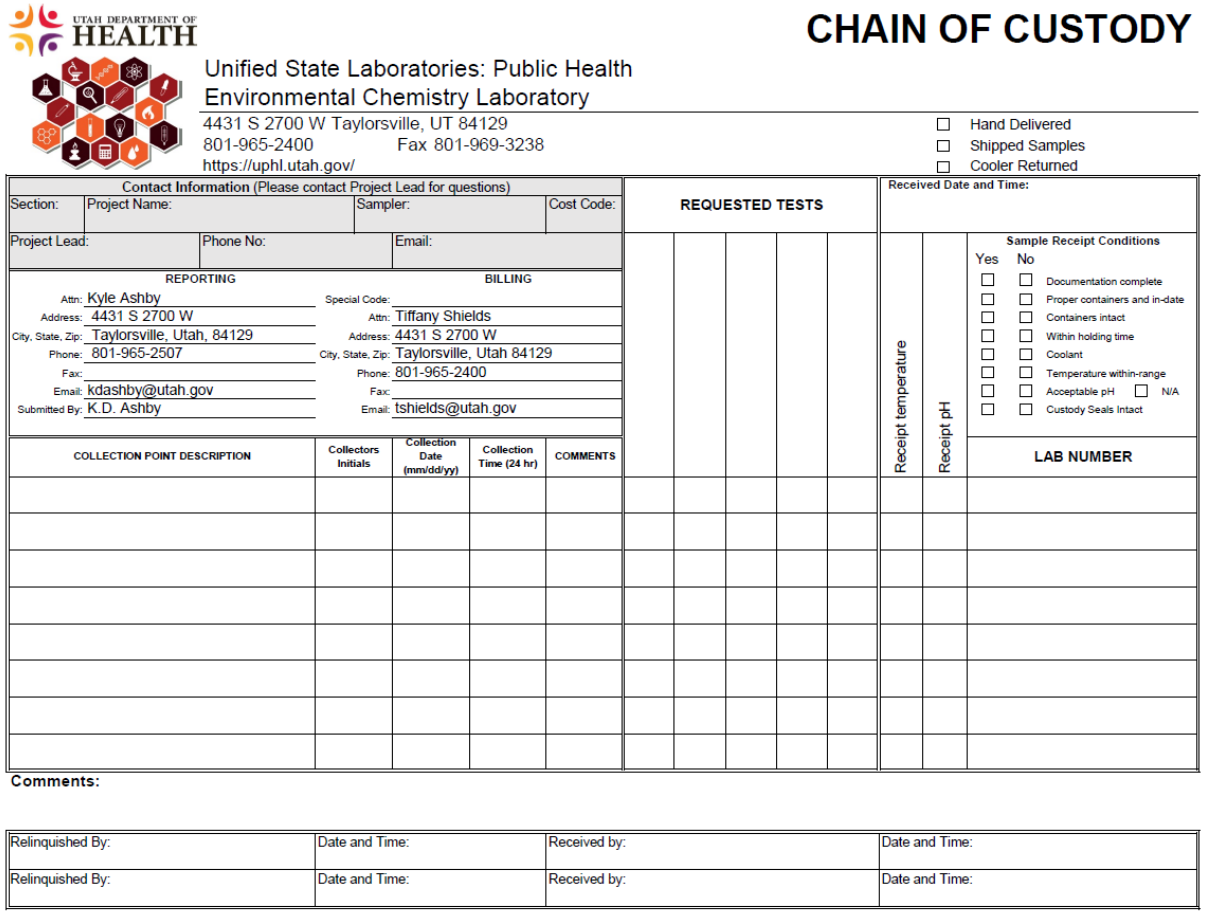
Upon completion of the sample analyses, the laboratory will submit the results to the Project Lead for review. All laboratory reports will be filed in the Division facility file.

The laboratory will retain the sample records according to UAC R444.

After sample results are accepted, the remaining sample(s) will either be disposed by the laboratory or given back to the sample team for final disposition.

UPHL Chain of Custody Form

UPHL's Chain of Custody Form can be found here: [Chain of Custody Sample Tracking Form DEQ]



UTAH DEPARTMENT OF HEALTH

CHAIN OF CUSTODY

Unified State Laboratories: Public Health
Environmental Chemistry Laboratory
4431 S 2700 W Taylorsville, UT 84129
801-965-2400 Fax 801-969-3238
https://uphl.utah.gov/

☐ Hand Delivered
☐ Shipped Samples
☐ Cooler Returned

Contact Information (Please contact Project Lead for questions)

Section:	Project Name:	Sampler:	Cost Code:
Project Lead:	Phone No:	Email:	

REPORTING

Attn: Kyle Ashby
Address: 4431 S 2700 W
City, State, Zip: Taylorsville, Utah, 84129
Phone: 801-965-2507
Fax:
Email: kdashby@utah.gov
Submitted By: K.D. Ashby

BILLING

Special Code:
Attn: Tiffany Shields
Address: 4431 S 2700 W
City, State, Zip: Taylorsville, Utah 84129
Phone: 801-965-2400
Fax:
Email: tshields@utah.gov

REQUESTED TESTS

Received Date and Time:

Receipt temperature | Receipt pH

Sample Receipt Conditions

Yes	No	
☐	☐	Documentation complete
☐	☐	Proper containers and in-date
☐	☐	Containers intact
☐	☐	Within holding time
☐	☐	Coolant
☐	☐	Temperature within-range
☐	☐	Acceptable pH ☐ N/A
☐	☐	Custody Seals Intact

COLLECTION POINT DESCRIPTION	Collectors Initials	Collection Date (mm/dd/yy)	Collection Time (24 hr)	COMMENTS	LAB NUMBER

Comments:

Relinquished By:	Date and Time:	Received by:	Date and Time:
Relinquished By:	Date and Time:	Received by:	Date and Time:

Appendix 2 Sample Container Types, Volumes, Preservation and Holding Time Requirements

MATERIALS FOR USE IN SAMPLE COLLECTION FOR
INORGANIC
ANALYTE DETERMINATIONS

Analyte	Recommended Container Material
Metals	PTFE, plastic, glass
Chloride	PTFE, plastic, glass
Cyanide	PTFE, plastic
Fluoride	PTFE, plastic
Nitrate	PTFE, plastic, glass
pH	PTFE, plastic, glass
Specific Conductance	PTFE, plastic, glass
Sulfate	PTFE, plastic, glass
Sulfide	PTFE, plastic, glass

[a]These recommendations are intended as guidance only and not inclusive of all possible analytes and materials. The selection of sample container should be made based on the nature of the sample, the intended end use of the data and the project data quality objectives.

RECOMMENDED SAMPLE HOLDING TIMES, PRESERVATION, COLLECTION QUANTITIES, AND DIGESTION VOLUMES/MASS FOR SELECTED

INORGANIC ANALYTE DETERMINATIONS IN AQUEOUS AND SOLID SAMPLES [a,b]

Analyte	Matrix	Fraction	Minimum Collection Volume/Mass	Preservation[1]	Digestion Volume	Holding Time[2]
Metals (except Hg and Cr^{6+})	Aqueous	Total/total recoverable	600 mL	HNO3 to pH<2	100 mL	6 months
		Dissolved	600 mL	Filter on site; HNO3 to pH<2	100 mL	6 months
		Suspended	600 mL	Filter on site;	100 mL	6 months
	Solid	Total	200 g	None	2 g	6 months
Hexavalent chromium	Aqueous		400 mL	≤6 °C	100 mL	24 hours
	Solid		100 g	≤6 °C		30 days to extraction
				≤6 °C	2.5 g	7 days from extraction to analysis
Mercury	Aqueous	Total	400 mL	HNO3 to pH<2	100 mL	28 days
		Dissolved	400 mL	Filter; HNO3 to pH<2	100 mL	28 days
	Solid	Total	200 g	≤6 °C	0.2 g	28 days
	Solid	Species	200 g	≤6 °C	0.2 g	5 days
Chloride	Aqueous		50 mL	≤6 °C	□	28 days
Cyanide	Aqueous		500 mL	≤6 °C; NaOH to pH>12	□	14 days
	Solid		100 g	≤6 °C	□	14 days
Fluoride	Aqueous		300 mL	≤6 °C	□	28 days
Nitrate	Aqueous		1000 mL	≤6 °C	□	28 days
Hexane Extractable Material (HEM; Oil & Grease)	Aqueous		1000 mL	≤6 °C HCl or H2SO4 to pH <2	□	28 days
	Solid		100 g	≤6 °C HCl or H2SO4 to pH <2		28 days when practical

RECOMMENDED SAMPLE HOLDING TIMES, PRESERVATION, COLLECTION QUANTITIES, AND DIGESTION VOLUMES/MASS FOR SELECTED

INORGANIC ANALYTE DETERMINATIONS IN AQUEOUS AND SOLID SAMPLES [a,b]

Analyte	Matrix	Fraction	Minimum Collection Volume/Mass	Preservation[1]	Digestion Volume	Holding Time[2]
pH	Aqueous		25 mL	NA	□	Analyze immediately
	Solid		20 g	NA	□	Analyze immediately
Specific Conductance	Aqueous		100 mL	NA	□	Analyze immediately
Sulfate	Aqueous		50 mL	≤6 °C	□	28 days
Sulfide	Aqueous		100 mL	4 drops 2N zinc acetate/100 mL sample; NaOH to pH>9;	□	7 days
	Solid		100 g	Minimize aeration; Store headspace free at ≤6 °C Fill sample surface with 2N zinc acetate until moistened; Store headspace free at ≤6 °C	□	7 days
Organic Carbon, Total (TOC)	Aqueous		200 mL	≤6 °C store in dark HCl or H_2SO_4 to pH <2;	□	28 days
	Solid		100 g	≤6 °C	□	28 days

[a] These recommendations are intended as guidance only. The selection of sample and digestion volumes/mass and preservation and holding times should be made based on the nature of the sample, the intended end use of the data and the data quality objectives.

[b] Additional sample quantities may need to be collected in order to allow for the preparation and analysis of QC samples, such as matrix spikes and duplicates.

[1] The exact sample extract, and standard storage temperature should be based on project-specific requirements and/or manufacturer's recommendations for standards. Alternative temperatures may be appropriate based on demonstrated analyte stability within a matrix, provided the data quality objectives for a specific project are still attainable.

[2] A longer holding time may be appropriate if it can be demonstrated that the reported analyte concentrations are not adversely affected by preservation, storage and analyses performed outside the recommended holding times.

Appendix 3 Utah Public Health Laboratory Quality Assurance Manual/Plan

Utah Department of Health
Public Health Laboratory (UPHL)
Environmental Chemistry Program (ECP)

Title: **Quality Manual**

SOP #: Lab QAP 0033 **Revision #:** 4 **Effective Date:** 11/27/2020

Written/Updated by: Alia Rauf
Reviewed Date: 11/18/2020
Original Source Documents: N/A

Testing Matrix: N/A

Approved by:

Eleanor Ojinnaka / EA
Chief Scientist (Print/Sign)

11/27/2020
Date

A. Polsworth / A. Rohrwasser
Laboratory Director/Interim Director of Operations (Print/Sign)

11/27/2020
Date

QUALITY MANUAL

For

Utah Public Health Laboratory

4431 S. Constitution Blvd (2700 West)
Taylorsville UT 84129-8600

Phone: (801) 965-2400

FAX: (801) 965-2486

Website Address: http://health.utah.gov/lab/

Name	Function (Unit)
Andreas Rohrwasser, PhD, MBA	Laboratory Director
Eleanor Ojinnaka	Chief Chemist
Alia Rauf	Quality Assurance Manager

Revision Number:	4	Effective Date:	January 2020

Section 2
Table of Contents

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Section 3
INTRODUCTION AND SCOPE

The purpose of this *Quality Manual* is to outline the management system for the Utah Public Health Laboratory—Environmental Chemistry Program. The *Quality Manual* defines the policies, procedures, and documentation that ensure analytical services continually meet a defined standard of quality designed to provide clients with data of known and documented quality and, where applicable, demonstrate regulatory compliance.

The *Quality Manual* sets the standard under which all laboratory operations are performed, including the laboratory's organization, objectives, and operating philosophy. The *Quality Manual* has been prepared to assure compliance with the 2009 TNI Environmental Laboratory Sector Standard – Volume 1 **–** Management and Technical Requirements for Laboratories Performing Environmental Analysis (EL-V1-M1 through M7-ISO-2009). This Standard is consistent with ISO/IEC 17025:2005 requirements that are relevant to the scope of environmental testing services, and thus, the laboratory operates a quality system in conformance with ISO/IEC 17025:2005(E).

The policies and procedures outlined are compliant with the various accreditation and certification programs listed in Appendix G. Also, the Quality Manual has been prepared for consistency with EPA's Certification Manual for Drinking Water methods and TNI standard

3.1 Scope of Testing

The laboratory's scope of analytical testing services includes those listed in Appendix H for the methods list SOP list Doc # 0005 Appendix A

3.2 Table of Contents, References, and Appendices

The Table of Contents is located in Section 2 and Appendices.

3.3 Glossary and Acronyms Used

Quality control terms are generally defined within the Section that describe the activity.

3.3.1 Glossary

The *Terms and Definitions* Section of Modules 1-7 in the 2009 TNI Environmental Laboratory Sector Standard – Volume 1 – Management and Technical Requirements for Laboratories Performing Environmental Analysis.

3.3.1.1 **The TNI Standard:** Modules 1-7 in the 2009 TNI Environmental Laboratory Sector Standard – Volume 1 – Management and Technical Requirements for Laboratories Performing Environmental Analysis (EL-V1, M1 through M7, ISO-2009).

3.3.2 Acronyms

Acronyms used in this document and their definitions include:

AB – Accrediting Body
ANSI – American National Standards Institute

ASQC	–	American Society for Quality Control
ASTM	–	American Society for Testing and Materials
Blk	–	Blank
°C	–	degrees Celsius
cal	–	calibration
CAS	–	Chemical Abstract Service
CCV	–	Continuing Calibration Verification
COC	–	Chain Of Custody
DO	–	Dissolved Oxygen
DOC	–	Demonstration Of Capability
EPA	–	Environmental Protection Agency
g/L	–	grams per liter
GC/MS	–	Gas Chromatography/ Mass Spectrometry
ICP-MS	–	Inductively Coupled Plasma-Mass Spectrometry
ICV	–	Initial Calibration Verification
ISO/IEC	–	International Organization for Standardization/International Electrochemical Commission
lb/in2	–	pound per square inch
LCS	–	Laboratory Control Sample
LFB	–	Laboratory Fortified Blank
LOD	-	Limit Of Detection
LOQ	-	Limit Of Quantitation
MDL	–	Method Detection Limit
MRL	-	Method Reporting Limit
mg/Kg	–	milligrams per kilogram
mg/L	–	milligrams per liter
MS	–	Matrix Spike
MSD	–	Matrix Spike Duplicate
NELAC	–	National Environmental Laboratory Accreditation Conference
NELAP	–	National Environmental Laboratory Accreditation Program
NIST	–	National Institute of Standards and Technology
SM	-	Standard Methods
ppb	-	parts per billion, same as ug/L
PT	–	Proficiency Test(ing)
PTP	-	Proficiency Testing Provider
PTPA	–	Proficiency Testing Provider Accreditor
QA	–	Quality Assurance
QC	–	Quality Control
QM	–	*Quality Manual*
RL	–	Reporting Level
RPD	–	Relative Percent Difference
RSD	–	Relative Standard Deviation
SOPs	–	Standard Operating Procedures
spk	–	spike
std	–	standard

TNI	-	The NELAC Institute
ug/L	–	micrograms per liter
UV	–	Ultra Violet
VOC	–	Volatile Organic Compound
WET	–	Whole Effluent Toxicity

3.4 Management of the *Quality Manual*

The Quality Manager is responsible for maintaining the currency of the *Quality Manual*.

The *Quality Manual* is reviewed annually by the Quality Manager and laboratory personnel to ensure it still reflects current practices and meets the requirements of any applicable regulations or client specifications. Sections of the manual are updated by making a change to the Section and then increasing the revision number by one. The cover sheet of the *Quality Manual* (Section 1) must be re-signed, and the Table of Contents (Section 2) is updated whenever a Section is updated.

The *Quality Manual* is considered confidential within the Utah Public Health Laboratory, also referred to as UPHL, and may not be altered in any way except by approval of the Laboratory Director, Chief Scientist and Quality Manager. If it is distributed to external users, it is for the purpose of reviewing the UPHL management system and may not be used for any other purpose without written permission.

Section 4
ORGANIZATION

The laboratory is a legally identifiable organization. The laboratory is responsible for carrying out testing activities and producing test results that meet the requirements for drinking water certification, TNI standard 2009, ISO/EIC 17025 Standard, and the needs of the client. Through application of the policies and procedures outlined in this Section and throughout the *Quality Manual*:

- The laboratory ensures that it is impartial and that personnel are free from commercial, financial, or other undue pressures that might influence their technical judgment.
- Management and technical personnel have the authority and resources to carry out their duties and have procedures to identify and correct departures from the laboratory's management system.
- Personnel understand the relevance and importance of their duties as related to the maintenance of the laboratory's management system.
- Ethics and data integrity procedures (see Section 5 – "Management" and Section 19 – "Data Integrity Investigations") ensure the personnel does not engage in activities that diminish confidence in the laboratory's capabilities.
- Confidentiality is maintained.

4.1 Organization

The laboratory is a state government laboratory. The Tax ID number is available upon request, if applicable.

The laboratory is located and operates in Utah. The physical address of the laboratory is: 4431 South 2700 West, Taylorsville, Utah 84129. The laboratory is part of the Utah Department of Health.

The laboratory's organization chart can be found in Appendix B of this *Quality Manual*. Additional information regarding the responsibilities, authority, and interrelationship of personnel who manage, perform, or verify testing is included in Section 5 –"Management" and Section 20 – "Personnel." These Sections also include information on supervision, training, technical management, job descriptions, quality personnel, and the appointment of deputies for key managerial personnel. The laboratory director is responsible for providing the resources needed to carry out lab testing and operations.

The laboratory has the resources and authority to operate a management system that is capable of identifying departures from that system and from procedures during testing and initiates actions to minimize or prevent them.

4.2 Conflict of Interest and Undue Pressure

The organizational structure indicated above minimizes the potential for conflicting or undue interests that might influence the technical judgment of analytical personnel. In addition, procedures are in place to prevent outside / inside pressures or involvement in activities that may affect competence, impartiality, judgment, operational integrity, or the quality of the work performed at the laboratory.

The potential conflict of interest among laboratory personnel can arise from several activities: employees involved in part-time employment, which could result in a direct conflict of interest, a QA manager responsible for reviewing a test method that she/he is performing, a QA manager who lacks independent oversight responsibility, etc.

UPHL operates as an impartial laboratory within the Utah Department of Health. UPHL ensures an impartial atmosphere free from undue pressure by separating the responsibilities of QA manager from the management of testing personnel. The QA manager functions as an independent reviewer reporting to management.

The state of Utah Health Department has policies and procedures in place to prevent commercial and financial, among other influences, that may negatively affect the quality of work or negatively reflect on competence, impartiality, confidentiality, judgment, or personal integrity. When hired, employees must sign the Conflict of Interest policy. (Department of Human Resource Management Rule R477-9-3 and UCA 67-16)
All UTAH department Health policies are at the link
https://healthnet.utah.gov/policies/human-resources-policies

In addition, employees must participate annually in the laboratory's training on Ethics and Data Integrity. After the training, employees must sign the Ethics and Data Integrity Agreement to guarantee their commitment to generate high-quality data and report to management any unacceptable practices.

Section 5
MANAGEMENT

The laboratory maintains a management system that is appropriate to the scope of its activities.

5.1 Management Requirements

Top management includes the Laboratory Director, Quality Assurance Manager, Technical Manager (Chief Chemist), Program Manager, and Section managers. They will be held to the roles and responsibilities as defined in Section 5.2.

Management's commitment to good professional practice and to the quality of its products is defined in the Quality Policy statement, Section 5.3.

Management has the overall responsibility for the technical operations and the authority needed to generate the required quality of laboratory operations. Management ensures communication within the organization to maintain an effective management system and to communicate the importance of meeting customer, statutory, and regulatory requirements. Management assures that system documentation is known and available so that appropriate personnel can implement their part. When changes to the management system occur or are planned and carried out, managers ensure that the integrity of the system is maintained.

Management is responsible for carrying out testing activities that meet the requirements of the TNI Standard, the ISO/IEC 17025 Standard, the Manual for Drinking Water certification, and meet the needs of the clients, mainly the Utah Division of Environmental Quality.

Managers implement, maintain, and improve the management system and identify non-compliance with the management system of procedures. Managers initiate actions to prevent or minimize non-compliance.

The Section Manager ensures technical competence in personnel operating equipment, performing tests, evaluating results, or signing reports, and limits the authority to perform laboratory functions to those appropriately trained and/or supervised. The Manager is responsible for maintaining training records of capability for all employees on the network drive and in each laboratory.

Management is responsible for defining the minimal level of education, qualification, experience, and skills necessary for all positions in the laboratory and ensuring that technical staff has demonstrated capability in their tasks.

Training is kept up to date as described in Section 20 – "Personnel" by periodic review of training records and through employee performance reviews.

Management bears specific responsibility for maintenance of the management system, ensuring that personnel are free from any commercial, financial, and other undue pressures that might adversely affect the quality of their work.

This includes defining roles and responsibilities to personnel, approving documents, providing required training, providing a procedure for confidential reporting of data integrity issues, and periodically reviewing data, procedures, and documentation. The assignment of responsibilities, authorities, and interrelationships of the personnel who manage, perform or verify work affecting the quality of environmental tests is documented in Section 20.

Management ensures that audit findings and corrective actions are completed within the required time frames.

Designated deputies are appointed by management during the absence of the Laboratory Manager, Technical Manager, or Quality Manager, and always if the absence is more than 15 days.

5.2 Management Roles and Responsibilities

5.2.1 Laboratory Director Utah Public Health Laboratory

The Laboratory Director is responsible for the overall quality, safety, finances, technical aspect, human resources, and service performance of the laboratory. The Laboratory Director provides the resources necessary to implement and maintain an effective quality and data integrity program.

a. Ensures that personnel are free from any commercial, financial, and other undue pressures that might adversely affect the quality of their work.
b. Give final approval to the laboratory's Quality Assurance program plan.
c. May suspend testing when documented quality for a method is in question.
d. Provide financial and personnel resources to carry out laboratory testing and operation.

5.2.2 Quality Manager

The Quality Manager (or designee) is responsible for the oversight and review of quality control data, but is independent of laboratory operations. The Quality Manager's training and proof of experience in QA/QC procedures, knowledge of analytical methods, and the laboratory's management system are available in the employee files.

5.2.2.1 Responsibilities

The Quality Manager is responsible for:

a. Serving as a focal point for QA/QC.
b. Arranging or conducting annual internal audits without outside (e.g., managerial) influence.
c. Be able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence;
d. Notifying management of deficiencies and monitoring corrective actions.
e. Oversight and review of quality control data.
f. Monitoring corrective actions.
g. Ensuring that the management system related to quality is implemented and followed at all times.
h. Monitoring and maintaining laboratory certifications.
i. Keeping this *Quality Manual* current.
j. Submitting, in writing, monthly QA reports to Laboratory Director through QA meetings. The monthly report consists of internal audit reports, QA activities for the month, plus corrective actions taken for any out-of-control problems.
k. Coordinating the distribution of proficiency testing samples.
l. Maintaining a log of all performance on proficiency test (PT) samples.
m. Initiating corrective action for a failed PT study.
n. Ensuring that appropriate corrective actions are taken to address procedures that do not meet the standards set forth in the *Quality Manual*, laboratory SOPs, or laboratory policies that may be temporarily suspended by the Laboratory Director.
o. Reviewing and approving all SOPs and policies prior to their implementation and ensuring all approved SOPs and policies are provided to laboratory personnel and are adhered to.

5.2.3 Technical Manager (Chief Chemist) and Program Manager

5.2.3.1 Responsibilities

The Technical Manager and Program Manager are responsible for:

a. Monitoring performance data and the validity of the analyses for the laboratory.
b. Maintaining current information on regulations and approved methodologies for various programs the Environmental Chemistry Program (ECP) serves.
c. Overseeing implementation of the QA program within the ECP.
d. Overseeing the implementation of corrective actions.
e. Responding to customer concerns.
f. Reviewing or ensuring that the data is verified and validated before reporting.
g. Providing help for the annual management review.
h. Performing annual internal audits assigned by QA Manager.
i. Providing help in updates to the *QA Manual*.
j. Preparing for onsite audits.
k. Maintaining the employee training records for demonstration of initial and ongoing capability.
l. Ensuring that all the analysts have the appropriate education and training to properly carry out the duties assigned to them and ensures that this training has been documented.
m. Reviewing and approving all SOPs and policies prior to their implementation and ensures all approved SOPs and policies are provided to laboratory personnel and are adhered to.
n. Reporting data to customers.
o. Establish communication with customers.
p. Communication with LIMS staff to fulfill section needs for data reporting.
q. Chief Chemist conducts monthly all hands chemistry staff meeting for training and providing information to the chemistry staff.

5.2.4 Laboratory Key Personnel Deputies

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

Table 5-1 Key Personnel Deputies

Key Personnel Roles	Key Personnel	Deputy
Laboratory Director	Andreas Rohrwasser (Interim)	Erik Christensen
Chief Scientist (Technical director)	Eleanor Ojinnaka	Kyle Ashby / Alia Rauf
QA Manager	Alia Rauf	Eleanor Ojinnaka

5.3 Quality Policy

Management's commitment to quality and the management system is stated in the Quality Policy below, which is upheld through the application of related policies and procedures described in the laboratory's *Quality Manual*, SOPs, and policies. Every laboratory employee must familiarize themselves with the quality documentation and implement the policies and procedures in their work. All employees are trained annually on ethical principles and procedures surrounding the data that is generated.

Quality Policy Statement
The management system's objective and the commitment of UPHL management is to consistently provide our customers with data of known and documented quality that meets their requirements. Our policy is to use sound professional practices. Laboratory Management is committed to maintaining the highest quality of service and complying with the Utah Public Health policies, TNI accreditation program, and the drinking water certification program. The laboratory ensures that personnel are free from any commercial, financial, and other undue pressures, which might adversely affect work quality. This policy is implemented and enforced through the unequivocal commitment of management, at all levels, to the Quality Assurance (QA) principles and practices outlined in this manual. However, the primary responsibility for quality rests with each individual within the laboratory organization. Every laboratory employee must ensure that the generation and reporting of quality analytical data is a fundamental priority. The laboratory maintains a strict policy of client confidentiality.

5.4 Ethics and Data Integrity System

The laboratory has an Ethics and Data Integrity policy that is included in Appendix E. The laboratory's Ethics and Data Integrity program, training, and investigations are discussed in the section "Data Integrity Investigations" outlined in Section 19.

5.5 Documentation of Management/Quality System

The management system is defined through the policies and procedures provided in this *Quality Manual* and written laboratory Standard Operating Procedures (SOPs) and policies.

5.5.1 Quality Manual

The *Quality Manual* contains the following required items:

5.5.1.1 Document title;

5.5.1.2 The laboratory's full name and address;

5.5.1.3 Name, address (if different from above), and telephone number of individual(s) responsible for the laboratory;

5.5.1.4 Identification of all major organizational units which are to be covered by this quality manual and the effective date of the version;

5.5.1.5 Identification of the laboratory's approved signatories;

5.5.1.6 The signed and dated concurrence (with appropriate names and titles) of all responsible parties including the quality manager(s), technical manager(s), and the agent who is in charge of all laboratory activities, such as the laboratory director or laboratory manager;

5.5.1.7 The objectives of the management system and a summary of or reference to the laboratory's policies and procedures;

5.5.1.8 The laboratory's official quality policy statement, which shall include management system objectives and management's commitment to ethical laboratory practices and to upholding the requirements of this Standard; and

5.5.1.9 A table of contents and applicable lists of references, glossaries, and appendices.

This *Quality Manual* contains or references all required elements as defined by the TNI Standard - V1:M2, Section 4.2.8.4.

5.5.2 Standard Operating Procedures (SOPs)

Standard Operating Procedures (SOPs) represent all phases of current laboratory operations; they include an effective date, revision number, and signature of the approving authorities and are available to all personnel. They contain sufficient detail such that someone with similar qualifications could perform the procedures. There are two types of SOPs used in the laboratory: 1) test method SOPs, which have specific requirements as outlined below, and 2) general use SOPs which document general procedures.

Each accredited analyte or method has an SOP. Sometimes an SOP is a copy of a method, and any additions are clearly described. Personnel are provided with the SOP template, which includes the following elements and can be found on G: drive in SOP submitted folder. The laboratory's test method SOPs include the following topics, where applicable:

i. identification of the method;
ii. applicable matrix or matrices;
iii. limits of detection and quantitation;
iv. scope and application, including parameters to be analyzed;
v. summary of the method;
vi. definitions;
vii. interferences;
viii. safety;
ix. equipment and supplies;
x. reagents and standards;
xi. sample collection, preservation, shipment, and storage;
xii. quality control;
xiii. calibration and standardization;
xiv. procedure;
xv. data analysis and calculations;
xvi. method performance;
xvii. pollution prevention;
xviii. data assessment and acceptance criteria for quality control measures;
xix. corrective actions for out-of-control data;
xx. contingencies for handling out-of-control or unacceptable data;
xxi. waste management;
xxii. references; and
xxiii. any tables, diagrams, flowcharts, and validation data.

5.5.3 Order of Precedence

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

- UPHL-ECP *Quality Manual*
- SOPs
- Policies
- Work Instruction from the Management

Section 6
DOCUMENT CONTROL

This section describes how the laboratory establishes and maintains a process for document management. Procedures for document management include controlling, distributing, reviewing, and accepting modifications. The purpose of document management is to preclude the use of invalid and obsolete documents.

Documents can be SOPs, policy statements, specifications, charts, textbooks, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, hard copy or electronic, and they may be digital, analog, photographic, or written.

The laboratory manages three types of documents: 1) controlled, 2) approved, and 3) obsolete.

A controlled document is one that is uniquely identified, issued, tracked, and kept current as part of the management system. Controlled documents may be internal or external documents, like policies and reference methods SOPs.

An approved document means it has been approved and either signed and dated, or acknowledged in writing or by secure electronic means by the issuing authority.

Obsolete documents are documents that have been superseded by more recent versions or are no longer needed.

6.1 Controlled Documents

All external and internal documents can be tracked by the All Document Tracking List on G: drive. G:\Bureau of Chem & Env Services\Document Control\Document Tracking List
All the SOPs are updated by the analyst, then reviewed and approved by the Program Manager or Chief Scientist and QA manager.

The SOPs are reviewed annually and policies are reviewed as needed to ensure their contents are suitable and in compliance with the current management systems requirements, and accurately describe current operations.

Approved copies of the SOP documents are kept in workstation binders in each laboratory location where operations are performed and also on a shared drive in the final SOPs folder on G: drive.

The analysts will submit their SOPs for managerial review in the working SOPs folder. The analysts will have full access to their initial submissions. Where practicable, the altered or new text shall be identified in the document in the working SOP folder. If the management starts reviewing a submission, they may want to inform the user about the review (i.e., email user).

The managers will review the submissions and correspond with the user until a final draft is created.

The QA managers place the final SOPs in the Final SOPs folder and notify all of the analysts to use the updated copy from the final folder and to remove the previous copy and stamp it as Obsolete document.

Analysts can only view approved SOPs in the "FINAL SOP" folder.
Analysts cannot add/create new files in the folder and cannot delete or modify existing folders. The records for SOPs are also maintained under the document control tracking index for the year.

This master list of controlled internal documents, SOPs, and policies include distribution, location, revision, and effective date.

All SOP documents are uniquely identified with 1) a unique number identification, 2) effective date, 3) revision identification, 4) page number, 5) the total number of pages (or a mark to indicate the end of the document), and 6) the signatures of the issuing authority (i.e., management).

Approved copies of documents are available to staff at all locations where operations are essential to the effective functions of the laboratory. An approved copy of this *Quality Manual* and the SOPs that the laboratory follows will be kept in a binder in each lab and made accessible to all laboratory personnel.

All other documents are stored in the document control folder on G: drive.
All the final approved SOPs are maintained at location G:\Bureau of Chem & Env Services\SOPs

A master list of controlled external documents and reference methods is also maintained that includes title, author, date of publication, revision, and location. A document list of the analytical method is maintained by the Quality Assurance Manager on G: drive. A printed copy of all the methods provided in common office areas and on G: drive.

6.1.1 Document Changes to Controlled Documents

6.1.1.1 Paper Document Changes

The document changes are approved by the Chief chemist / Program Manager and Quality Manager.
The changes that do not involve process modifications, but clarifications may be performed without a revision change.

Amendments/modifications to documents are incorporated into a new revision and reissued when the document is reviewed and updated on or before its scheduled review cycle.
The modified document is then copied and distributed, and obsolete documents are removed according to the master list of controlled documents.

Revision history is required for the SOPs and other documents. SOP 0079 describes the review process for SOPs.

6.1.1.2 Electronic Document Changes

The suggested revisions to electronic documents are presented to Chief Chemist / Program and Section Managers and the QA manager for review and approval.

6.2 Obsolete Documents

All invalid or obsolete documents are removed from the general distribution or otherwise prevented from unintended use.

In the case of obsolete documents retained for legal use or historical knowledge preservation, paper copies are appropriately marked as obsolete and dated and retained in archived binders in the laboratories. All the electronic copies are stored and moved to the archived document folder.

All the old document's hard copies stamped with the "Obsolete' document. Staff are informed to use the updated revision of the document. The tracking list for Documents and Forms have the updated document revision. All documents issued to laboratory personnel are reviewed and approved for use by the QA manager and Chief Chemist prior to use. A master list of all the forms and SOPs are created, identifying the current revision and effective date.

Section 7
REVIEW OF REQUESTS, TENDERS, AND CONTRACTS

The review of all new work ensures that oversight is provided so that requirements are clearly defined, the laboratory has adequate resources and capability, and the test method is applicable to the customer's needs. This process ensures that all work will be given adequate attention without shortcuts that may compromise data quality.

Contracts for new work may be formal bids, signed documents, verbal, or electronic. The client's requirements, including the methods to be used, must be clearly defined, documented, and understood. Requirements might include target analyte lists, project-specific reporting limits (if any), project-specific quality control requirements (if any), turnaround time, and requirements for data deliverables. The review must also cover any work that will be subcontracted by the laboratory.

The supervisors are supposed to document new work on the network drive at location G:\Bureau of Chem & Env Services\Projects and Contract Documentation Folder and can use the form 002 for documentation at the location

G:\Bureau of Chem & Env Services\Document Control\Forms\All Forms

7.1 Procedure for the Review of Work Requests

The Laboratory director, the Chief Chemist, or Program Manager and Chief Chemist determine if the laboratory has the necessary accreditations and resources, including schedule, equipment, deliverables, and personnel to meet the work request.

The review of the requests, tenders, and contracts for the testing need to be documented in a folder on the G: drive called "projects and contract documentation" by using Form 002 at G:\Bureau of Chem & Env Services\Forms.

The Laboratory Director or Chief Chemist and section manager are responsible for informing the client of the results of the review if it indicates any potential conflict, deficiency, lack of accreditation, or inability of the lab to complete the work satisfactorily.

The client is informed of any deviation from the contract, including the test method or sample handling processes. All differences between the request and the final contract are resolved and recorded before any work begins. The contract must be acceptable to both the laboratory and the client. The documentation is maintained in the "projects and contracts documentation" folder on G: drive.

The review process is repeated when there are amendments to the original contract by the client. The participating personnel are given copies of the amendments. The Program manager and Chief Chemist are responsible to maintain the amendments in the project folder.

Note: For repetitive routine tasks, the review may be made only at the initial inquiry stage or on granting of a contract for on-going routine work performed under a general agreement with the client, provided the client's requirements don't change.

7.2 Documentation of Review

The records are maintained for every contract or work request, when appropriate. This includes 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 and can be maintained with the project folder by using form 002.
Records of all project-related communication with the client (including e-mails, fax, telephone conversation, etc.) are kept in the project folder.

Section 8
SUBCONTRACTING OF ENVIRONMENTAL TESTS

A subcontract laboratory is defined as a laboratory external to this laboratory, or at a different location than the address indicated on the front cover of this manual, that performs analyses for this laboratory.

When subcontracting analytical services, the laboratory assures work requiring accreditation is placed with an appropriately accredited laboratory or one that meets applicable statutory and regulatory requirements for performing the tests.

8.1 Procedure

The Program Manager and Chief Chemist maintain the list of subcontractors and certification of the laboratory from whom they subcontract the samples.

A copy of the certificate is maintained as evidence of compliance. This information is maintained by the Program Manager and Chief Chemist on G: drive in the "Pass-through work information folder" at G:\Bureau of Chem & Env Services\ pass through Work.

The Program Manager reviews the Laboratory certification and analytes list to ensure the subcontracting laboratory has the appropriate accreditation to do the work.

The Section Manager must notify the client of the intent to subcontract the work in writing. When possible, the laboratory should gain the approval of the client to subcontract their work prior to implementation.

The laboratory performing the subcontracted work is identified in the final report. The laboratory assumes responsibility to the client for the subcontractor's work, except in the case where a client or a regulating authority specifies which subcontractor is to be used.

UPHL sends the subcontracting laboratory original analysis report to the client.

Section 9
PURCHASING SERVICES AND SUPPLIES

The laboratory ensures that purchased supplies and services that affect the quality of environmental tests are of the required or specified quality by using approved suppliers and products. Reagent quality is verified by routine blank analysis for each method to meet the blank requirement for each method.

The laboratory has procedures for the purchasing, receiving, and storage of supplies that affect the quality of environmental tests.

9.1 Procedure

The Supervisors approve the supplier of services and supplies and approve technical content of purchasing documents prior to ordering.

Each analyst is responsible for tracking and ordering standards, reagents, solvents, and supplies for their respective methods.

To order chemicals and supplies, the staff will determine what supplies are needed and will enter the required, information into SharePoint, which is the state purchasing website. https://sp.health.utah.gov/sites/purchasing/Pages/Home.aspx

For logging into the SharePoint website, the analysts and managers have a username and password that is the same as their network access information.

The information needed to place an order is as follows:

Name of the item - be as descriptive as possible.

Vendor Name

Catalog Number

Name of Person Requesting the Item

Quantity

Unit Size - for example, one case of 1000, pkg of 100, one bottle, etc.

Unit Price

Grant ID - this is the account number associated with the respective section.

If a PO number or contract number is known, this can also be entered.

Vendor quotes or other paperwork may also be attached to the request.

Once the information is entered, submit the request.

If the item has already been requested the analyst can search for the previous request and reorder the same item.

An email will be sent to the section supervisor for approval. The supervisor goes into SharePoint and approves the order. Once the request is approved, the lab purchasing person will order the item and mark the request as Ordered.

When the items arrive, the packing slip must be signed by the analyst or someone else in the section. The records are maintained in SharePoint for purchasing approval.

Evaluation of suppliers is accomplished by ensuring the supplier ships the product or material ordered and that the material is of the appropriate quality by signing packing slips or other supply receipt documents. The purchasing documents contain the data that adequately describe the services and supplies ordered. The description may include type, class, grade, identification, specifications, or other technical information.

The supplies received are inspected for breakage, leaks, or any other damage. The supplies and chemicals are checked and the supplies received are stored according to the manufacturer's recommendations, laboratory SOPs, or test method specifications.

Any documents received with the supplies and services, including specifications, certificates of analyses, warranties, maintenance records, calibration records, etc. are kept on file in each laboratory with workstation binder or maintenance logs by the Analyst and Section Manager. Policy E-17 describes the supplies receiving procedure and finance documentation process.

The purchased supplies and reagents that affect the quality of the tests are not used until they are inspected or otherwise verified as complying with requirements defined in the test method. All the reagents are used by confirming the analysis of negative and positive control

9.2 Approval of Suppliers

The UPHL Purchasing Department maintains a list of approved suppliers. The State of Utah purchasing list can be seen on purchasing.gov. The vendors have to give a bid to become state vendors. The vendors give a bid to get the contract.

Section 10
SERVICE TO THE CLIENT

The laboratory collaborates with clients and/or their representatives in clarifying their requests and in monitoring laboratory performance related to their work. Each request is reviewed to determine the nature of the request and the laboratory's ability to comply with the request within the confines of prevailing statutes and/or regulations without risk to the confidentiality of other clients.

Quality Assurance Objectives (QAOs) – Client QA Program Plans

Data Quality Objectives (DQO)

Utah Public Health Laboratories (UPHL) supports the Local, State, Federal government, and municipalities with analytical services for regulatory, non-regulatory, and investigative purposes.

UPHL, therefore, has established and implemented Standard Operating Protocols that include the QA/QC requirements specified in local, State, and U.S. Federal Statutes.

Client Data Quality Objectives (DQO)
Local, State, and Federal Statutes are the basic documents that define the minimum QA and QC requirements of the analytical services provided by UPHL. UPHL does not perform field-sampling services. Each data-using organization is responsible for preparing the SOPs for the sampling procedures that will yield results that are representative of the system being measured. Specific details of the sampling criteria are addressed in their respective Quality Assurance Project Plans.

State of Utah Agencies
UPHL's principal client is the Utah Department of Environmental Quality (UDEQ). UDEQ performs regulatory and non-regulatory work to protect and improve Utah's air, land, and water. The UDEQ has five divisions with various programs that implement state and federal regulations to improve and protect our environment. Following are the UDEQ divisions and services provided by UPHL:

- Utah Division of Water Quality (DWQ)
  UPHL provides analytical service to DWQ for metals, inorganic and organic contaminants in water collected from lakes, streams, industrial effluents, and underground. UPHL assures that laboratory methodology is consistent with the requirements of the Clean Water Act (CWA).

- Utah Division of Drinking Water (DDW)
  The analytical support provided to DDW's is for the analysis of drinking water samples for the content of metals, inorganics, organic contaminants, physical parameters, and microbial contaminants. UPHL assures that laboratory methodology is consistent with the requirements of the Safe Drinking Water Act (SDWA).

- Utah Division of Waste Management and Radiation Control (DWMRC)
  The analytical support provided to DWMRC is for the analysis of samples primarily from wastewater and solids for physical characteristics, metals, inorganic, and organic contaminants. UPHL assures that laboratory methodology complies with the Solid and Hazardous Waste regulations, SW-846.

- Utah Division of Air Quality (DAQ)
  The primary support for DAQ is for the analysis of lead in air filters to help UDAQ monitor air quality in Utah. UPHL assures that laboratory methodology complies with the Clean Water Act (CWA).

- Division of Environmental Response and Remediation (DERR)
  The primary support for DERR involves the analysis of unknown contaminants in water and solid samples for hazardous metals, inorganic and organic chemicals. UPHL also provides support with laboratory services for emergency response.

- Non-DEQ State Agencies
  The State Agencies outside the Utah DEQ normally request lab services as defined under the Utah DEQ or Federal regulations.

- Private Sector Clients
  UPHL also provides analytical services to private sector clients, primarily to meet local, State, and Federal regulatory requirements. UPHL, therefore, implements the same QA/QC requirements as are implemented for local, State, and U.S. Federal agencies.

- Utah Water Quality Alliance (UWQA)
  UDDW, UPHL, and approximately 30 public water systems in Utah have formed an alliance called the Utah Water Quality Alliance. Four groups of the Alliance members are formed

from water utilities from the four corners of the state and are comprised of the Northern utilities, the Southern part, the Eastern part, and the Wasatch front. The main objective of the Utah Water Quality Alliance is a shared commitment to continuous enhancement of drinking water quality delivered to the community. UPHL provides analytical services on emerging contaminants to drinking water utilities of the UWQA.

10.1 Client Confidentiality

The laboratory confidentiality policy is to not divulge or release any information to a third party without proper authorization. Third party requests for data and information are referred to the client.

All the electronic data (storage or transmissions) are kept confidential, based on technology and laboratory limitations, as required by the client or regulation. Laboratory personnel will ensure that all data transmitted or forwarded to a client is subject to accepted practices to ensure confidentiality. Human Resources will release a Confidential Access and Confidentiality Authorization, Agreement, and Acknowledgement (AAA) to all UDOH employees at the start of each fiscal year and new employees at time of hire using the Utah Performance Management System. Employees shall read and acknowledge the Confidential Access and Confidentiality (AAA) in the Utah Performance Management (UPM) system on an annual basis.

All new Utah Public Health employees have to acknowledge and sign the Confidential Access and Confidentiality Policy Number: 01.1 1 from general administration for the state of Utah Health Department. A current copy of the Confidentiality Agreement can be found at the end of this Section. For data security, all the computers are password protected and online state accounts require multifactor authentication (MFA) and two-factor authentication to access.

CONFIDENTIALITY AGREEMENT
November 20, 1998
Utah State Department of Health
Division of Disease Control and Prevention

The Division of Disease Control and Prevention operates under strict rules of confidentiality. Much of the information received by the laboratory such as the name of persons being tested, the origin of samples being submitted, and the type of testing being requested must not be released to inappropriate persons, organization or agencies.

1. **The results of clinical testing results are not given to individuals who have been tested. Results go back to the provider who submitted the specimen. Results of clinical testing can be shared with authorized individuals within the Division of Disease Control and Prevention, local health departments, or individuals authorized by the original provider.**

2. **The result of environmental testing may be reported to individuals who submitted the samples or to representatives of the agency or organization that submitted the samples. Results of environmental testing may also be provided to authorized individuals within the Division of Disease Control and Prevention, local health departments or the Department of Environmental Quality.**

3. **The results of toxicology testing may only be reported to representatives from the Medical Examiner's Office, or a representative of law enforcement or investigative agencies.**

4. **Results are not given over the phone unless you are absolutely sure you know who you are talking to. If there is any doubt, tell the individual that you will call them back with the results. Return the call with the phone number listed in the phone book and ask to speak with the person requesting the results.**

5. **If any question arises concerning who is authorized to receive any of the above information, consult with the supervisor.**

6. **Any infraction of these rules may result in corrective or disciplinary action.**

I have read and considered the rules of confidentiality and have had any questions answered satisfactorily. I understand the seriousness of confidentiality and that a breach of the rules may lead to disciplinary action which could include dismissal.

Employee name (print): _____

Signature: _____

Date: _____

Signature of Supervisor: _____

Date: _____

References: R477-9. Employee Conduct, Government Records Access and Management Act [GRAMA]

Original to Personnel File
Make copy for Employee

UTAH DEPARTMENT OF HEALTH
CONFIDENTIAL ACCESS AND CONFIDENTIALITY DIRECTIVE

This directive provides each Utah Department of Health (UDOH) employee with the Department guidelines regarding confidential information. This directive may require each organizational unit within the Department to develop a more detailed description for how confidential information will be handled. Each supervisor is responsible to supplement this directive as necessary and attach the supplement as part of this directive. Each supervisor is also responsible to train individual employees in specific confidential information handling procedures within the organizational unit. This directive also places responsibility on the employee to become familiar with the confidentiality requirements of the employing unit.

INSTRUCTIONS:

The employee will read and initial each of the provisions of this directive, acknowledging that each provision has been reviewed and discussed with the supervisor.

DIRECTIVE:

1._____As an employee of the Department you may have access to confidential information. This access may be part of your direct job duties. It also includes access incidental to your primary job duties. Confidential information is protected by federal and state law. Confidential information may take many forms, including paper, electronic, and verbal. Confidential information includes medical, personnel, financial and demographic information about individuals, health care providers, and facilities, Department employees, and information proprietary to other companies and agencies or persons.

2._____Public health work and Department operations rely heavily on the gathering and proper use of confidential information. Improperly using or disclosing confidential information harms public health efforts and may expose you or the Department to legal liability.

3._____You may access and use confidential information only for which you have a need to know to do your work.

4._____You may not discuss confidential information, including the names of individuals, health care providers and facilities, Department employees, and information proprietary to other companies or persons, except as necessary to do your work and you must take reasonable measures to safeguard confidential information from improper disclosure.

5._____You may not in any way divulge, copy, release, sell, loan, review, alter or destroy any confidential information except as properly authorized by your supervisor.

6._____This document may not cover all restrictions on your access to or use of confidential information. Your employing agency and other law or Department policy may also apply to the confidential information held by the Department. Your employing agency may provide specific training concerning confidential information to which you have access.

10.2 Client Support

The communication with the client or their representative is maintained to provide proper instruction and modification for testing. The technical staff is available to discuss any technical questions or concerns the client may have.

Delays or major deviations to the testing are communicated to the client immediately. The Section Manager / Chief Chemist and Program Managers notify clients of any problems with their samples discovered during the analysis and/or data verification. The ECP staff regularly communicates with DEQ staff through emails and meetings as necessary to ensure their needs are met. All staff within UPHL-ECP (Section Managers, Quality Manager, and Analyst) are responsible for fulfilling the clients' needs.

The laboratory will provide the client with all the requested information pertaining to the analysis of their samples. An additional charge may apply for additional data/information that was not previously agreed upon or requested prior to the time of sample analysis.

Utah Water Quality Alliance (UWQA) Meeting:
The Laboratory staff attends monthly meetings with members of the UWQA. At the meeting, feedback is received on data quality and laboratory services, which allows the lab to improve processes to enhance customer support. Laboratory staffs also participates in the planning of new water monitoring projects that need laboratory testing.

10.3 Client Feedback

The laboratory seeks both negative and positive feedback following the completion of projects and periodically for ongoing projects. Feedback provides acknowledgment, corrective actions where necessary, and opportunities for continuous improvement.

Negative customer feedback is documented as a customer complaint (see Section 11 – "Complaints"). Appropriate measurements are taken to address Customer related inquiries and issues. All real concerns are discussed in QA meetings. The feedback is analyzed and used to improve the management system, testing, and customer service.

The customers are provided with a survey link within reports to provide feedback. The Customer Relations Manager reviews these surveys and delivers them to the Chief Chemist, Manager to address the concern. The Chief Chemist / Program Manager contacts the customer and concerns are documented and addressed.

Section 11
COMPLAINTS

The purpose of this Section is to ensure that customer complaints are addressed and corrected. This includes requests to verify results or analytical data. Complaints provide the laboratory with an opportunity to improve laboratory operation and client satisfaction.

Monthly meetings are conducted to improve UPHL and DEQ communication; discussion includes workload, new projects, budget, or other issues.

The complaints by customers or other parties are reviewed by management, and appropriate action is determined. All customer complaints are documented by the person receiving the complaint in the customer communication log and addressed by the related Section Manager or Program Manager, or Chief Chemist.

If it is determined that the complaint has merit and that further action is required, the complaint will be addressed and documented as a non-compliance, using the corrective action report and following the steps of the corrective action system procedures outlined in Section 14.

If it is determined that a complaint is without merit, it is documented and the client is contacted by Chief Chemist / Section Manager to resolve any issues and the process thus ends.

The Section Manager is responsible for documenting all the communication or complaints in the communication log on G: drive. The Section Managers, QA Manager and Program Manager are responsible for documenting any condition that has affected the quality of analytical data.

If a complaint requires a Corrective Action Record, the supervisor is responsible for filing the Corrective Action Record. The Corrective Action Record should include the steps being taken to prevent future occurrences of these events.

The complaint log must be maintained, reviewed, and administered by the Section Managers, Program Manager, and QA manager. Complaints are dated and documented under the communication folder for the year.

The Chemical and Environmental Laboratory Section Manager/Program Manager and QA Manager will document all corrective actions that have been implemented as a result of the customer complaint in the Communication log to address the problem. The communication and complaint is documented at the location G:\Bureau of Chem & Env Services\Communication\Complains

There is a survey posted to get customers' feedback and to improve services and communication. The surveys are delivered to the Customer Relations Manager. The Customer Relations Manager checks the survey and sends it to the related Section Manager to take appropriate action. The survey link for customer feedback is:
https://www.surveymonkey.com/r/environmentalchemistry

The problem and solution are logged in the communication log by the person taking any further action to solve the issue.

Chemical Environmental Management will review the individual complaints and complaint log and trends observed brought to attention at the Environmental Quality Assurance meeting.

A complaint such as a concern that data is repeatedly late should be reviewed for preventive action (see Section 15 – "Preventive Action") to minimize a future occurrence.

Section 12
CONTROL OF NON-CONFORMING ENVIRONMENTAL TESTING WORK

Non-conforming work is work that does not meet acceptance criteria or requirements. The two types of exceptions that require action are defined as non-conformances and non-compliances.

A non-conformance is the type of exception that occurs during analysis or procedure where a particular result, such as a QC spike recovery or a calibration evaluation, does not conform to requirements. They are remedied according to the actual procedure itself.

Non-conformances can include departures from standard operating procedures, test methods, or unacceptable quality control results (see Section 27 – "Quality Assurance for Environmental Testing").

The non-compliance is the type of exception where a failure of an analytical or quality assurance system is observed. The non-compliances are remedied through the corrective action process and are documented using a Corrective Action Form located at the G: drive using the form 001.

Identification of non-conforming work can come through customer complaints, quality control and instrument calibration, evaluating consumable materials, staff observation, final report review, management reviews, and internal and external audits, among any other procedural errors.

12.1 Exceptionally Permitted Departures from Documented Policies and Procedures

Customer requests for departures from laboratory procedures are approved and documented by management. The planned departures from procedures or policies do not require audits or investigations.

12.2 Non-Conforming Work

12.2.1 Analytical Batch - QC Responsibilities. Whenever an analytical procedure QC parameter deviates from the range or condition specified in the Reference Analytical Test Method, the analyst will initiate an investigation, qualify data (if needed), and document findings in the QA Batch Raw Data Package.

12.2.2 Samples in defective QA Batches will be re-analyzed in QA Batches with acceptable QC results.

12.2.3 Samples that cannot be re-analyzed in QA Batches with acceptable QC results will not be reported as acceptable for regulatory use. The analyst must notify the ECP management as soon as possible. Upon notification, the ECP management will initiate client relations actions and also initiate Corrective and Preventative Actions (CAPA).

12.2.4 Analytical Method SOPs. Each Method SOP contains method-specific summaries, which itemize the QC samples, their requirements, and their QC limits as specified by each Reference Analytical Test Method.

12.2.5 QC Decision Instructions. Appendix A or the individual method SOP outlines the requirements for QC sample types in an analytical QA Batch and the appropriate responses to the QC results. Each regulatory method will specify additional QC samples that must also be analyzed and evaluated. Corrective actions must be taken as specified in the referenced method.

The lab policy for the control of non-conforming work is to identify the non-conformance and determine and take appropriate action. All employees have the authority to stop work on samples when any aspect of the process does not conform to laboratory requirements.

The laboratory evaluates the significance of the non-conforming work and takes corrective action immediately. The customer is notified if their data has been impacted. The laboratory allows the release of non-conforming data only with approval of a Section Manager / Program Manager and Chief Chemist, and on a case-by-case basis. Non-conforming data is clearly identified in the final report (see Section 28 – "Reporting the Results").

The discovery of a nonconformance for results that have already been reported to the customer must be immediately evaluated for the significance of the nonconformance, its acceptability to the customer, and the determination of the appropriate corrective action. Documentation is required.

The procedure for investigating and taking appropriate corrective actions of non-conforming work is described in Section 14 – "Corrective Actions". Section 14.3 describes procedures for Technical Corrective Actions.

Formal corrective action procedures must be followed for non-conforming work that could reoccur (beyond expected random QC failures) or where there is doubt about the laboratory's compliance to its own policies and procedures.

The investigation and associated corrective actions of non-conforming work involving alleged violations of the company's Ethics and Data Integrity policies must follow the procedures outlined in Section 19 – "Data Integrity Investigations".

12.3 Stop Work Procedures

Laboratory personnel are to notify the Section Manager of any nonconformance. The Section Manager reviews the significance of the nonconformance and develops a course of action. If data are questionable, the Chief Chemist / Program Manager and Quality Assurance Manager may be involved in the review and clients are notified.

When an investigation of nonconformance indicates that the cause of the nonconformance requires that a method be restricted or not used until modifications are implemented, the Laboratory Director will immediately notify the customer.

The laboratory will hold all relevant reports to clients pending review. The Quality Assurance Officer must be involved in the resolution of the issue and must verify that the issue is resolved before work may resume. The personnel are notified by the Section Manager when the resumption of work is authorized. The Section Manager and Quality Assurance Officer will document the issue, root cause, and resolution using the corrective action procedures described in Section 14 – "Corrective Action".

The reporting of non-conforming work involving alleged violations of the company's Ethics and Data Integrity policies must be reported to the Quality Assurance Officer and chemical laboratory director. Procedures described in Section 19 – "Data Integrity Investigations" are followed.

The resumption of work, after work has been stopped, is authorized by the Laboratory Director.

Section 13
IMPROVEMENT

Improvement in the overall effectiveness of the laboratory management system is a result of the implementation of the various aspects of the laboratory's management system: quality policy and objectives (Section 5 – "Management"); internal auditing practices (Section 17.1 – "Internal Audits"); the review and analysis of data (Section 27 – "Quality Assurance for Environmental Testing"); the corrective action (Section 14 – "Corrective Action") and preventive action (Section

15 – "Preventive Action") process; and the annual management review of the quality management system (Section 18 – "Management Review") where the various aspects of the management/quality system are summarized and evaluated, and plans for improvement are developed.

In addition, the Laboratory Director and Chief Chemist periodically work with external consultants, including personnel from the State's Organizational Development and Performance Management Office-Executive Director's Office, to continuously monitor and improve the quality of service. They evaluate laboratory processes (i.e., sample turnaround times), suggest ideas for improvements, and monitor progress.

Section 14
CORRECTIVE ACTION

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

Deficiencies cited in external assessments, internal quality audits, data reviews, customer feedback/complaints, control of nonconforming work, or managerial reviews are documented and require corrective action. Corrective actions taken are appropriate for the magnitude of the problem and the degree of risk.

14.1 General Procedure

The laboratory uses CAR Form 001 to document and track corrective actions. An effective Corrective Action and/or Preventive Action capable of satisfying the client, QA needs, and the basic regulatory requirements is accomplished by implementing and fully documenting the following nine basic steps:

a. Identification of the problem, nonconformity, or incident or the potential problem, nonconformity, or incident.

b. Evaluation of the impact of the problem and potential impact on laboratory operations and client services.

c. Development of an Investigation Protocol and assignation of responsibilities.

d. Analysis of Investigation results with appropriate documentation.

e. Creation of Action Plan listing all the tasks that must be completed to correct and/or prevent the problem.

f. Implementation of the Action Plan.

g. Follow-up actions with verification of the completion of all tasks, and an assessment of the appropriateness and effectiveness of the actions taken.

h. The PT Corrective Action Check. It is recommended that analysts perform the investigation steps following the PT failure checklist Form 012 to review data for any proficiency test samples that are missed. To evaluate the cause of a failed PT, a raw sample data QC check is the first step.

i. Form 012 will guide through the process of determining the cause of failed PT samples.

The Analyst, Section Managers, and Quality Manager are responsible for initiating corrective action when a nonconformance is found that could reoccur (beyond expected random QC failures) or where there is doubt about the compliance of the laboratory to its own policies and procedures. The Quality Assurance Manager is responsible for monitoring and recording corrective action.

All deficiencies are investigated and a corrective action plan is developed and presented at a QA meeting for effective corrective action. The corrective action is implemented if determined necessary in the Quality Assurance meeting. The team members can suggest further action or root cause determination and alternate implementation if needed.

The implementation is monitored for effectiveness. When satisfactory corrections have been made, the CAR is closed by being reviewed and signed off by the person initiating the CAR, the Quality Assurance Manager, and all members of the QA team.

The Quality Assurance Manager may utilize the laboratory's internal auditing process for follow-up monitoring of the corrective action and its effectiveness.

14.1.1 Cause Analysis

When failures due to systematic errors have been identified, the first step of the corrective action process is the initial investigation and determination of root cause(s) of the problem. The records are maintained on G: drive in the CAR folder and hard copies are maintained in a binder in the general office area. The nonconformance requires corrective action to show that the root cause(s) was investigated, and includes the results of the investigation.

When there are non-systematic errors where the initial cause is readily identifiable or expected random failures (e.g. failed quality control), a formal root cause analysis is not performed and the process begins with selection and implementation of corrective action (also see Section 14.3 "Technical Corrective Actions").

14.1.2 Selection and Implementation of Corrective Actions

Where uncertainty arises regarding the best approach for analysis of the cause of exceedances that require corrective action, appropriate personnel will recommend corrective actions that are appropriate to the magnitude and risk of the problem and that will most likely eliminate the problem and prevent a recurrence. The Section Manager ensures that corrective actions are discharged within 30 days or less.

14.1.3 Monitoring of Corrective Action

The Quality Assurance Manager and Section Managers will monitor the implementation of the CAR. The Quality Assurance Manager is responsible for the documentation of the corrective action and to ensure that the corrective actions are effective. The quality manager is responsible for closing and monitoring the CAR.

14.2 Additional Audits

Where the identification of nonconformances or departures from normal lab procedures cast doubt on the laboratory's compliance with its own policies and procedures or it is not compliant with drinking water certification and TNI regulations, the laboratory ensures that the appropriate areas of activity are audited in accordance with Section 17 – "Internal Audits" as soon as possible.

In many cases, the additional audits are follow-ups after the corrective action has been implemented to ensure it is effective. These are done when a serious issue or risk to the laboratory has been identified.

14.3 Technical Corrective Action

The sample data associated with a failed quality control check are evaluated for the need to be reanalyzed or qualified. Unacceptable quality control results are documented, and if the evaluation requires a cause analysis, the cause and solution are recorded (also see Section 12 – "Control of Nonconforming Environmental Testing Work"*).*

Analysts routinely implement corrective actions for data with unacceptable QC measures. First level correction may include re-analysis without further assessment. The test method SOP addresses the specific actions to take, which are then followed. Otherwise, corrective actions start with assessment of the cause of the problem.

Corrective actions for nonconformance that may reoccur (beyond expected random QC failures) or where there is concern that the laboratory is not in compliance with its own policies and procedures requires that a corrective action report using form 001 be completed (see Section 14.1).

QA team managers review corrective action reports and suggest improvements, alternative approaches, and procedures where they are needed. If the data reported are affected adversely by the nonconformance, the affected data is clearly identified in the report and the customer is notified.

Section 15
PREVENTIVE ACTION

Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

Preventive action includes but is not limited to:
The review of QC data to identify quality trends, regularly scheduled staff quality meetings to ensure staff is knowledgeable in quality procedures, review of client feedback to look for improvement opportunities, review of proficiency testing data to look for analytes that were nearly missed, annual managerial reviews, scheduled instrument maintenance, and internal audits.

When improvement opportunities are identified or preventive action is required, action plans are developed, implemented, and monitored to reduce the likelihood of the occurrence of nonconformities.

Procedures for preventive actions include the initiation of such actions and subsequent monitoring to ensure that they are effective.

All personnel have the authority to offer suggestions for improvements and to recommend preventive actions; however, management is responsible for implementing preventive action.

Section 16
CONTROL OF RECORDS

Records are a subset of documents, usually data recordings that include annotations, such as daily refrigerator temperatures posted to a laboratory form, lists, spreadsheets, or analyst notes on a chromatogram. Records may be on any form of media, including electronic and hard copy. Records allow for the historical reconstruction of laboratory activities related to sample-handling and analysis.

The laboratory maintains a record system appropriate to its needs, records all laboratory activities, and complies with applicable standards or regulations as required. Records of original observations and derived data are retained to establish an audit trail. Records help establish factors affecting the uncertainty of the test and enable test repeatability under conditions as close as possible to the original.

16.1 Records Maintained

Records of all procedures to which a sample is subjected while in possession of the laboratory are kept. The laboratory retains all original observations, calculations, and derived data (with sufficient information to produce an audit trail), calibration records, personnel records, and a copy of the test report for a minimum of five years from the generation of the last entry in the records. At a minimum, the following records are maintained by the laboratory to provide the information needed for historical reconstruction:

i) all raw data (hard copy or electronic) for calibrations, samples, and quality control measures, including analysts' worksheets and data output records (chromatograms, strip charts, and other instrument response readout records);

ii) a written description or reference to the specific method(s) used, which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value (a copy of all pertinent Standard Operating Procedures);

iii) laboratory sample ID code;

iv) date of analysis;

v) time of analysis is required if the holding time is seventy-two (72) hours or less, or when time-critical steps are included in the analysis (e.g., extractions and incubations);

vi) instrumentation identification and instrument operating conditions/parameters (or reference to such data);

vii) all manual calculations (including manual integrations);

viii) analyst's or operator's initials/signature or electronic identification;

ix) Sample preparation, including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, and reagents;

x) Test results (including a copy of the final report);

xi) Standard and reagent origin, receipt, preparation, and use;

xii) Calibration criteria, frequency, and acceptance criteria;

xiii) Data and statistical calculations, review, confirmation, interpretation, assessment, and reporting conventions;

xiv) Quality control protocols and assessment;

xv) Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;

xvi) Method performance criteria including expected quality control requirements;

xvii) Proficiency test results;

xviii) Records of demonstration of capability for each analyst;

xix) A record of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record;

xx) Correspondence relating to laboratory activities for a specific project;

xxi) Corrective action reports;

xxii) Preventive action records;

xxiii) Copies of internal and external audits including audit responses;

xxiv) Copies of all current and historical laboratory SOPs, policies, and *Quality Manual*s;

xxv) Sample receiving records (including information on any interlaboratory transfers);

xxvi) Sample storage records;

xxvii) Data review and verification records;

xxviii) Personnel qualification, experience, and training records;

xix) Archive records; and

xx) Management reviews.

SOP 0080 describes the data handling and storage process.

16.2 Records Management and Storage

The laboratory maintains a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage, and reporting. The data is recorded immediately and legibly in permanent ink (data generated by automated data collections systems is recorded electronically). Corrections are initialed and dated with the reason noted for all corrections other than transcription errors. A single line strikeout is used to make corrections so that the original record is not obliterated.

For the electronic records the LIMS system is able to track the changes to every table in the database by audit trail history. This includes sample login, sample results, reports, and customers' information.

The technical electronic records for the network drives are backed up to the state capital main server every day. The databases for LIMS and APPX are stored indefinitely in the system's databases.

Records, including electronic records, are easy to retrieve, legible, and protected from deterioration or damage; held secure and in confidence; and are available to accrediting bodies for a minimum of five years or as required by regulation or contract. The records that are stored only on electronic media are supported by the hardware and software necessary for their retrieval.

The laboratory Section Manager, or designee can access network backup electronic data records by filing a request through a helpline.

All the electronic quality documents are stored and organized by year in the document control folder on the G: drive. The hard copies are stored in the common office area in binders. Quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions.

All the hard copies of the analysis are stored on-site for 3- 5 years. The sample analysis records are sent to the state archive for storage for an additional ten years. See the Document form 053 for archive procedure at Chem & Env Services\Document Control\State Archives. All the QA records, including the sample-receiving request sheets, IDC/MDL, training record, instrument maintenance record, are kept for seven years. The process is in Sec 9 SOP 0080

Archived information and access logs are protected against fire, theft, loss, environmental deterioration, vermin, and in the case of electronic records and electronic or magnetic sources. Archived records have limited access and are checked out by the Archived manager through an access log.

In the event that the laboratory transfers ownership or goes out of business, records are maintained or transferred according to client instructions. Appropriate regulatory and state legal requirements concerning laboratory records shall be followed.

The Utah Public Health Lab follows the Utah Public Health Policy Number 13.28 for the Destruction, Disposal, and Reuse of Protected Health Information Media.

16.3 Legal Chain of Custody Records

Evidentiary sample data are used as legal evidence. Special handling procedures for evidentiary samples are performed for Sample Custody- Storage and Final Disposition.

16.3.1 Sample Receipt at the Laboratory

Upon arrival at the Utah Public Health Laboratory (UPHL) samples will be logged in and assigned a laboratory sample number, also known as the sample identification number. Inadequate or inappropriate samples will be noted and described upon receipt at the laboratory. The log entry recorded in the chain of custody record will show:

16.3.2 Sample Security
Ensuring the integrity of the Chain of Custody sample is of utmost importance. The number of individuals handling the sample must be kept to a minimum. The Chain of Custody Custodian or a designated alternate shall review the forms, tags, seals, and samples to see that all information described in Section 8.2 is completed. After the review and each entry have been addressed, the sample and paperwork will be placed in secure storage in sample receiving.

16.3.3 Samples to be analyzed for volatile compounds (Currently only THMs) will be stored in a refrigerated environment separate from the other samples. The sample storage area will remain locked at all times, to be opened only by the Chain of Custody Custodian or one of the designated alternates.

16.3.4 When an analyst needs a sample for testing, they must contact the Chain of Custody Custodian to arrange to check out the sample. The sample or portion of the sample will be released only to the responsible analyst, and by signature with date, time, and activity.

16.3.5 The analyst is responsible for the care and custody of the sample once it is released to them. They must be prepared to testify that the sample was in their possession and viewed or secured in the laboratory at all times from the moment it was released by the custodian until it was returned to the custodian.

16.3.6 The analyst must return the sample to the custodian or provide secure storage for the sample prior to leaving the area where the sample is being processed.

16.3.7 When the analyst has no immediate need for the sample it must be returned to the custodian and received by signature with date, time, and action.

16.3.8 Samples will be discarded after maximum holding times have been exceeded or after six months from the time of receipt unless otherwise directed by the client organization. The sample containers will be discarded following current laboratory disposal procedures found in the laboratory safety manual.

16.3.9 In order for the Utah Public Health Laboratory to demonstrate the reliability of its evidence for enforcement of action, it must be able to prove controlled possession of samples from receipt to discard.

16.3.10 An example of the Chain of Custody form can be found in Section 26.1.1.

Section 17
AUDITS

Audits measure laboratory performance and verify compliance with accreditation/certification and project requirements. Audits specifically provide management with an on-going assessment of the management system. They are also instrumental in identifying areas where improvement in the management/quality system will increase the reliability of data. Audits are of four main types: internal, external, performance, and system. Section 17.5 discusses the handling of audit findings.

17.1 Internal Audits

Annually, the laboratory prepares a schedule of internal audits to be performed during the year. These audits verify compliance with the requirements of the management/quality system, including analytical methods, SOPs, the *Quality Manual*, ethics policies, data integrity, other laboratory policies, and the TNI Standard and Drinking Water Standard.

It is the responsibility of the Quality Manager to plan and organize audits as required by the schedule and requested by management. These audits are carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

In addition to the scheduled internal audits, it may sometimes be necessary to conduct special audits as a follow-up to corrective actions, PT results, complaints, regulatory audits, or alleged data integrity issues. These audits address specific issues.

The area audited, the audit findings, and corrective actions are recorded. Audits are reviewed after completion to assure that corrective actions were implemented and effective. The Program Manager or Chief Scientist and Analyst are responsible for providing the corrective action response for the internal findings to the QA manager in a timely manner.

17.2 External Audits

It is the laboratory's policy to cooperate and assist with all external audits, whether performed by clients or an accrediting body. Management ensures that all areas of the laboratory are accessible to auditors as applicable and that appropriate personnel are available to assist in conducting the audit.

17.3 Performance Audits

Performance audits may be Proficiency Test Samples, internal single-blind samples, double-blind samples through a provider or client, or anything that tests the performance of the analyst and method.

Proficiency Test Samples are discussed in Section 27 – "Quality Assurance for Environmental Testing".

17.4 System Audits

The Laboratory's management system is audited through annual management reviews. Refer to Section 18 – "Management Reviews" for further discussion of management reviews.

17.5 Handling Audit Findings

Internal or external audit findings are responded to within the time frame agreed to at the time of the audit. The response may include action plans that could not be completed within the response time frame. A completion date is established by management for each action item and included in the response.

The responsibility for developing and implementing corrective actions to findings is the responsibility of related Section Managers. At the end of each year internal audit findings and corrective action are documented along with the internal audit reports.

Audit findings that cast doubt on the effectiveness of the laboratory operation to produce data of known and documented quality or that question the correctness or validity of sample results must be investigated. Corrective action procedures described in Section 14 – "Corrective Action" must be followed. The clients must be notified in writing if the

investigation shows the laboratory results have been negatively affected and the client's requirements have not been met. The laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work was involved.

All investigations that result in findings of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients. See Section 19 (Data Integrity Investigation) for additional procedures for handling inappropriate activity.

Section 18
MANAGEMENT REVIEWS

Top management reviews the management system on an annual basis and maintains records of review findings and actions.

18.1 Management Review Topics

The following are reviewed to ensure their suitability and effectiveness. The Management Report Audit (MRA) list includes the following topics:

- the suitability of policies and procedures;
- reports from managerial and supervisory personnel;
- the outcome of recent internal audits;
- corrective and preventive actions;
- assessments by external bodies;
- the results of inter-laboratory comparisons or proficiency tests;
- changes in the volume and type of the work;
- customer feedback;
- complaints;
- recommendations for improvement;
- other relevant factors, such as quality control activities, resources, and staff training.

18.2 Procedure

Management review audits (MRA) will occur annually.

A MRA will look at the policies, processes, and procedures used to ensure the quality of the data generated by the Utah Public Health Laboratory.

The MRA will evaluate the effectiveness of the QA system through a review of the QA committee meeting summaries, problem tracking log, corrective action reports, complaints, and QA Manager reports to the Laboratory Director.

The final report of the MRA will be discussed in the QA committee meeting and the documentation maintained by the Laboratory Director.

Findings and follow-up actions from management reviews are recorded. Management will determine appropriate completion dates for action items and ensure they are completed within the agreed-upon time frame.

Section 19
DATA INTEGRITY

In addition to covering data integrity investigations, this Section covers all topics related to ethics and data integrity policies, procedures, and training.

Utah Public Health Laboratory is committed to ensuring the integrity of its data and providing valid data of known and documented quality to its clients. The elements in Utah Public Health Laboratory's Ethics and Data Integrity program include:

- Documented data integrity procedures signed and dated by top management.
- An Ethics and Data Integrity Policy signed by all management and staff. This policy is signed, dated, and distributed to the employees by management.
- Annual data integrity training.
- Procedures for confidential reporting of alleged data integrity issues.
- An audit program that monitors data integrity (see Section 17 – "Audits") and procedures for handling data integrity investigations and client notifications.

19.1 Ethics and Data Integrity Procedures

The Ethics and Data Integrity Policy provides an overview of the program. Written procedures that are considered part of the Ethics and Data Integrity program include the following:

- Ethics and Data Integrity Policy (located directly below). Each employee signs the agreement at the time of new employee orientation.
- Manual integration procedures (SOP 100PR) that employees review and sign.
- Corrective action procedures (reference Section 14 of this *Quality Manual*).
- Procedures for Data Integrity Investigations (Appendix -E10).
- Data Integrity training procedures (Appendix -E9).

<u>Ethics and Data Integrity Policy</u>
This policy provides guidelines for making ethical decisions concerning the use and reporting of analytical data and supporting quality control information. This policy applies to all staff in the Utah Public Health Laboratory. These ethics standards encompass all activities performed in relation to the generation, recording, validation, reporting, and storage of laboratory data.
The guidelines are intended to assist analysts and supervisors in generating traceable, legally defensible data, and ensure that analysts and supervisors understand that they are expected to follow high ethical standards.

UTAH PUBLIC HEALTH LABORATORY ETHICS STATEMENT:
The UPHL is committed to generating traceable, legally defensible data. The UPHL's commitment is to ensure the integrity of all our data. All employees are expected to perform their work in an honest and ethical manner.

PROCEDURE:
To implement this Quality Assurance Policy on *Ethics and Data Integrity,* the UPHL shall:

1. Distribute this statement to all UPHL employees and new employees. The personnel must review and sign the ethics agreement and participate in the annual ethics training.
2. Implement training for employees and new hires. This training will include giving examples of acceptable and unacceptable laboratory practices.
3. Require employees to sign an *Ethics and Data Integrity Agreement* as a condition of employment.

4. Describe procedures and responsibilities for reporting and investigating possible ethics violations.
5. Provide points of contact within the UPHL for assisting employees with questions on laboratory ethics and related policies.
6. All laboratory employees are required to follow the guidelines of the *Ethics and Data Integrity Program.*
7. Noncompliance with the policy will result in disciplinary action that may include termination of employment.

Management reviews data integrity procedures yearly and updates these procedures as needed.

19.2 Training

Data integrity training is provided as a formal part of new employee orientation and a refresher is given annually for all employees. The employees are required to understand that any infractions of the laboratory data integrity procedures shall result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment, or civil/criminal prosecution. This is discussed in the Ethics and Data Integrity Policy. Every employee is required to attend required training and is monitored through a signature attendance sheet.

An agenda is provided to each trainee prior to the training class. Data integrity training emphasizes the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient. The following topics and activities are covered:

- organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting;
- how and when to report data integrity issues;
- record keeping;
- training, including discussion regarding all data integrity procedures;
- data integrity training documentation;
- in-depth data monitoring and data integrity procedure documentation; and
- specific examples of breaches of ethical behavior such as improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards.

When contracted technical or support personnel are used, the Laboratory Chief and Section Manager are responsible for ensuring that they are trained to the laboratory's management system and data integrity procedures, competent to perform the assigned tasks, and appropriately supervised. SOP 058 for ethics training for new employees.

Topics covered are provided in writing to all trainees.

19.3 Confidential Reporting of Ethics and Data Integrity Issues

Confidential reporting of data integrity issues is assured through maintaining an *Open-Door Policy* to encourage two-way communications. Managers should create an atmosphere where employees feel comfortable in discussing sensitive work-related issues.

19.4 Investigations

All investigations resulting from data integrity issues are conducted confidentially. They are documented and notifications are made to clients who received any negatively affected data that did not meet the client's data quality requirements.

Section 20
PERSONNEL

Utah Public Health Laboratory employs competent personnel based on education, training, experience, and demonstrated skills as required. The laboratory's organization chart can be found in Appendix B.

20.1 Overview

All personnel are responsible for complying with all quality and data integrity policies and procedures that are relevant to their area of responsibility.

All personnel who are involved in activities related to sample analysis and evaluation of results or who sign test reports must demonstrate competence in their area of responsibility. Appropriate supervision is given to any person in training, and the trainer is accountable for the quality of the trainee's work. Personnel is qualified to perform the tasks they are responsible for based on education, training, experience, and demonstrated skills as required for their area of responsibility.

The pre-screen process includes a review of their qualifications, including education, training, and work experience, to verify that they have adequate skills to perform the tasks.

20.2 Job Descriptions

The Laboratory Director, Chief Chemist, Program manager, QA manager, Section Managers, Analysts, and sample receiving staff are responsible for the quality of work produced. The QA team is comprised of the Laboratory director, Environmental Chemistry Program QA manager, Section Managers, Analysts, and the sample-receiving technicians who have specific roles in assuring implementation of the Quality System. Job descriptions are available for all positions that manage, perform, or verify work affecting data quality. An overview of top management's responsibilities is included in Section 5 – "Management".

20.2.1 Analyst QA/QC responsibilities

Responsible for quality control implementation for methods assigned. Participate in the improvement of the QA/QC program plan.

Performs analytical procedures and data recording in accordance with SOPs that have been approved by the Chief Chemist, Program Manager, and QA manager.

Performs data processing and data verification.

Initiates appropriate corrective action for out-of-control situations, such as instrument malfunction, calibration failure, contamination, or any other non-conformance as appropriate. The Reports persistent or recurring out-of-control situations to the Section Manager. All communications and information, including data collected during a Corrective

Action Investigation, must be archived. The analyst and/or the QA manager will accomplish this by storing images of hardcopy and records of e-mail files.

Assists with sample disposal as assigned.

Assists in training new staff and in cross-training staff. Reports errors and problems to Section Manager. Performs routine maintenance of instruments, performs scheduled instrument maintenance, maintains instrument logbook. Writes and updates SOPs.

20.2.2 Sample Receiving responsibilities

Promptly logs samples into the computer. Maintains a review system to ensure correct entry. Contacts the appropriate Section Manager or designee for assistance as needed, such as for non-routine samples, rush samples, and samples from special projects.

Notifies the Section Manager or designee of rush or high priority samples upon arrival in the lab. Delivers to the lab or analyst the samples and a copy of the request forms as soon as possible after sample receipt.

For chain of custody samples, a copy of the chain of custody form must be given to the analyst or Section Manager. Must keep the chain of custody refrigerator organized so that samples may be easily retrieved. The request sheets are also scanned and maintained in the BMI database.

Samples with very short holding times (48 hours or less) must be logged in as soon as possible and delivered to the labs within two hours of receiving them. Turbidity, pH, Temperature, TDS, TSS, TVS, Heterotrophic plate count (HPC), Total & Fecal Coliforms by membrane filtration, Total Coliform and E.coli by Colilert samples fall in this group. HPC samples (drinking and surface water) and SWTR source water compliance samples have the shortest holding time. HPC samples must be delivered immediately to the analyst or refrigerated in the sample receiving area, with a message to the analyst that samples have been received and are ready for analysis.

BOD sample bottles must be delivered immediately to the analyst. If the analyst is not in the building, the sample should be refrigerated in the sample receiving area with a message to the analyst that the sample has been received, and is ready for analysis.

One member serves on the QA team.

Writes SOPs and updates sample receiving SOPs.

20.2.3 LIMS Staff responsibilities

Whenever a change is made in a LIMS system, the programmer will document the change made in the program code. The Program Manager will notify all LIMS users of the effects of the change by email.

All LIMS program changes, requested by the users, must be pre-approved by the laboratory director or his/her designee.

The computer programmer will assist in training new analysts. They will also assist in training analysts when changes are made in the LIMS programs. The computer programmer will assist analysts section managers in solving computer program problems.

20.3 Training

All personnel are appropriately trained and competent in their assigned tasks before they contribute to functions that can affect data quality. It is management's responsibility to ensure personnel are trained. Training records are used to document management's approval of personnel competency. The date on which authorization and/or competence is confirmed is included.

20.3.1 Training for New Staff

New staff members are given the following training:

Newly hired employees receive orientation training beginning the first day of employment by the Company. Orientation training consists of initial health and safety training including general laboratory safety, personal protection, and building evacuation. Orientation also includes quality assurance program training, data integrity training, and an overview of the Company's goals, objectives, mission, and vision.

All technical staff receive training to develop and demonstrate proficiency for the methods they perform. New analysts work under supervision until the supervisory staff is satisfied that a thorough understanding of the method is apparent and proficiency has been demonstrated through a precision and accuracy study that has been documented, reviewed, and approved by the Section Manager. Data from the study is compared to method acceptance limits. If the data is unacceptable, additional training is required. The analyst may also demonstrate proficiency by producing acceptable data through the analysis of an independently prepared proficiency sample.

20.3.2 Ongoing Training

Staff members are given the following ongoing training:

After completion of training, the laboratory management will continue to provide supervision by someone who is familiar with the test methods and procedures, the objective of the calibration or test, and the assessment of the results for the tests being performed.

Individual proficiency is demonstrated annually for each method performed for methods that are applicable to precision and accuracy studies. Data from initial and continuing proficiency demonstrations are kept in the workstation binder and in the individual's training folder for five years. Ongoing and Initial Demonstration of Capability is described in sec 27.4

Section 21
ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS

21.1 Environmental

The laboratory facility is designed and organized to facilitate the testing of environmental samples. Environmental conditions are monitored to ensure that conditions do not invalidate results or adversely affect the required quality of any measurement. Such environmental conditions, including humidity, voltage, temperature, and light, are controlled and managed by DFCM.

Environmental tests are stopped when the environmental conditions jeopardize the results. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests.

21.2 Work Areas

Work areas may include access and entryways to the laboratory, sample receipt area, sample storage area, sample process area, instrumental analysis area, chemical and waste storage area, and data handling and storage area.

Access to and use of areas affecting the quality of the environmental tests is controlled by restriction of areas to authorized personnel only. See Section 21.4 below.

All the parts of the laboratory should be appropriately cleaned to support environmental testing and ensure an unencumbered work area. The Section Managers and Analysts are responsible for keeping the laboratory area clean to avoid contamination.

The laboratory space is arranged to minimize cross-contamination between incompatible areas of the laboratory.

21.3 Floor Plan

A floor plan can be found in Appendix C.

21.4 Building Security

The laboratory is kept secure during all hours; only the authorized personnel can access the laboratory.

A Visitor's Logbook is maintained for every visitor to sign in and out. The visitors must be accompanied by laboratory personnel at all times when they are in the laboratory areas.

While in the facility, visitors are required to wear a visitor's badge and must be accompanied by their hosts at all times.

Section 22
ENVIRONMENTAL METHODS AND METHOD VALIDATION

Methods and/or procedures are available for all activities associated with the analysis of the sample, including preparation and testing. For purposes of this section, "method" refers to both the sample preparation and determinative methods.

Before being put into use, a test method is confirmed by a demonstration of capability or method validation process. All methods are published or documented. Deviations from the methods are allowed only if the deviation is documented, technically justified, authorized by management, and accepted by the customer. Methods are listed in Appendix H.

22.1 Method Selection

A reference method is a method issued by an organization generally recognized as competent to do so. (When ISO refers to a standard method, that term is equivalent to a reference method.) When a laboratory is required to analyze a parameter by a specified method due to a regulatory requirement, the parameter/method combination is recognized as a reference method.
The laboratory will use methods that meet the needs of the customer. Such methods will be based on the latest edition of the method unless it does not meet the needs of the customer. The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.

22.2 Method Validation

The reference methods are validated by performing an initial demonstration of capability, and additional requirements are discussed for each method and technology.

Standard methods from regulatory sources are primarily used for all analyses. Validation is also performed for standard methods applied outside their intended scope of use. Validation is dependent upon the method application and may include analysis of quality control samples to develop the precision and accuracy of the information for the intended use. A final method validation report is generated, which includes all data in the validation study.

Non-standard methods are validated prior to use. This includes the validation of modified standard methods to demonstrate comparability with existing methods. Demonstrations and validations are performed and documented prior to incorporating technological enhancements and nonstandard methods.

Method validation and Demonstration of Capability procedures can be found in each laboratory with the method workstation binders. See Method Check list Form 042.

22.3 Estimation of Analytical uncertainty

Analytical Uncertainty: A subset of uncertainty measurement that includes all laboratory activities performed as part of the analysis. UPHL is not providing the measurement of uncertainty for the data reported to the customers.

22.4 Data Reduction

Data Handling and reporting SOP 0080
The analyst calculates final results from raw data, or appropriate computer programs provide the results in a reportable format. The test methods provide required concentration units, calculation formulas, and any other information required to obtain final analytical results

The laboratory has manual integration procedures that must be followed when integrating peaks during data reduction. The laboratory's manual integration policy is outlined in the manual integration SOP.

All raw data must be retained, and is maintained as described in Section 16 – "Control of Records." To ensure that data are protected from inadvertent changes or unintentional destruction, the laboratory uses data transfer processes (both manual and automated) and procedures to check calculations.

22.5 Data Review Procedures

Data review procedures are located in Section 27.8 – "Data Review."

Section 23
CALIBRATION REQUIREMENTS

23.1 General Equipment Requirements

The laboratory provides all the necessary equipment required for the correct performance of the scope of environmental testing performed by the laboratory.

All equipment and software used for testing and sampling are capable of achieving the accuracy required for complying with the specifications of the environmental test methods as specified in the laboratory SOPs.

Equipment is operated only by authorized and trained personnel (see Section 20 – "Personnel").

The laboratory has procedures for the use, maintenance, handling, and storage of equipment, and they are readily available to the laboratory. Manuals provided by the manufacturer of the equipment provide information on use and maintenance; handling and storage information for the equipment are stored in the laboratory by the instruments.

The procedures ensure the proper functioning of the equipment and prevent contamination or deterioration. The instrument maintenance logs are kept with the instruments in the work area.

All equipment is calibrated or verified before being placed in use to ensure that it meets laboratory specifications and relevant standard specifications.

Test equipment, including hardware and software, are safeguarded from adjustments that would invalidate the test result measurements by limiting access to the equipment and using password protection where possible.
The equipment is isolated to prevent its use or is clearly labeled as being out of service until it has been shown to function properly. If it is shown that previous tests are affected, then procedures for nonconforming work are followed, and results are documented (see Section 12 – "Control of Nonconforming Environmental Testing Work" and Section 14 – "Corrective Action").

Each item of equipment and software used for testing, and/or are significant to the results is uniquely identified. Records of equipment and software are maintained. This information includes the following:

a) identity of the equipment and its software;

b) manufacturer's name, type identification, serial number, or other unique identifier;

c) checks that show equipment complies with specifications of applicable tests;

d) manufacturer's instructions, if available, or a reference to their location;

e) dates, results, and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;

f) documentation of all routine and non-routine maintenance activities and reference material verifications;

g) any damage, malfunction, modification, or repair to the equipment; and

h) date received and date placed into service (if available).

i) An updated equipment list is on G: drive. Instruments that are under a service contract are also on G: drive

j) Service engineers perform all updates on software and hardware.

23.1.1 Inorganic Section Equipment List

This list, along with lists for other subtypes (organic, metals, and water micro) can be found on the following pages.

Test	**Equipment Name or ID**	**Serial Number**	**Alternate (Manufacturer) Serial Number**	**Room Number**	**Installation Date**	**Note**
Conductivity	Thermo Scientific ORION STAR A212 (Meter)	X44800		238B		
	Thermo Scientific ORION 013005MD (Probe)	WS-10034				
TSS/TDS	Mettler Balance AE200	I17558				
Turbidity	HACH 2100AN Turbidimeter	9604000757				
TVS	Thermo Scientific Thermolyne Muffle Furnace Model # F48028	0150331001120326				
PO4	Tuttnauer Brinkmann Heidolph 2340M Autoclaves	#1: 1102549 #2: 1101644				
Total Cyanide	Lachat Micro Dist A17102	190400002339			4/25/19	
TDS	Emerson Pump Model: SA55NXGTB-4142 0323V4BG18DX	0194				
TDS	180º Oven Fisher Scientific Model #06916 (Oven 1)	#1: 611945-319				

	180º Oven Fisher Scientific Model # 825F (Oven 2)	#2: 407N0042				
BOD	HACH HQ440d multi (Meter)	190400015954		238A	4/26/19	
	HACH LBOD101 (Probe)	190943039554			4/26/19	
TSS	104º Ovens VWR Model # 1330GM	#1: 0400503		238B		
		#2: 05102706				
COD	HACH DRB200 Dryblock LTV082.53.400 01	13100C0028		232A		*We don't use it anymor e*
Sulfide/Residu al Chlorine	HACH UV DR3900	1514314				
Balance	OHAUS GT 410	2425				
Ion Chromatograp hy	Thermo Scientific DIONEX ICS 1100 #1	11071294				
	Thermo Scientific DIONEX Autosampler AS-DV	11080153				
	Thermo Scientific DIONEX ICS 1100 #2	12031316				
	Thermo Scientific DIONEX Autosampler	11080155				
Hexavalent Chromium	Thermo Scientific DIONEX ICS 1100 #3	11071295				
	Thermo Scientific Autosampler AS-DV	12040050				

	Thermo Scientific Detector-DIONEX VWD	12040098				
	Thermo Scientific DIONEX Auxiliary Pump AXP	V10PFT03DX2				
Flow Injection Analysis	Lachat QuickChem 8500 Series 2	#1: 140100001624				
		#2: 140100001623				
		#3: 191100002258			11/18/19	
		#4: 190400002221			4/15/19	
		#5: 191100002259			11/18/19	
		#6: 130600001554				
	Lachat Autosampler ASX 520 Series	#1: 140100002229	#1:101395A520			
		#2: 140100003228	#2:091394A520			
		#6: 130500002197	#6:041398A520			
	Lachat Instruments XYZ autosampler ASX - 560	#3: 101953A560			11/18/19	
		#4: 121872A560			4/15/19	
		#5: 101949A560			11/18/19	
	Lachat Reagent Pump Model RP-150 Series ISM1135	#1: 416836-2				
		#2: 478429-1				
		#3: J19000530			11/18/19	
		#4: L18002855			4/15/19	
		#5: J19000598			11/18/19	
		#6: 423580-2				
pH	Thermo Scientific Orion Dual Star	03653				

	pH/ISE Benchtop					
Chlorophyll A	Shimadzu UV-1601 UV254	700009				*This is for Organic lab. Not checked .*
TOC	Total Organic Carbon Analyzer Model TOC VCSH Shimadzu	H51104335110CS	638-91062-22 (Part#)			
	Shimadzu Autosampler ASI-V model # ASI SA24, 40 mL E	H52104301337SA	638-93140-02 (Part#)			
Alkalinity	Mettler Toledo Titrator T50	B201599522	51109020			
	Autosampler Rondo Tower	B204642394	51108201			
TKN	Westco Scientific Instruments Easy Distillation	1159		232A		We don't use these anymore
	AIM LAB AIM 600 Digestion System Controller	5008A15178				
	AIM 600 Block	5008A15175				
Refrigerators	Frost Environmental Rooms Inc.	F65597201		232		
	Fisher Scientific Isotemp Plus Model # MR7255-GAEE-FS	121358361130304				

23.1.2 Organic Section Equipment List

Instrumentation & Equipment					

Organic Section				**Install Date/ Age**
Rm 235	REFRIG/FREEZE	Thermo Refrigerator		
		Fisher Explosion-Proof Refrig/Freezer		
Rm 235B	GC-ECD (REX)	Agilent 7890A GC		2014 5 yrs
		Agilent 7693 Autosampler		
	GC-ECD (CODY)	Agilent 6890N GC		2000 19 yrs
		Agilent 7683 Autosampler		
	Gilson 215 SPE System w/ MiniPULS3			
Rm 235C	HPLC-QQQ (FERB)	Agilent 1200 Degasser Model# G1379B		2011 8 yrs
		1260 Infinity Binary Pump – Model# G1312B		
		1200 Series Thermostatted Column Compartment – Model# G1316B		
		1260 Infinity High Performance Autosampler – Model# G1367E		
		1200 Series Autosampler Thermostat – Model# G1330B		
		6400 Series Triple Quadrupole LC/MS System with ESI – Model# G6460A Mass Hunter Workstation Software: LC/MS Data Acquisition for 6400 Series Triple Quadrupole, Version B.06.00, Build 6.0.6025.3 SP3 Qualitative Analysis, Version B.06.00, Build 6.0.633.0 Quantitative Analysis, Version B.05.02, Build 5.2.365.0 for QQQ		
	GC-MS (PHIN)	Agilent 5975 MS	US52431021	N/A
		Agilent 6890 GC	CN10539010	
		Agilent 7683B Autosampler		
	GC-MS (8260/Tet)	Agilent 5975C MS	US10313609	N/A
		Agilent 7890A GC	CN10281170	
		Agilent 7693 Autosampler		

	GC-FID (TPH)	Agilent 6890 GC	CN10437069		N/A
		Agilent 7683B Autosampler			
	GC-ION TRAP (525)	Varian 431-GC	GC1004B511		N/A
		Varian 220-MS	MS1006W033		
		Varian CP-8400 Autosampler			
	HPLC Carbamate System	Waters 2695 Separations Module			2010 9 yrs
		Waters 2475 Multi λ Fluorescence Detector			
		Waters Post Column Reaction Module			
		Waters Temperature Control Module II			
		Waters Reagent Manager x2			
	UV-VIS	Beckman DU 520 General Purpose UV-VIS Spectrophotometer w/ Single-cell Module			<2004 >15 yrs
	BALANCE	OHAUS Explorer Balance			
	ELISA	Abraxis CAAS Model# 2925	1056		2018 1 yrs
Rm 241	REFRIG/FREEZE	Fisher Isotemp Refrigerator			
		Thermo Scientific Freezer x2			
		Fisher Explosion-Proof Refrigerator			
Rm 241A	BALANCE	Mettler Toledo PB303 Balance			
	SONICATOR	Branson Sonifier 450			
	CONCENTRATOR	Zymark TurboVap II x2			
	EXTRACTOR	Dionex ASE 200 Accelerated Solvent Extractor			
	MIXERS	VWR Vortexer x2			
		Fisher Vortex Mixer			
		VWR Orbital Shaker			
		Eberbach Shaker			
	CENTRIFUGE	VWR Clinical 200			

Rm 241 B	REFRIG/FREEZE	Fisher Isotemp Refrigerator x4			
Rm 243	REFRIG/FREEZE	Fisher Isotemp Refrigerator			
		Baxter Explosion-Proof Cryo-Fridge			
	WATER SYSTEM	Barnstead 18 MW Organic-Free Water System			
Rm 243A	GC-MS P&T (524.3)	Agilent 6890N GC		Not In Use	
		Agilent 5975 MS			
		OI Analytical Eclipse 4660 P&T			
		OI Analytical 4551-A Autosampler			
		OI Analytical 4551-A Sample Cooler			
Rm 243B	GC-MS P&T (8260)	Agilent 6890 GC	US00035135		<2004 >15 yrs
		Agilent 5973N MS	US01160197		
		Atomx P&T	US14080003R		2016 3 yrs
	GC-MS P&T (524.2)	Agilent 7890A GC	CN10111193		2010 9 yrs
		Agilent 5975C MS	US10103010		
		OI Analytical Eclipse 4660 P&T	F141459082		
		OI Analytical 4551-A Autosampler			
		OI Analytical 4551-A Sample Cooler			

23.1.3 Metals Section

Test Used For	**Equipment ID and Name**	**Serial Number**	**Alternate (Manufacturer) Serial Number**	**Room Number**	**Install Date/ Age**
General	Branson Ultrasonic 8510			230	
6010/6020/200.7 200.8	CPI International MOD Block	#1: 000228 1211	SYST-0530-0000	230	
General	Mettler Toledo AX205 Balance	1122193408		230	
General	Mettler Toledo MS303TS	B519903696	48.28.3.3383.1564	226	
Hg	Thermo Scientific Precision Water Bath Model 2841	185631-1585		226	

200.7	Thermolyne 2200 Hotplate Model HPA2235M	237990871381		226	
200.8	Perkin Elmer ELAN DRC II w/ Autosampler AS 93 plus	A100720510		Surplus	
	Polyscience Recirculator Model 3370	G53189		Surplus	
200.7/6010	Thermo Fisher iCAP 7400	IC74DU0322		226A	8/7/19 <1 yrs
	ThermoFlex CMD Recirculating Chiller	112262390119052 9		226A	
	ASX-280 Autosampler	061501A280		226A	
Se by AA	Perkin Elmer PinAAcle 500 Atomic Absorption Spectrophotome r	P5PS18041802		226A	2018 1 yrs
	Perkin Elmer FIAS 100	100S5060707		226A	
200.8	Agilent Technologies 7700 Series ICP-MS	JP12402067		226A	2012 78yrs
	ASX 500 Series ICP-MS Autosampler Model # G3286A	US081237A520		226A	
Hg	Perkin Elmer FIMS 100 Hg Analysis System with Autosampler S10	101S13030202		226A	2005 14 yrs
	Perkin Elmer FIMS 100 Hg Analysis System with Autosampler AS90	101S5020201		226A	
200.8/UCMR3	Perkin Elmer Elan DRC-e	W1200409		226C	2004 15 yrs
	Polyscience Recirculator	G39432		226C	

	Model #3370				
Reagent Water	Continental Water Systems Inc. ModuLab Modupure Model # LEHPU 10 1002	90031		226A	
General	Precisa Instruments Inc. Precisa XB220A	10273		226A	
Hg in solids	Teledyne Hydra II	US19081005		226	7/30/19 <1 yrs

23.1.4 Water Micro

Water Micro Section									
Rm 354	MIXER/SHAKER	Vortex-Genie Mixer x2							
		PALL Gelman Laboratory Shaker							
		Dynal Rotamix							
		Thermolyne Maxi Mix Plus							
	REFRIG/FREEZE	Marvel Mini-Freezer							
		Fisher IsoTemp Refrigerator							
	INCUBATOR	Thermo Scientific Precision Incubator x4							
		Fisher IsoTemp CO2 Incubator							
	WATERBATH	Thermo Precision Waterbath							
	MISCELLANEOUS	IBS Fireboy Plus							
		LEICA Quebec Darkfield Colony Counter							
		Quanti-Tray Sealter Model 2X (IDEXX)							
		Lab-Line Instruments Slide Warmer							
		Sorvall Rc3C Plus Centrifuge							
		Branson 1510							

			Sonicator				
Rm 353B	MISCELLANEOUS		Accumet AB15 pH Meter				
			Precision Scientific Waterbath				
			New Brunswick Scientific Model DP200 Programmable Dispensing Pump				
			Autoclave (Bio-Med Engineering)				
			Fisher IsoTemp Refrigerator				

23.2 Support Equipment

Support Equipment includes but is not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices, and volumetric dispensing devices.

All support equipment is maintained in proper working order. Records are kept for all repair and maintenance activities, including service calls.

All raw data records are retained to document equipment performance. These records include logbooks, datasheets, or equipment computer files.

23.2.1 Support Equipment Maintenance

Regular maintenance of support equipment like balances, ovens, refrigerators, freezers, incubators, water baths, and pH meters is conducted annually by the QA balance company.

Records of maintenance for support equipment are documented in the QA manager's file. A sticker is posted on the instrument serviced. Each piece of support equipment does not necessarily have its *own* logbook but must be documented. Maintenance logbooks may be shared with equipment that is housed in the same laboratory area.

Table 23-1 Summary of Support Equipment Calibration And Maintenance

Instrument	Activity	Frequency	Documentation
Balance	1. Clean 2. Check alignment 3. Service contract	1. Before use 2. Before use 3. Annually	Log book Post annual service date on balance
ASTM Class 1 Weights	1. Only use for the intended purpose 2. Use plastic forceps to handle 3. Keep in case 4. Re-calibrate	1. Every year if weight is used for daily checks 2. Every 5 years if weight is used only to check working standard	Keep certificate

Table 23-1 Summary of Support Equipment Calibration And Maintenance			
Instrument	**Activity**	**Frequency**	**Documentation**
		weights which are then used for the daily checks	
NIST Traceable Thermometer	Use to certify in house thermometers	Every 5 years	Keep certificate
Thermometers: 1. Glass and electronic 2. IR thermometer	Check at the temperature used against a reference NIST certified thermometer	1. Annually for glass and electronic 2. Quarterly for dial and IR thermometers	Calibration factor and date of calibration on thermometer and worksheet/log book
pH meters	Calibration: 1. pH buffer aliquot are used only once 2. Buffers used for calibration will bracket the pH of the media, reagent, or sample tested	Before use	Log book
pH probe	Maintenance: Use manufacturer's specifications	As needed	Log book
photometer	1. Keep cells clean 2. Service contract. Check wavelength settings with color standards	Annually	Post service date on balance
Automatic or digital type pipettes	Calibrate for accuracy and precision using reagent water and analytical balance	Quarterly	Logbook binder
Refrigerators, Freezers, and BOD incubators	1. Thermometers are immersed in liquid to the appropriate immersion line 2. The thermometers are graduated in increments of 1°C or less	Temperatures are recorded each day in use	Log book
Sterilizer	1. Use spore strips or ampoules 2. Maintenance of autoclave by service contract	1. One sterilizing cycle per month 2. Once per year	Log book in Water Micro section

Table 23-1 Summary of Support Equipment Calibration And Maintenance			
Instrument	**Activity**	**Frequency**	**Documentation**
Microbiological incubators and water baths	1. Thermometers in each unit are immersed in liquid to the appropriate immersion line 2. The thermometers will be graduated in increments of 0.5°C (0.2°C increments for tests which are incubated at 44.5°C) or less	Temperature of incubators and water baths will be recorded twice a day for each day in use with readings separated by at least four hours	Worksheet/log book

23.2.2 Support Equipment Calibration

Calibration requirements for analytical support equipment are in Tables 23-3 and 23-4.

All support equipment is calibrated or verified annually over the entire range of use using NIST traceable references where available. The results of the calibration of support equipment must be within specifications or: (1) the broken equipment is removed from service until repaired, or (2) records are maintained of correction factors to correct all measurements. If correction factors are used, this information is clearly marked on or near the equipment. Any balance or pipette not in use should be removed from the lab and should have a sticker designating that it is not in use.

The calibration of balances used in the Lab should be checked on the day of use. All balances are provided with a balance log book/binder that is kept with the balance in the lab. The calibration check of the balance on the day of use must be documented. The same procedure also applies to the pipette calibration. The annual and quarterly pipette calibration checks should be maintained in the pipette calibration binder in the lab.

Mechanical devices shall be verified prior to first use and on a quarterly basis; mechanical devices used at more than one volume shall be verified at volumes bracketing the range of use and at the mid-point of the volumes used by the device; On each day of use, the following equipment, balances, ovens, refrigerators, freezers, incubators, and water baths, shall be checked and documented. The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.

Volumetric dispensing devices (except Class A glassware and glass microliter syringes) are checked for accuracy on a quarterly basis.

Records of temperature for thermometer checks for fridges and ovens are maintained in each laboratory, including:

- initial performance of the autoclave functional properties (supplied by the installer);
- temperature demonstration of sterilization continuous monitoring device or maximum registering temperature;
- every cycle, record date, contents, the maximum temperature reached, pressure, time in sterilization mode, total run time, and analyst initials;

- annual maintenance check to include a pressure check and calibration of temperature device.

For microbiology analyses, the following additional records can be found in Appendix I.

Table 23-2 Calibration Acceptance Criteria for Support Equipment

Equipment	Type of Calibration/ Number of Standards	Frequency	Acceptance Limits	Corrective Action
Analytical Balance	Accuracy determined using accredited NIST weights Minimum of 2 standards bracketing the weight of interest Inspected and calibrated by accredited person annually	Daily or prior to use	± 0.2%	Clean, check level, insure lack of drafts, and once unit is warmed up, recheck. If it fails, call service
Minimum-Maximum Thermometers	Against NIST-traceable thermometer	Yearly	±2 °C	Replace
InfraRed Temperature Guns	Against NIST-traceable thermometer	Quarterly at appropriate temperature range for intended use	± 2°C	Repair/replace
Volumetric Dispensing Devices (Eppendorf ® pipette, automatic dilutor or dispensing devices)	One delivery by weight. Using DI water, dispense into tared vessel. Record weight with device ID number	Quarterly	± 2% Calculate accuracy by dividing weight by stated volume times 100 for percent	Adjust Replace

23.3 Analytical Equipment

23.3.1 Maintenance for Analytical Equipment

All equipment is properly maintained, inspected, and cleaned.

Maintenance of analytical instruments and other equipment may include regularly scheduled preventive maintenance or maintenance on an as-needed basis. All instrument maintenance and malfunctions are documented in logbooks in each laboratory by the instruments on the bench area.

This becomes part of the laboratory's permanent records. A description of what was done to repair the malfunction and proof of return to control are also documented in the

maintenance log. All instrument maintenance contracts are maintained on G drive at the location G:\Bureau of Chem & Env Services\Contracts-Instruments

23.3.2 Instrument Calibration

Initial instrument calibration and continuing instrument calibration verification are an important part of ensuring data of known and documented quality. If more stringent calibration requirements are included in a mandated method or by regulation, those calibration requirements override any requirements outlined here or in laboratory SOPs. Generally, procedures and criteria regarding instrument calibrations are provided in the Method SOPs. All equipment used that affect the quality of test results are calibrated prior to use and on a continuing basis (see Section 23 – "Calibration Requirements").

All instruments are calibrated according to the reference method requirement.
If there is no method requirement listed in the reference method the laboratory uses R^2 $\geq$.990 for the curve fit.

Section 24
MEASUREMENT TRACEABILITY

Measurement quality assurance comes in part from the traceability of standards to certified materials.

Reagents – All reagents used at Utah Public Health Laboratory must be documented upon arrival and upon opening so that analyses may be tracked to particular containers of reagents. They must be stored in such a manner as to maintain their integrity. Each section must keep a certificate of purity and must be traceable to the vendor and certificate of analysis.

Standards – All standards must be documented upon arrival. Each individual standard used in the laboratory must be traceable to the vendor and certificate of analysis. The standards must be stored in such a manner as to maintain their integrity according to manufacture instructions. Additionally, all preparations of standards must be documented.

Chemical Purity (grade of the chemical)

- Highest purity: Analytical Reagent grade, Spectral grade, HPLC
- Trace Grade: Highest purity for trace analysis GC/MS and ICP/MS analysis
- Good Purity: (ACS Grade)
- Low Purity: Laboratory grade, Technical grade

Utah Public Health Laboratory uses reagent grade chemicals and reagents for analysis as specified in the SOP methods. For some trace analysis, trace grade chemicals are used.
A list of suppliers is maintained for ordering from SharePoint. Supplies and services that affect the testing are evaluated by performing PT sample analysis and performance of second source QC samples results.

24.1 Reference Standards

Reference standards, such as ASTM Class 1 weights, are calibrated by an entity that can provide traceability to national or international standards. The following reference standards are sent out to be calibrated to a national standard as indicated in Section 23 – "Calibration Requirements"—currently, *QA balance* checks weights annually and provides the certificate.

- Class 1 weight. NIST traceable reference thermometers
- Pipette calibration

24.2 Reference Materials
Reference materials, where commercially available, are traceable to national standards of measurement, or to Certified Reference Materials, usually by a Certificate of Analysis.

24.3 Transport and Storage of Reference Standards and Materials
The laboratory handles and transports reference standards and materials in a manner that protects the integrity of the materials. Reference standard and material integrity is protected by separation from incompatible materials and/or minimizing exposure to degrading environments and to prevent cross-contamination.

Reference standards and materials are stored according to the manufacturer's recommendations, method SOP requirements, and separately from samples.
All standards and reference materials are stored according to the manufacture's storage conditions and reference method SOPs.

24.4 Reference Standards, Reference Materials, and Reagents
The laboratory maintains records for all standards, reagents, reference materials, and media, including the manufacturer/vendor date of receipt (If applicable)

24.4.1 <u>Labeling of Stock Standards, Reagents, Reference Materials, and Media</u>
When the chemical is received analyst must keep the Certificate of Analysis. Keep all Certificates of Chemicals and Standards in binders in each laboratory. All reagents and chemicals are recorded in reagent logbooks. All reagents and chemicals are given Unique ID# when documenting in the reagent book.

The records for Reagents and Standard Log Books should include

- ☐ Name of the reagent
- ☐ All standards and reagents will have a Control or ID number. This can be given by Log Book #, Page #, and line # for unique ID, or can be generated from LIMS ID
- ☐ Manufacturer's LOT
- ☐ Vendor
- ☐ Date of receipt
- ☐ Date of opening
- ☐ Manufacturer's expiration date (if no dry reagent – six years after receipt; solutions – one year after preparation or opening)
- ☐ Storage Instruction (consult the label for proper storage)
- ☐ Analyst Initials

For Standard, Reagent Container Labeling, preprinted self-adhesive labels should contain the following information:

- ☐ Control number or ID (Logbook number, Numbered pages, numbered lines for ID)
- ☐ Date of receipt
- ☐ Date of opening
- ☐ Expiration Date
- ☐ Analyst Initials

If the original container does not have an expiration date provided by the manufacturer or vendor, it is not required to be labeled with an expiration date. If an expiration date is provided, it must be labeled with the expiration date.

In methods where the purity of reagents is not specified, analytical reagent grade is used. If the purity is specified, that is the minimum acceptable grade. Purity is verified and documented according to Section 9 – "Purchasing Services and Supplies".

24.4.2 Prepared Standards, Reagents, Reference Materials, and Media

Records for standards, reagents, reference materials, and media preparation include:

- ☐ traceability to purchased stock or neat compounds
- ☐ reference to the method of preparation
- ☐ date of preparation
- ☐ an expiration date after which the material shall not be used (unless its reliability is verified by the laboratory)
- ☐ preparer's initials (if prepared)

Reagent and standard preparation instructions:

- ☐ List of reagent preparation instructions should include the name of the Method and Reagent (Example Method 1, 2, 3, 4, etc).
- ☐ Document instruction for the prepared standard or reagent in the book and give reference number (this can be listed).
- ☐ Note book number and page number for reference for the prepared standard reference.

Prepared Standard and Reagents Preparation Log Books:

- ☐ Give the ID or control numbers to prepared standard
- ☐ Name, e.g. 100ppm VOC
- ☐ Reference the control numbers or ID of the Stock used to prepare the working or intermediate
- ☐ Reference to reagent preparation instructions
- ☐Date of preparation
- ☐Date of Expiration
- ☐Analyst Initials

Prepared Reagent Labels

(Require the following information on labels)
ID or control numbers of prepared standard or reagent: _____
Name:_____
Concentration:_____
Analyst Initials: _____
Preparation Date:_____
Expiration Date:_____

The Standards, reference materials, and reagents shall not be used after their expiration date. The expiration dates can be extended if the reference standard or material's integrity is verified. The extended date may not be beyond the expiration date of the referenced standards used to re-verify.

Section 25
COLLECTION OF SAMPLES

Utah Public Health Laboratory does not provide sampling services. The laboratory's responsibility in the sample collection process lies in supplying the sampler with the necessary coolers, reagent

water, sample containers, preservatives, sample labels, custody seals, COC forms, ice, and packing materials required to properly preserve, pack, and ship samples to the laboratory.
The Chemical and Environmental Laboratory provides the reagents necessary for the preservation of samples in the field.

25.1 Sampling Containers

The laboratory offers clean sampling containers for use by clients.

25.1.1 Preparing Container Orders

The sample containers are bought from three different vendors.

16 Industrial containers
17 IDEXX
18 Quality Environmental Containers

Preservation and new bottles commination check; SOP 038SR is used for this process. All sample bottle requests go to the sample receiving section. A sample kit order form is filled by a person taking the order that contains client information and bottle orders. Sample receiving prepares bottles according to the request. Bottle preservation is listed in SOP 038SR. Most bottles are picked up by the client; some are shipped to the address on the form.

25.1.2 Sampling Containers, Preservation Requirements, and Holding Times

All the bottles purchased from dependable containers have preservatives.

Sampling container, preservation, and holding time requirements can be found below. If preservation or holding time requirements are not met, the procedures in Section 12 – "Control of Nonconforming Environmental Testing Work" are followed.

Table 25-1 Sampling Preservation and Container, Holding Time Requirements

Test: Method	Container Type	Volume	Preserve	Holding Time
Ammonia: Method EPA 350.1	Plastic[1]	500 ml	H_2SO_4 pH < 2 store at 4-6ºC	28 Days
Alkalinity(See Total Alkalinity SM2320B)	Plastic[1]	125 ml	Store at 4-6ºC	14 Days
$BOD_{5\ and}$ CBOD: Method EPA 5210B	Plastic[1]	900 ml	No preservative, store at 4-6ºC	48 Hours
Carbamates: Method EPA 531.1 Pass through method	Amber Glass[2] with Teflon cap liner	40 ml	1.2 ml Monochloracetic Acid Buffer, store at 4-6ºC, Sodium Thiosulfate if residual chlorine present	28 Days
Chlorinated Pesticides (Soil): Method EPA 8151 Pass through method	Wide Mouth[3] Glass with Teflon lined lid	4 oz	Keep cool at 4-6ºC	Extract within 14 Days; Analyze within 40 Days
Chloride: Method EPA 325.2	Plastic[1]	900 ml	Store at 4-6ºC	28 Days
Chlorophyll a: Method SM10200H	Opaque Plastic[1]	Variable Filtration	Keep frozen (filter)	28 Days

		Volume		
Chromium VI: Method 218.7	Plastic[1]	125 ml	Store at 4-6ºC Ammonium Sulfate/Ammonium Hydroxide	14 Days
Coliforms Total & E.coli Colilert – Drinking water & pools: Method SM9223B	Sterile plastic	100 ml	Sodium Thiosulfate, store at 4-6ºC	30 Hours
Coliforms Total & Fecal SM 9223 B	Sterile plastic	100 ml	Sodium Thiosulfate, store at 4-6ºC	8 Hours
Color: Method SM 2120 B	Plastic[1]	250 ml	No preservative, store at 4-6ºC	48 Hours
Legionella SM 9260J	Plastic	1 L	All samples at ambient temperature to the laboratory in the insulated cooler are acceptable. Delivery within 24 Hours	Refrigerate samples if not process within 24-48 hrs.
Conductivity EPA 120.1 (See Specific Conductivity)	Plastic[1]	120 ml	Store at 4-6ºC	28 Days
Copper/Lead: Method EPA 200.8	Plastic[1]	2 liter	4 ml HNO_3 to pH <2 add on arrival at the lab	6 Months
Cyanide (Total and amenable to chlorination): Method EPA 335.4	Plastic[1]	500 ml	NaOH to pH>12 Ascorbic acid in the presence of residual chlorine	14 Days
Dissolved Solids: Method SM2540C, EPA 160.1 (See Solids)	Plastic[1]	1 liter	Store at 4-6ºC	7 Days
HAAs (Haloacetic Acids): SM6251B	Glass[2] with Teflon lined septum	4/40 ml	65 mg NH_4CI, store at 4-6ºC	Extract within 14 Days; Analyze within 14 Days
Ion Chromatography Bromide Method EPA 300.1	Plastic[1]	125 ml	NA	28 Days
Ion Chromatography: Chlorite Method EPA 300.1	Plastic[1]	125 ml	Store at 4-6ºC Ethylenediamine Opaque bottle	14 Days
Ion Chromatography Chlorate, Bromate: Method EPA 300.1	Plastic[1]	125 ml	Ethylenediamine	28 Days
EPA Method 300.0 Chloride, Fluoride, Sulfate	Plastic	125 ml / Chemistry	No Preservation Chloride, Fluoride, Only cool sulfate to 4 ºC	28 Days
Lead/Copper: Method EPA 200.8	Plastic[1]	2 liter	4 ml HNO_3 to pH<2 add on arrival at the lab	6 Months
Metals: (See Total Metals)	Plastic[1]	250 ml	HNO_3 to pH<2	6 Months
Mercury: (See Total Metals)	Plastic[1]	250 ml	HNO_3 to pH<2	28 Days
Nitrate Plus Nitrite[4]: Method EPA 353.2	Plastic[1]	125 ml	H_2SO_4 to pH<2 store at 4-6ºC	28 Days
Nitrite: Method EPA 353.2	Plastic[1]	125 ml	No preservative,	48 Hours

			store at 4-6ºC	
Nutrients (Total phosphate: Method 365.1, Nitrate plus Nitrite Method EPA 353.2)	Plastic[1]	500 ml	H_2SO_4 to pH<2 Store at 4-6ºC	28 Days
Odor: Method EPA 140.1	Amber Glass[2]	250 ml	No preservative, store at 4-6ºC	24 Hours
Organohalides and PCBs: Method EPA 8081,8082 Water	Amber Glass[2] With Teflon lined lid	1 Liter	If residual chlorine present, 3 mg sodium thiosulfate, store at 4-6ºC (0.08 % sodium thiosulfate)	Extract within 7 Days; Analyze extract within 40 Days
Organohalides and PCBs(Soil): Method EPA 8081, 8082 Pass through method	Wide Mouth Glass[2] with Teflon lined lid	4 oz	Keep cool at 4-6ºC	Extract within 14 Days; Analyze extract within 40 Days
Perchlorate: Method EPA 314.0	Plastic[1] or Glass[2]		None	28 Days
Perfluorinated Compounds: Method EPA 537	Plastic[1]	250 ml	5.0 g/L Trizma Store at 4-6ºC	Extract within 14 Days; Analyze extract within 28 Days
Pesticides, Herbicides, Chlorinated Acids: Method EPA 515.1 Pass through method	Amber Glass[2] with Teflon cap liner	1 liter	Store at 4-6ºC, Sodium Thiosulfate if residual chlorine present	Extract within 14 Days; Analyze the extract within 28 Days
pH: Method EPA 150.1	Plastic[1]	120 ml or 1 Liter	No preservative	Analyze Immediately,within 24 Hours
Phosphate, total: Method EPA 365.1 (See Nutrients)	Plastic[1]	500 ml	H_2SO_4 to pH<2 Store at 4-6ºC	28 Days
Ortho-Phosphate	Plastic	900 ml	Store at 4-6ºC,	48 Hours
Semi Volatile Organic Compounds: Method EPA 525.2 Pass through method	Amber Glass[2]	1 liter	50 mg sodium thiosulfate, to pH<2 with HCI, store at 4-6ºC	Extract within 14 Days; Analyze extract within 30 Days
Semi Volatile Methods EPA 625 Pass through method	Amber Glass[2] with Teflon cap liner	2/1 liter	Store at 4-6ºC, If residual chlorine add 8 mg/L sodium thiosulfate	Extract within 7 Days; Analyze extract within 40 Days
Semi Volatile Organics (Soil): Method EPA 8270 Pass through method	Wide Mouth Glass[2] with Teflon lined lid	4 oz	Keep cool at 4-6ºC	Extract within 14 Days; Analyze extract within 40 Days
Semi Volatile Organics(Water): Method	Glass, Amber with Teflon	1 liter	0.08 % sodium thiosulfate if	Extract within 7 Days; Analyze

EPA 8270 Pass through method	lined lid		residual chlorine, store at 4° C	extract within 40 Days
Silica: Method SM 4500 Sio_2 F	Plastic[1]	1 Liter	Cool 4-6ºC	28 Days
Solids: Total Suspended Method EPA 160.2	Plastic[1]	1 Liter	Store at 4-6ºC	7 Days
Solids: Total Dissolved Method SM2540C, EPA 160.1	Plastic[1]	1 Liter	Store at 4-6ºC	7 Days
Solids: Total Volatile Method EPA 160.4	Plastic[1]	900 ml	Store at 4-6ºC	7 Days
Specific Conductivity: Method EPA 120.1	Plastic[1]	120 ml	Store at 4-6ºC	28 Days
Sulfate: Method EPA 375.2,	Plastic[1]	125 ml	Store at 4-6ºC	28 Days
Sulfide: Method EPA 376.2	Plastic[1]	120 ml	3 Drops Zinc Acetate & NaOH to pH>9	7 Days
Surfactants: Method SM 5540C Pass through method	Amber Glass[2]	1 liter	No preservative, Store at 4-6ºC	48 Hours
Suspended Solids: Method EPA 160.2 (See Solids)	Plastic[1]	1 Liter	Store at 4-6ºC	7 Days
TCLP(Toxic Characteristic Leaching Procedure)-Metals: Mercury Method EPA 1311 Pass through method	Wide Mouth Glass[2] or Plastic[1]	16 oz solid or 4 L of Liquid	Preserve with Nitric Acid to pH <2 after TCLP	Mercury: 7 Days to TCLP, 28 Days to Analyze
TCLP(Toxic Characteristic Leaching Procedure)-Metals: Other Metals Method EPA 1311 Pass through method	Wide Mouth Glass[2] or Plastic[1]	16 oz solid or 4 L of Liquid	Preserve with Nitric Acid to pH <2 after TCLP	Other Metals: 7 Days to TCLP, 180 Days to Analyze
TCLP(Toxic Characteristic Leaching Procedure)-Organics: Semi-VOAs Method EPA 1311 Pass through method	Wide Mouth Glass[2] with Teflon lined lid	8 oz (240 ml)[3]	Keep cool at 4-6ºC	Semi Volatiles: 7 Days to TCLP, 40 Days to Analyze
TCLP(Toxic Characteristic Leaching Procedure)-Organics: VOAs** EPA 1311 ZHE Pass through method	Wide Mouth Glass[1] with Teflon lined lid	8 oz (240 ml)[3]	Keep cool at 4-6ºC	Volatiles: 14 Days to TCLP ZHE; 14 Days to Analyze
Method 537, 537.1 Perfluorinated Compounds	Polypropylene	250 ml	1.25 g / 250 ml of Trizma ≤ 10 C	14 Days

ELISA EPA 546 Total Microcystins Anatoxin (EPA 545) Cylinderspermum	Unpreserved 250 mL amber glass bottles or preserved 4 oz//250 mL amber glass bottle with PTFE-lined screw caps.	250 ml	Sample chill to ≤10°C during shipment Drinking water samples Sodium thiosulfate will be added at the final concentration of 10 mg/100ml Surface water samples No preservative required Anatoxin Sodium Bisulfate	14 days
THM/TTHM: Method EPA 524.2	Glass[2] with Teflon lined septum	2/40 ml	3 mg sodium thiosulfate, Store at 4-6ºC	14 Days
TOC: Method SM5310B	Amber Glass[2]	4 to 6 oz	H_2SO_4 to pH < 2 Store at 4-6ºC	28 Days
Total Alkalinity: Method SM2320B	Plastic[1]	125 ml	Store at 4-6ºC	14 Days
Total Chemistry (Various methods and analytes)	Plastic[1]	1 Liter	Store at 4-6ºC	Variable, depending on analyte
Total Metals (Drinking and Wastewater): Methods EPA 200.7, EPA 200.8, EPA 200.9, EPA 245.1 (Mercury)	Plastic[1]	250 ml	HNO_3 to pH<2	Mercury: 28 Days Other Metals: 6 Months
Total Metals (Soils/Sediments and Sludges): Methods EPA 6010, EPA 6020, and EPA 7471 (Mercury) Pass through method	Wide Mouth Plastic[1] or Glass[2]	4 oz[3]	Store at 4-6ºC	Mercury: 28 Days Other Metals: 6 Months
TPH: Method EPA 8015 (Modified) Pass through method	Glass[2] with Teflon lined septum	2/40 ml	No preservative store at 4-6ºC	Extract within 14 Days; Analyze extract within 40 Days
Turbidity: Method EPA 180.1	Plastic[1]	900 ml	Store at 4-6ºC	48 Hours
UV-254: Method SM 5910B	Amber Glass[2]	4oz	No preservative store at 4-6ºC	As soon as possible, not to exceed 48 Hours
Volatile Organic Compounds: Method EPA 524.2 Pass through method	Glass[2] with Teflon lined silicon septum	3/40 ml Includes Trip Blank	25 mg ascorbic acid, to pH<2 with HCL, store at 4-6ºC	14 Days
Volatile Organic	Glass[2] with	2/40 ml	Store at 4-6ºC	14 Days

Compounds: Method EPA 624 Pass through method	Teflon lined septum		10mg/L of sodium thiosulfate if residual chlorine present; If testing for aromatics, use HCl to pH < 2	
Volatile Organic Compounds (Soil): Method EPA 8260 Pass through method	Wide Mouth Glass[2,3] with Teflon lined lid	4 oz	Keep cool at 4-6ºC	Extract within 14 Days; Analyze extract within 14 Days
Volatile Organic Compounds(Water): Method EPA 8260 Pass through method	Glass[2] with Teflon lined septum	2/40 ml	Store at 4-6ºC Add sodium thiosulfate, if residual chlorine present	14 Days
Volatile Solids: Method EPA 160.4 (See Solids)	Plastic[1]	900 ml	Store at 4-6ºC	7 Days

[1] All plastic containers, as specified by the Method, will be new, with the proper preservative added for the type of sample to be collected.

[2] All glass containers, as specified by the Method, will be washed with soap and water, rinsed with de-ionized water, rinsed with distilled water, and oven-dried.

[3] The above sample containers assume that the sample is 100% solids and uniform particle size. If the sample is less than 100% solid a larger sample volume is required.

**No longer performed at State Health Laboratory, but a sample may be received preserved as indicated and then analyzed by a subcontracting laboratory.

[4] Procedure for pH out of range nitrate and nutrient bottles

25.2 Bottle Preservation: For Nitrate and Nutrient

For the small nitrate bottles, three drops of sulfuric acid will be added to the bottles. This will decrease the number of samples received out of pH range.

25.2.1 Samples received with pH out of range

For compliance samples, if the sample is received within 48 hours of the time it was sampled, sulfuric acid will be added drop wise until the pH is <2. If the sample was received outside of 48 hours, sample receiving will call and ask the customer to recollect. If recollection is not possible the analyst will be notified and the sample will be analyzed and reported with a qualifier.

For total nutrient bottles outside of pH range received within 48 hours, add the same amount of acid as is used initially for bottle prep (2 mL of 1:7 sulfuric acid). Mark the bottle cap with the new pH. If they are received beyond 48 hours, do not add more preservative; just test the pH and mark the bottle and the results will be flagged. Due to large amounts of dirt in some of the samples there will likely be samples that are still over pH 2 after acid addition; the final report will be flagged in these cases.

For dissolved nutrient bottles outside of pH range received within 48 hours, add the same amount of acid as is used initially for bottle prep (1 mL of 1:7 sulfuric acid). Mark the bottle with the new pH. If they are received beyond 48 hours, do not add more preservative; just test the pH and mark the bottle and the results will be flagged.

25.3 Sample Receiving & Documentation

The Environmental Chemistry Program staff has the primary QA/QC responsibility for the accessioning of all environmental samples for storage or testing. The following paragraphs describe the basic conditions and requirements under which the ECP will accept environmental samples for analysis for regulatory compliance under the laboratory environmental QA plan. Samples which cannot meet these conditions will not be accepted by the ECP without flagging the sample and any result produced from the testing of the sample.

25.4 Sample Acceptance Criteria

ECP sample receiving staff will ensure that sample acceptance criteria are met. The sample receiving staff will document and notify an ECP supervisor/manager when sample acceptance criteria are not met. Sample receiving staff will assign a laboratory accession number to each sample received, followed by the entry of sample information and test requests into the ECP LIMS. Another staff member performs a second entry data review in the LIMS to minimize error during the entry of sample information into the UPHL LIMS. All samples will be stored in storage areas as designated by an ECP supervisor/manager or designee.

25.4.1 Sample Documentation

The Sample Documentation must be present in order for a sample to be accepted at UPHL without flagging the sample and any result produced from the testing of the sample. At a minimum, the documentation must include the following information:

25.4.1.1 Sample identification that unambiguously matches the identification on each container of the physical sample, e.g., a field identification code. Currently, this is being recorded as the SITE ID number in combination with a SOURCE code, e.g., the DEQ-DWQ Storet code.

25.4.1.2 Any additional information necessary to describe and characterize the sample.

25.4.1.3 Sample matrix description, e.g., drinking water, solid, non-aqueous liquid, aqueous, saline/estuarine, chemical waste, biological tissue. Currently, this is being recorded as the SAMPLE TYPE code.

25.4.1.4 Location, date, and time of collection.

25.4.1.5 Collector's name, customer's name, and customer ID code. Some customers may not know their ID Code. Currently for drinking water samples, the ID code is related to the water system number. The customer ID code will need to be determined and documented during sample check-in.

25.4.1.6 Regulatory programs requiring compliance, if any. Currently, this is being indicated by the UPHL cost code, e.g., CWA (CC 350), SDWA (CC 361), RCRA (CC 365), etc.

25.4.1.7 Regulatory methods and target analytes being requested, e.g., EPA525.1; SDWA SVOC organics.

25.4.1.8 Preservation applied in the field, e.g., "packed in ice." Currently, chemical preservation information is printed on most of the sample container labels and request forms which are provided by UPHL to the customer.

25.4.1.9 Chain of custody documentation, if indicated by the client and/or regulator. The chain of custody forms and chain of custody seals must be sufficient to meet legal and evidentiary standards.

25.4.1.10 Documentation for field QC samples being required by the client e.g., trip blanks, field blanks, equipment blanks, duplicates, or other field-submitted quality control measures.

25.4.1.11 Comments recorded by UPHL personnel, dated and signed, which detail actions taken at the time of sample receipt to bring a sample/document package into compliance with the UPHL QA plan. Currently, these records are made on or attached to the request forms.

25.4.2 Physical Sample

The Physical Sample must meet the following criteria, in addition to those prescribed in Section 25.4.1, for the ECP to accept the sample for regulatory testing without qualifications.

25.4.2.1 Container type and volume for both field and QC samples as specified for the test method.

25.4.2.2 UPHL container QA/QC identification, e.g., the container provided by UPHL with UPHL labels.

25.4.2.3 Container in satisfactory condition e.g. no cracks, no leaks, etc.

25.4.2.4 Custody Seals, if required, should be tamper-proof and intact with date and initials that match those on the chain of custody form. The custody seals may be applied either to the individual caps on each sample container or to the shipping container in which they were delivered.

25.4.2.5 Durable sample labels and/or tags affixed and marked with information consistent with that on the accompanying documentation, as described in Section 25.4.1.

25.4.2.6 The sample identification for each sample container must be unique (e.g., if multiple containers are provided for one test, e.g., VOC analysis, each container will be assigned an additional identifier such as A, B, C, etc.)

25.4.2.7 Chemical preservatives added should be recorded on each sample container label.

25.4.2.8 Preservation characteristics designated for measurement at the time of receipt, as found in Table 25-1, e.g., the temperature and pH.

25.4.3 Samples not meeting criteria

Samples which do not meet the ECP Acceptance criteria may be accepted under the following conditions:

25.4.3.1 If the ECP sample receiving staff or manager, in contact with the sampler or client, is able to complete the requirements listed, all corrections must be recorded (dated and initialed) in the sample documentation. The sample may then be processed as a compliant sample.

25.4.3.2 If the ECP sample receiving staff or manager, in consultation with the sampler/client, is unable to complete the requirements listed, the sample may be accepted for provisional testing, which must be specifically authorized by the client. All client communications must be recorded (dated and initialed) in the sample

documentation. In addition, all test results associated with the non-compliant sample must be flagged in the LIMS, indicating that the sample did not meet established acceptance criteria. A comment must be added to the sample documentation and on all test results reported to the client, describing how the sample was deficient.

25.4.4 Preservation Check

Prior to or concurrent with testing, the contents of each sample container will be checked for preservation and temperature by the sample receiving staff

25.4.5 Test Method Requirements

For test Methods not listed, the containers and preservatives will be utilized as described in the test method.

25.5 Sampling Records

The following relevant sampling data are recorded: sampling procedure used, the date and time of sampling, the identification of the sampler, environmental conditions (if relevant), the sampling location.

The sample receiving procedure SOP 0082 has detailed sample login processing documentation

Section 26
HANDLING SAMPLES AND TEST ITEMS

26.1 Sample Receipt

When samples are received at the laboratory, chain-of-custody is reviewed, the condition is documented, samples are given unique identifiers, and they are logged into the sample tracking system. Also, sample acceptance policy E-21 and Sample receiving SOPs for sample handling and documentation.

26.1.1 Chain of Custody

The chain of custody or sample submission sheets from the field are reviewed. This documentation is completed in the field and provides a written record of the handling of the samples from the time of collection until they are received at the laboratory. Section 25 – "Collection of Samples" outlines what information is needed on this record. The chain of custody form also provides information on what type of testing is being requested and can act as an order for laboratory services in the absence of a formal contract. Chain of custody and any additional records received at the time of sample submission are maintained by the laboratory. An example of the Chain of Custody form can be found below:

CHAIN OF CUSTODY

Unified State Laboratories: Public Health
Bureau of Chemical and Environmental Services
4431 S 2700 W Taylorsville, UT 84119-8600
801 965 2400 Fax 801 969 3238
http://health.utah.gov/lab/chemistry

☐ Hand Delivered
☐ Shipped Samples
☐ Cooler Returned

System/Agency Name:	System/Agency Number:	Cost/Project Code:	REQUESTED TESTS	Received Date and Time:

REPORTING/CONTACT
Attn:
Address:
City, State, Zip:
Phone:
Fax:
Email:
Submitted By:

BILLING (list if different)
Special Code:
Attn:
Address:
City, State, Zip:
Phone:
Fax:

Sample Receipt Conditions

	Yes	No
Documentation complete	☐	☐
Proper containers and in-date	☐	☐
Containers intact	☐	☐
Within holding time	☐	☐
Coolant	☐	☐
Temperature within range	☐	☐
Acceptable pH ☐ N/A	☐	☐
Custody Seals Intact	☐	☐

COLLECTION POINT DESCRIPTION	Collectors Initials	Collection Date (mm/dd/yy)	Collection Time (24 hr)	COMMENTS	Receipt temperature	Receipt pH	LAB NUMBER

Dispatched By:	Date and Time:	Courier Company Name:	Invoice/Airbill #:
Relinquished By:	Date and Time:	Received by:	Date and Time:
Relinquished to USL:PH by:	Date and Time:	Received at USL:PH by:	Date and Time:

Ensuring the integrity of the Chain of Custody sample is of the utmost importance. The number of individuals handling the sample must be kept to a minimum. The Chain of Custody Custodian or a designated alternate shall review the forms, tags, seals, and samples to see that all information described in the Section is completed. After the review and each entry has been addressed, the sample and paperwork will be placed in secure storage in a locked cabinet in the sample receiving area.

26.1.1.1 Samples to be analyzed for volatile compounds will be stored in a separate refrigerated environment from the other samples. The sample storage area will remain locked at all times, to be opened only by the Chain of Custody Custodian or one of the designated alternates.

26.1.1.2 When an analyst needs a sample for testing, they must contact the Chain of Custody Custodian to arrange for checking out the sample. The sample, or portion of the sample, will be released only to the responsible analyst and by signature with date, time, and activity.

26.1.1.3 The analyst is responsible for the care and custody of the sample once it is released to them. They must be prepared to testify that the sample was in their possession and viewed or secured in the laboratory at all times from the moment it was released from the custodian until it is returned to the custodian.

26.1.1.4 The analyst must return the sample to the custodian or provide secure storage for the sample prior to leaving the area where the sample is being processed.

26.1.1.5 When the analyst has no immediate need for the sample, it must be returned to the custodian and received by signature with date, time, and action.

26.1.1.6 Samples will be discarded after maximum holding times have been exceeded or after six months from the time of receipt unless otherwise directed by the client organization. The sample containers will be discarded following the current laboratory disposal procedures found in the laboratory safety manual.

26.1.1.7 In order for the Utah Public Health Laboratories to demonstrate the reliability of its evidence for enforcement of action, it must be able to prove controlled possession of samples from receipt to discard.

26.2 Sample Acceptance

The laboratory has a sample acceptance policy that is made available to sample collection personnel. An example is provided in Section 25. It emphasizes the need for the use of water-resistant ink, providing proper documentation (to include sample ID, location, date and time of collection, collector's name, preservation type, sample type, and any special remarks about the sample), labeling of sample containers to include a unique sample ID, use of appropriate containers, adherence to holding times, and sample volume requirements. In addition, the laboratory has nonconformance/corrective action procedures to handle samples that don't meet the requirements above or show signs of damage, contamination, or inadequate preservation. Data will be appropriately qualified where samples are reported that do not meet sample acceptance requirements.

Criteria regarding preservation, holding time, and sample volume requirements can be found in Section 25. If these conditions are not met, the client is contacted prior to any further processing, then 1) the sample is rejected as agreed with the client, 2) the decision to proceed is documented and agreed upon with the client, 3) the condition is noted on the Chain of Custody form and/or lab receipt documents, and 4) the data are qualified in the report.

26.2.1 Preservation Checks

The following preservation checks are performed and documented upon receipt:

26.2.1.1 Thermal preservation:

a) For temperature preservation, the temperature must be within ± 2°C of the required temperature unless otherwise stated. For samples that require preservation at 4°C, the acceptable range is "from just above freezing to 6°C".
b) Samples that are delivered to the lab the same day as they are collected are likely not to have reached a fully chilled temperature. This is acceptable if the samples were received on ice and the chilling process has begun.
c) Record on the receipt form if ice is present and its temperature.

26.2.1.2 Chlorine checks:

a) the laboratory can show that the received sample containers are from their laboratory;
b) sufficient sodium thiosulfate was in each container before sample collection to neutralize at minimum 5 mg/l of chlorine for drinking water and 15 mg/l of chlorine for wastewater samples;
c) one container from each batch of laboratory-prepared containers or lot purchased ready-to-use containers is checked to ensure the efficacy of the

sodium thiosulfate to 5 mg/l chlorine or 15 mg/l chlorine as appropriate and the check is documented; and

d) chlorine residual is checked in the lab and actual concentration is documented with the sample sheet.

26.2.1.3 pH checks:

a) The pH of samples requiring acid/base preservation is checked upon sample receipt or upon initiation of analysis.

26.3 Sample Identification: Sample Receipt at the Laboratory

Samples, including subsamples, extracts, and digestates, are uniquely identified. Upon arrival at the Utah Public Health Laboratories (UPHL) samples will be logged in and assigned a laboratory sample number, also known as the sample identification number. Inadequate or inappropriate samples will be noted and described upon receipt at the laboratory. The log entry recorded in the chain of custody record will show:

26.3.1 Laboratory sample number

26.3.2 Date and time of collection

26.3.3 Exact sampling location

26.3.4 Name of sampler

26.3.5 Storet or system identification number

26.3.6 Source of sample

26.3.7 Use of the water when applicable

26.3.8 Analyses requested

26.3.9 Date and time the sample is transferred to the UPHL custody

26.3.10 Signature of the sampler

26.3.11 Signature of the receiver

26.3.12 Condition of samples as received (sealed, unsealed, broken container, improper container, sample improperly preserved, sample QNS, or other pertinent remarks)

26.3.13 Name of the project

26.3.14 Date and time of sampling to the date and time of laboratory receipt.

26.3.15 Unique field identification number linked to the laboratory sample ID

26.3.16 Analyses requested (including applicable approved method numbers) linked to the laboratory sample ID.

26.3.17 Comments regarding rejection (if any).

All documentation received regarding the sample, such as memos or chain of custody, are retained.

26.4 Sample Storage

Storage conditions are monitored for any required criteria, verified, and the verification recorded in logbooks.

Samples that require thermal preservation are stored under refrigeration that is at 4 C +/- 2°C of the specified preservation temperature unless regulatory or method-specific criteria require something different. For samples with a specified storage temperature of 4°C, storage at a temperature above the freezing point of water to 6°C is acceptable.

Samples are held secure, as required. Samples are accessible only to laboratory personnel.

Samples are stored apart from standards, reagents, food, or potentially contaminating sources, so that cross-contamination is minimized. All portions of samples, including extracts, digestates, leachates, or any product of the sample is maintained according to the required conditions.

26.5 Sample Disposal

Samples are retained a minimum of 10 days after the report is sent out unless other arrangements have been made with the client.

Samples are disposed of according to local, State, and Federal regulations. All the samples are disposed of according to the waste stream disposal procedure in SOP 065

Section 27
QUALITY ASSURANCE FOR ENVIRONMENTAL TESTING

Utah Public Health Laboratory has procedures for monitoring the validity of the testing it performs. The qualities of test results are recorded in such a way that trends are detectable, and where practicable, are statistically evaluated. To evaluate the quality of the test results, the laboratory utilizes certified reference materials and proficiency testing samples. In addition to procedures for calibration, the QA program from LIMs monitors quality control indicators such as blanks, laboratory control samples (LCS), duplicates, surrogates, and internal standards to assess precision and accuracy. Proficiency Testing samples are also analyzed to assess laboratory performance. Pre-defined criteria, the action is taken to correct the problem and to prevent incorrect results from being reported. Data associated with quality control data outside of criteria and still deemed reportable will be qualified so the end-user of the data may make a determination of the usability of the data - see Section 28 – "Reporting of Results."

27.1 Essential Quality Control Procedures

The quality control procedures specified in test methods are followed by laboratory personnel. The most stringent of control procedures is used in cases where multiple controls are offered. If it is not clear, which is the most stringent, that mandated by test method or regulation is followed.

For test methods that do not provide acceptance criteria for an essential quality control element or where no regulatory criteria exist, acceptance criteria are developed.

Written procedures to monitor routine quality controls including acceptance criteria are located in the test method SOPs; acceptance limits for QC samples are in method SOPs.

- laboratory control samples to monitor test variability of laboratory results;
- use of calibrations, continuing calibrations, certified reference materials, and/or PT samples to monitor the accuracy of the test method;
- measures to monitor test method capability, such as limit of detection, limit of quantitation, and/or range of test applicability, such as linearity;
- use of regression analysis, internal/external standards, or statistical analysis to reduce raw data to final results;
- use of reagents and standards of appropriate quality and use of second source materials as appropriate;
- procedures to ensure the selectivity of the test method for its intended use;
- measures to assure constant and consistent test conditions, such as temperature, humidity, exhaust fan, etc. When required by the test method; The DFCM controls the building temperature, humidity, and light necessary for the instrument performance.
- use of sterility checks for equipment, media, and dilution water for microbiology; and
- use of positive and negative culture controls for microbiology.
- Lab DI water quality check is monitored every month to make sure the quality meets the criteria specified in SOP 068. All results are documented.

27.2 Internal Quality Control Practices

Analytical data generated with QC samples that fall within all prescribed acceptance limits indicate the test method is deemed to be in control.

QC samples that fall outside QC limits indicate the test methods are deemed to be out of control (nonconforming) and that corrective action is required and/or that the data are qualified (see Section 12 – "Control of Nonconforming Environmental Testing Work" and Section 14 - "Corrective Actions").

Detailed QC procedures and QC limits are included in test method standard operating procedures (SOPs); Appendix A is a comprehensive list of Analytical Methods and Supporting QA Systems. The Analytical Method SOPs list the overall precision and accuracy QC objectives for the analyses.

27.2.1 General Controls

The following general controls are used:

27.2.1.1 Positive and Negative Controls such as:

a) Blanks (negative)
b) Laboratory control samples (positive)
c) Sterility checks and control cultures (positive and negative).

27.2.1.2 Selectivity is assured through:

a) absolute and relative retention times in chromatographic analyses;
b) two-column confirmation when using non-specific detectors;
c) use of acceptance criteria for mass-spectral tuning (found in test method SOPs); and

d) use of the correct method according to its scope assessed during method validation.

27.2.1.3 Consistency, Variability, Repeatability, and Accuracy are assured through:

a) proper installation and operation of instruments according to manufacturer's recommendations or according to the processes used during method validation;

b) monitoring and controlling environmental conditions (temperature, access, proximity to potential contaminants);

c) selection and use of reagents and standards of appropriate quality;

d) cleaning glassware appropriate to the level required by the analysis as demonstrated with method blanks sample receiving glassware cleaning SOP;

e) following SOPs and documenting any deviation, assessing for impact, and treating data appropriately;

f) testing to define the variability and/or repeatability of the laboratory results, such as replicates;

g) use of measures to assure the accuracy of the test method, including calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures; and

h) use of duplicate plate counts on positive samples (microbiology only).

27.2.1.4 Test Method Capability (also see Section 22 – "Environmental Methods and Method Validation") is assured through:

a) Establishment for each method of the limit of quantitation or reporting level.

b) Establishment of the range of applicability such as linearity as required by the method.

27.2.1.5 Data reduction is assured to be accurate by:

a) selection of appropriate formulae to reduce raw data to final results such as regression;

b) following specific procedures for data reduction such as manual integration procedures;

c) periodic review of data reduction processes to assure applicability; and

d) microbiological calculations, data reduction, and statistical interpretations specified by each test method.

27.2.1.6 Sample specific controls are used to evaluate the effect of a sample matrix on the performance of the selected analytical method (not a measure of laboratory performance).
Examples:

- Matrix Spike and Matrix Spike Duplicate (MS/MSD)
- Surrogate Spikes
- Sample Duplicates

27.2.1.7 The following table summarizes the key elements of a quality control system for a laboratory performing chemistry and microbiology testing.

Table 27-1 Essential Quality Control Elements for Chemistry			
Item	**Frequency**	**Acceptance Criteria**	**Corrective action**
Method Blank	1/batch	Less than MRL	Reanalysis, take corrective action. If reanalysis is not possible qualify data. Sample less than MRL can be accepted without Qualifier.
Positive Control Laboratory Control Sample)	1/batch	Method specific	Reprocess or reanalyze. Corrective action: reanalysis; if reanalysis is not possible qualify data.
Matrix Spike Matrix Spike Duplicates Lab. Spike Bank Lab Spike duplicate *Note : Samples are designed as data quality indicators for a specific sample using the designated method. These controls alone are not used to judge a laboratory's performance.*	Per method requirement	Method specific	Corrective action and qualify data
Surrogate spikes *See note above.*	Per method requirement	Method specific	Corrective action and qualify data
Matrix Duplicates	Per method requirement	Method specific	Corrective action and qualify data
Continuing Calibration Verification	Per method requirement	Method specific	Reanalyze standard immediately; Corrective action. Recalibrate if second fails
Initial Calibration Verification	Start of each analytical run	Method specific If method not specified use correlation factor ($r^2 \geq .995$	Reanalyze standard immediately; Corrective action.

List of the LIMS QC Names:

CAL_BLANK	Calibration Standard 1	CHEMISTRY
CAL_STD1	Calibration Standard 1	CHEMISTRY

CAL_STD2	Calibration Standard 2	CHEMISTRY
CAL_STD3	Calibration Standard 3	CHEMISTRY
CAL_STD4	Calibration Standard 4	CHEMISTRY
CAL_STD5	Calibration Standard 5	CHEMISTRY
CAL_STD6	Calibration Standard 6	CHEMISTRY
CAL_STD7	Calibration Standard 7	CHEMISTRY
CAL_STD8	Calibration Standard 8	CHEMISTRY
CAL_STD9	Calibration Standard 9	CHEMISTRY
CSTD_HIGH	Check Standard - High value	CHEMISTRY
CSTD_LOW	Check Standard - Low	CHEMISTRY
CSTD_MID	Check Standard - Mid range value	CHEMISTRY
CSTD_MRL	Check Standard - Minimum Reporting Limit	CHEMISTRY
CSTD_VAR	Continuing Cal Standard	CHEMISTRY
DUP	Duplicate - Lab	CHEMISTRY
IB	Instrument Blank	CHEMISTRY
ICS	Interference Check Sample	CHEMISTRY
IPC	Instrument Performance Check	CHEMISTRY
IS	Internal Standard	CHEMISTRY
LFB	Lab Fortified Blank	CHEMISTRY
LFB_MRL	Lab Fortified Blank - Minimum Reporting Limit	CHEMISTRY
LFBD	Lab Fortified Blank Duplicate	CHEMISTRY
LFBD_MRL	Lab Fortified Blank Duplicate	CHEMISTRY
LFBD2	Lab Fortified Blank Duplicate number 2	CHEMISTRY
LFM	Lab Fortified Matrix	CHEMISTRY
LFMD	Lab Fortified Matrix Duplicate	CHEMISTRY
LRB	Lab Reagent Blank	CHEMISTRY
MDL	Method Detection Limit Standard	CHEMISTRY
PCHECK	Performance Check	CHEMISTRY
QCS	QC Sample	CHEMISTRY
RB	Reagent Blank	CHEMISTRY
RINSE	Instrument Rinse	CHEMISTRY
SRM	Secondary Reference Material	CHEMISTRY
SURR	Surrogate	CHEMISTRY
TB	Trip Blank	CHEMISTRY
GGA_BOD	Glucose Glutamic Acid Standard for BOD	INO
ICS_N	Instrument Control Standard - Total Nitrogen	INO
LFBH_BOD	LFB - High value for BOD	INO
LFBL_BOD	LFB - Low value for BOD	INO
LFBM_BOD	LFB - Mid range value for BOD	INO

NO2	Nitrite Check	INO
SDW	Seeded Dilution Water for BOD	INO
UDW	Unseeded Dilution Water for BOD	INO
MESURR	Methylated Surrogate	OR

27.2.2 Specific Controls

27.2.2.1 Method Blanks

Method blanks are processed along with and under the same conditions as the associated samples to include all steps in the method. A method blank must be analyzed at a minimum of one per preparation batch. The method blank is used to assess the samples in the preparation batch for possible contamination during the preparation and processing steps.

The batch is defined as the environmental samples that are processed with the same conditions, method, and personnel, using the same lots of reagents, not to exceed the analysis of twenty environmental samples, not including method blanks, LCS, matrix spikes, and matrix duplicates. The matrix of the method blank must be similar to the associated samples and be free from any analytes of interest. (Process within twenty-four hours)
Method blanks are not required for some analyses.
Contaminated blanks are identified according to the acceptable limits in the test method SOPs.

Method blank accepted limits should be less than reporting limits.
The laboratory identifies a blank as contaminated when analyte results are greater than for the acceptance criteria.
When a blank is determined to be contaminated, the cause must be investigated and measures are taken to minimize or eliminate the problem.

Data that are unaffected by the blank contamination (non-detects or other analytes) are reported unqualified.

Sample data that are suspect due to the presence of a contaminated blank are reanalyzed, qualified with a qualifier, or voided.

27.2.2.2 Laboratory Control Samples (QCS, SRM) (Different Source of Lot Number)

Laboratory Control Samples (LCS) are prepared from analyte-free water or another clean matrix and spiked with verified and known amounts of analytes for the purpose of establishing precision or bias measurements. Some method analyzes lab fortified spike (LFB) as a second source.

Laboratory control samples are analyzed at a frequency and spiked level within the calibration rangeby method, regulation, or client request, whichever is more stringent. The standard frequency of LCS preparation and analysis is one per analytical batch or as otherwise stated in a laboratory SOP. Exceptions would be for those analytes where no spiking solution is available.

Batch is defined as the environmental samples that are analyzed/prepared with the same method and personnel, using the same conditions, lots of reagents, not to exceed the analysis of twenty environmental samples, not including method blanks, LCS, matrix spikes, and matrix duplicates.

Number of samples run in a batch is specified in the method SOPs.
The analytes to be spiked in the LCS are specified in the test method SOP. Utah Public Health runs 5% frequency for matrix spike.

The results of laboratory control samples (LCS) are calculated in percent recovery or other appropriate statistical technique that allows comparison to established acceptance criteria. The laboratory documents the calculation as follows:

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

Where
%R = Percent recovery
AV = Analyzed Value
TV = True Value

The individual LCS is compared to the acceptance criteria as publish the mandated test method, or where there are no established criteria, the laboratory established limits as described above. LIMs calculates and evaluates the recovery criteria. All QC limits are based on method QC requirements and are entered in the LIMS from the analyst.

27.2.2.3 Matrix Spikes and Matrix Spike Duplicates

Matrix Spikes and Matrix Spike Duplicates (MS/MSD) are environmental samples fortified with a known amount of analyte to help assess the effect of the matrix on method performance. Matrix duplicates are performed on replicate aliquots of actual samples. The composition is usually not known

For MS/MSD results outside established criteria, the data are reported with appropriate data qualifying codes. Only the data from the spiked sample is qualified. The relative percent difference (RPD) between spiked matrix duplicate determinations is to be calculated as follows:

$$RPD = \frac{|D_1 - D_2|}{\left(\frac{|D_1 + D_2|}{2}\right)} \times 100$$

D1 is the First sample value, D2 is the second sample value

The precision calculation model is described below in 27.3.3.

27.2.2.4 Surrogate Spikes

Surrogate spikes are substances with chemical properties and behaviors similar to the analytes of interest used to assess method performance in individual samples. Surrogates are added to all samples (in test methods where surrogate use is appropriate) prior to sample preparation or extraction.

Surrogate recovery results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory uses ± 50%.

For surrogate results outside established criteria, data are evaluated to determine the impact.

27.3 Method Selection and Validation

The methods described are testing procedures recognized and authorized by published government regulation as acceptable for generating data for the detection and monitoring of a specific contaminate for compliance with a specific regulation. The Reference methods are validated by determining the LOD or LOQ, and precision and bias using the procedures outlined below. Form 042 can provide a check list for method validation.

27.3.1 Limit of Detection (LOD), Minimum Detection Limit (MDL)

The Limit of Detection (LOD, MDL) is the laboratory's estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect in their facility. See the SOP 0067 MDL determination procedure.

LODs are not required for any component for which spiking solutions or quality control samples are not available. These include pH and temperature.
The laboratory will select methods with LODs that are expected to meet the intended data use.

LODs are determined in samples that represent the quality system matrices to be evaluated. All sample processing/preparation steps and all determinative steps are used to validate the method for all targeted analytes. The representative quality system matrix will be free from the target analytes of interest or interfering analytes that impact the LOD.

When the method or applicable regulation specifies a LOD study, only the specified method will be used.
The laboratory uses the following procedure to determine the LOD for the method using 40 CFR Appendix B to Part 136, Definition and Procedure for the Determination of the Method Detection Limit - Revision 2
The laboratory follows this document to process and derive the LOD and will retain all the supporting data.

Once the LOD has been determined, the validity of the LOD is verified by a detection (value above zero) for each target analyte in a quality control sample of a representative quality system matrix. The concentration of the analytes in the sample will be no more than 3 times the derived LOD unless the test contains multiple analytes. In the latter case, the concentration of the target analytes will be no greater than 4 times the LOD. This verification will be performed on each instrument that is used for the test.

LODs are performed/repeated:

- before reporting the LOD for a given analyte
- any time there is a change that affects how the method is performed or

- When there is a change in instrumentation that affects the sensitivity of the analysis.

LODs are verified annually for each quality system matrix/technology/analyte combination.

27.3.2 Limit of Quantitation

The Limit of Quantitation (LOQ) is an estimate of the minimum amount of a substance that can be reported with a specified degree of confidence.

If an LOD study is not performed, concentration values less than the Limit of Quantitation are not reported but are appropriately flagged.

LOQs are not required for components or properties for which spiking solutions or QC samples are not available. These include pH and temperature.

An LOQ study includes all sample processing and analysis steps in the analytical method. The study is performed in each quality system matrix for which the test will be performed. The procedure is documented and all supporting data are retained. The resulting LOQ will be above the LOD (if determined).

The laboratory will verify the LOQ by the analysis of a QC sample containing the analytes of concern at a concentration of 1 to 2 times the derived (claimed) LOQ. The LOQ is considered verified if the recovery of each analyte is within the laboratory's acceptance limits or the client's data quality objectives.

The LOQ be verified annually for each quality system matrix, technology, and analyte unless the LOD was determined or confirmed.

27.3.3 Precision and Bias

The Precision is a measure of the average percent difference between duplicate test results, without regard to how close their average found value is to the actual known concentration.

Precision is the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision is usually expressed as standard deviation, variance, or range, in either absolute or relative terms.

Bias is the systematic error that contributes to the difference between the mean of a significant number of test results and the accepted reference value.

Precision and bias using non-reference, modified reference or laboratory-developed methods are established using the procedure outlined below and compared to the criteria established by the client (when requested), the method, or the laboratory.

Precision and bias are determined by processing samples through all phases of the method (sample preparation, cleanup, analysis, etc.) and are evaluated across the analytical calibration range of the method. This study is performed for all quality system matrices for which the test is to be used.

27.3.3.1 Standard Deviation: When the same test is performed repeatedly on the same type of sample under approximately the same conditions, the resulting group of data points will be scattered around an average value due to noise in the analytical

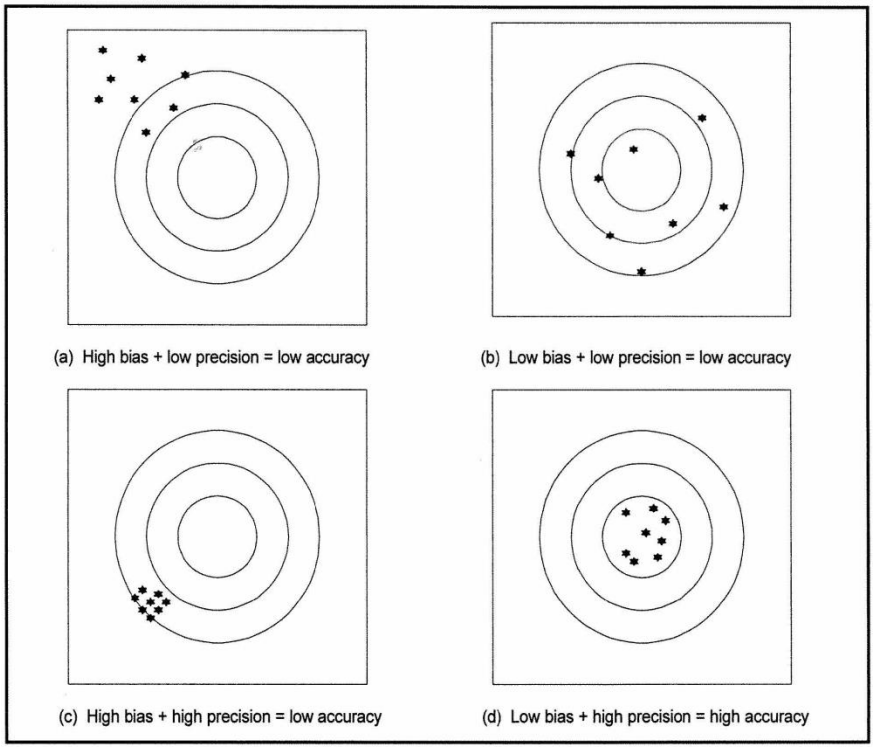
system. The standard deviation, s, is a calculated estimation of how widely the data points are scattered around their average value, the mean.

27.3.3.2 Calculation: The equation used by the LIMS to calculate an estimate of a standard deviation (S) is:

$$S^2 = \frac{1}{n-1}\left[\sum_{i=1}^{n} X_i^2 - \frac{\left(\sum_{i=1}^{n} X_i\right)^2}{n}\right]$$

It is very important that environmental conditions should be kept constant whenever a particular analytical test method is being performed, i.e., *always* follow the method SOP.

27.3.3.3 Precision, Bias, and Accuracy: The following chart demonstrates visually the relationship that exists between Precision, Bias, and Accuracy for a group of points found on a scatter plot where the central point is the goal or target.



a) Bias. Bias is a measure of systematic error. When a sample of known concentration is tested repeatedly, the Bias is determined by how close the average test value is coming to the actual, known value. For example, the data sets represented by A and B in figure 14.2 are both very scattered showing low precision but the data in set D is averaged around the true value

and therefore has a lower bias than the data in set B. A data set with low bias, such as in Panel D, is sometimes referred to as unbiased.

b) Accuracy. Accuracy is a measure of a test's ability to produce a result that on average is close to the true value. Accuracy can be measured by determining the percent recovery (%R) by testing either a spiked blank, i.e., a LFB, or a spiked sample, i.e., a LFM. Unless the referenced analytical test method prescribes otherwise, only spiked blank test results will be used to calculate accuracy. Some analytical test methods require that a chart plotting the standard deviation of sequential accuracy measurements be maintained for monitoring the test system or for determining the acceptability of the data. Example calculation:

IF [LFB] true=14.2 and
IF [LFB] found =15.2 then
%R found= (15.2/14.2)x100%
%R = 107%

27.3.4 Selectivity

Selectivity is the capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances (EPA-QAD).

The laboratory evaluates selectivity through procedures defined in the test method SOPs. These selectivity measurement procedures include mass spectral tuning, second column confirmation for PCB, chromatographic retention time window, sample blanks, ICP interelement interference checks, and instrument performance checks, and are performed according to the method as specified in the method SOPs.

27.3.5 Documentation for LOD, IDC, ODC, DOL

The IDOC(s) for each analyst is documented. The section managers are responsible for keeping documentation of training records of each analyst for the demonstration of capabilities and making sure the records are kept with the method workstation binder.

Each instrument will have a method workstation binder which contains critical information for auditors. It may be viewed at any time, and should be kept up to date. Contents of the Method Workstation Binder for LOD (MDL), DOC, and ODC include the following items that will be maintained in the binder for each analyst:

1. A typical run sequence, showing all QC.
    a. Any extraction or digestion pages associated with the batch.
    b. Method references section.
    c. Attach supporting instrument documentation which is the source of numbers used for the IDC, ODC, and LOD determination.
2. An initial demonstration of capability study for each analyte of a method.

Annual MDL studies after the initial demonstration of capability and ongoing demonstration of capability. The guidance For IDC performance is in Form 052; Use Form 008, 009 for documenting IDC. If results are unacceptable to meet the required criteria, the Analyst can repeat the analysis by locating and correcting the source of the problem.

27.4 Demonstration of Capability

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

Before reporting any data with a given method, a satisfactory DOC is performed. Thereafter, each analyst demonstrates continuing proficiency through the procedures outlined in Ongoing Demonstration of Capability.

27.4.1 Initial Demonstration of Capability (IDOC)
An IDOC is performed:

- Before using any method
- Each time there is a change in instrument type, personnel, or method and
- If the laboratory or analysts has/have not performed the method in a twelve-month period.

The IDOC(s) for each analyst is documented in the Work Station Binder in each laboratory. The document identifies the analyst(s) involved in preparation and/or analysis; matrix; analyte(s), class of analyte(s), or measured parameter(s); the method(s) performed; the laboratory-specific SOP used for analysis (including revision number); the date(s) of analysis; and a summary of the results used to calculate the mean recovery and standard deviations.

All raw data, preparation records, and calculations for each IDOC are retained and are available for review at each work station.

The IDOC(s) for each analyst is documented. The section managers are responsible of keeping training records of each analyst and making sure the records are kept with each method workstation binder as well.

27.4.2 Ongoing Demonstration of Capability (DOC)
After the demonstration of capability is completed, on-going proficiency is maintained and demonstrated at least annually. Each analyst is expected to consistently meet the QC requirements of the method, the laboratory SOP, client requirements, and/or the TNI Standard. Ongoing DOCS are documented in work station binders in each laboratory along with the instruments. The analyte(s) shall be diluted in a volume of clean quality system matrix (a sample in which no target analytes or interferences are present at concentrations that will impact the results of a specific method) sufficient to prepare four (4) aliquots at the concentration specified in the method, or four replicates at a mid-level concentration of calibration range spike. Form 052 for guidance
Form 008, 009. For calculation documentation. If the method or regulation does not specify acceptance limits, the % Relative Standard Deviation must be less than 20%. To be considered acceptable, an initial demonstration of capability must meet all acceptance criteria.

27.5 Calibration

Section 23.2.2 includes information on the calibration of support equipment. This Section covers the calibration of analytical equipment. The sample results are quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification.

Initial instrument calibration and continuing instrument calibration verification are important in ensuring data of known and documented quality. If more stringent calibration

requirements are included in a mandated method or by regulation, those calibration requirements override any requirements outlined here or in laboratory SOPs. Generally, procedures and criteria regarding instrument calibrations are provided in laboratory method SOPs.

27.5.1 Initial Instrument Calibration

27.5.1.1 Records:
Initial instrument calibration includes calculations, integrations, acceptance criteria, and associated statistics referenced in the test method SOPs.

Sufficient raw data records are collected to allow reconstruction of the initial instrument calibration. These include, at a minimum, calibration date, test method, instrument, analysis date, analyte names, analysts signature or initials, concentration and response, calibration curve or response factor, or unique equation or coefficient used to reduce instrument responses to concentration. Calibration date and expiration date (when recalibration is due) is documented for equipment requiring calibration, where practicable (see Section 23.1).

27.5.1.2 Number of Standards and Concentrations:
If the reference or mandated method does not specify the number of calibration standards to use, the minimum number is three, not including blanks or a zero standard, except as noted below.
For instrumentation where single-point calibration is recommended by manufacturer's instructions, such as with some ICP and ICP/MS technologies (with a zero and single point calibration), the following apply:

a) For single point plus zero blank calibrations, the zero point and the single point standard are analyzed prior to the analysis of samples, and the linear range of the instrument is established by analyzing a series of standards, one of which is at the lowest quantitation level.

b) Zero blank and single point calibration standards are analyzed with each analytical batch for methods where they are specified.

c) A standard corresponding to the limit of quantitation is analyzed with each analytical batch and must meet established acceptance criteria when using single-point plus zero blank calibrations.

d) The linearity of a single point plus zero blank calibrations is verified at a frequency established by the method or the manufacturer.

The lowest calibration standard (MRL STD) is the lowest concentration for which quantitative results can be reported without qualification. The lowest calibration standard is at or below the Limit of Quantitation (LOQ or MRL) and is greater than the Limit of Detection (LOD or MDL). Results that are less than the LOQ are considered to have increased uncertainty and are either reported with a qualifier code or explained in the case narrative. The results above LOD or MDL and below MRL can be reported with a qualifier "J." The results within the calibration range do not require any data qualifier.

The highest calibration standard is the highest concentration for which quantitative results can be reported. Data reported exceeding the highest calibration standard without dilutions is considered to have increased uncertainty and are reported with a qualifier code or reanalyzed with dilution.

27.5.1.3 Evaluation, Verification, and Corrective Action:
All initial instrument calibrations are verified with a standard obtained from a second source traceable to a national standard when commercially available. If a second source is not available, a standard prepared from a different lot may be used.

Criteria for the acceptance of initial instrument calibration is established (e.g., correlation coefficient or relative percent difference) and defined as listed in Appendix A and the method SOPs. The criteria used are appropriate for the calibration technique.

Where appropriate, the laboratory has manual integration procedures (SOP # 100PR) that are adhered to when evaluating calibration data.

Any samples that are analyzed after an unacceptable initial calibration are re-analyzed or the data are reported with qualifiers, appropriate to the scope of the unacceptable condition (see Section 12 – "Control of Nonconforming Environmental Testing").

Quantitation is always determined from the initial calibration unless the test method or applicable regulations require quantitation from the continuing instrument calibration verification.

Corrective actions are performed when the initial calibration results are outside acceptance criteria. Calibration points are not dropped from the middle of the curve unless the cause is determined and documented. If the cause cannot be determined, the calibration curve is re-prepared. If the low or high calibration point is dropped from the curve, the working curve is adjusted, and sample results outside the curve are qualified. The calibration acceptance criteria are included with every test method SOP.

27.5.2 Continuing Instrument Calibration Verification
27.5.2.1 Records:

The calculations and associated statistics for continuing instrument calibration are included or referenced in the test method SOPs for organic, inorganic, and metal SOPs.

Sufficient raw data records are retained to allow reconstruction of the continuing instrument calibration verification. Continuing instrument calibration verification records connect the continuing verification date to the initial instrument calibration.

Where appropriate, the laboratory has manual integration procedures (SOP100PR) that are adhered to when evaluating calibration data if there is any manual integration performed.

27.5.2.2 Frequency:
The Calibration is verified for each compound, element, or other discrete chemical species by following the criteria listed in method SOPs. When an initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration shall be verified prior to sample analyses by a continuing instrument calibration verification with each analytical batch.
Calibration verifications are performed:

- at the beginning and end of each analytical batch, except for instances when an internal standard is used. For methods employing internal standards, one verification is performed at the beginning of the analytical batch. Some methods have more frequent CCV requirements (see specific SOPs).

- When it is expected that the analytical system may be out of calibration or might not meet Calibration verification acceptance criteria.
- When the time period for calibration or the most recent calibration verification has expired.
- for all analytical systems that have a calibration verification requirement. Requirements can be found in method SOPs. Most inorganic and Metals methods require the CCV to be analyzed after every ten samples.

27.5.2.3 Evaluation, Verification, and Corrective Actions:
The validity of the initial calibration is verified prior to sample analysis by use of the continuing instrument calibration verification (CCV) standard.
Acceptance criteria for each method are posted on method SOPs and Appendix A.

Corrective action is initiated for CCV results that are outside of acceptance criteria (see Section 12 – "Control of Nonconforming Environmental Testing").

When the CCV fails, examine the run to determine if the cause of the failure only affects the failed CCV. Examples of this type of failure include: missed autosampler injection, low/no internal standard (IS) in the CCV, or CCV spiked at an incorrect concentration. In this case, another CCV, which is analyzed immediately (before analysis of further samples) can be run to verify the curve. If the second CCV passes, then analysis may resume. Data prior to a failing CCV is considered valid if this second CCV passes. The use of a second CCV is only applicable if the failure can be identified and only affects the failed CCV. The cause of the failure must be documented if a second CCV is run. If the failure cannot be identified or documentation is not performed, the samples preceding the failure back to the last passing verification is not considered valid.

27.5.3 Unacceptable Continuing Instrument Calibration Verifications
If routine (corrective action) for continuing instrument calibration verification fails to produce a second consecutive (immediate) calibration verification within acceptance criteria, then a new calibration is performed until acceptable performance is demonstrated after corrective action.

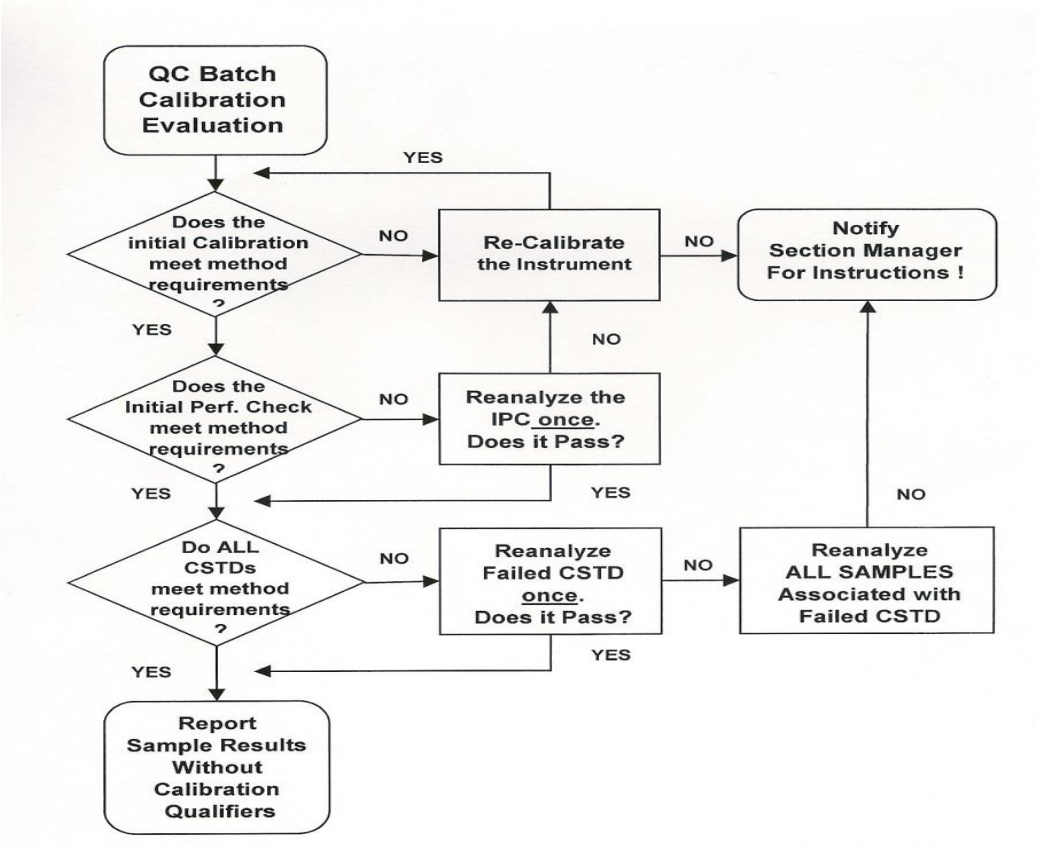
For any samples analyzed on a system with an unacceptable calibration verification or failed QC sample, some results may be useable if qualified and under the following conditions:

a) If the acceptance criteria for positive control are exceeded high (high bias) and the associated samples are below detection, then those sample results that are non-detects may be accepted and reported as non-detects.

b) If the acceptance criteria are exceeded low (low bias) and there are samples that exceed the maximum regulatory limit, then those exceeding the regulatory limit may be reported. Otherwise, the samples affected by the unacceptable verification shall be re-analyzed after a new calibration curve has been established, evaluated, and accepted

27.6 QA Evaluation for Each Batch

In general, the QA batch for each method will adhere to the following scheme if any part of the method QC has not met method requirements ### The samples re-analyzed and data reported with appropriate data qualifying codes if required.



27.7 Proficiency Test Samples and Inter-laboratory Comparisons

27.7.1 Compliance to Accreditation Requirements

The laboratory analyzes at least two TNI-compliant PT samples per calendar year for each accreditation Fields of Proficiency Testing (FoPT) for which the laboratory is accredited. An exception is made for analytes where there is no PT available from any PTPA approved PT provider at least twice per year. In these cases, the lab will run the PTs in the minimum time frame the PTs are available and not at all if they are not available.

The successive PTs are analyzed at least five months apart and no more than 7 months apart unless the PT is being used for corrective action to maintain or reinstate accreditation, in which case the dates of successive PT samples for the same accreditation FoPT is at least fifteen days apart.

27.7.2 PT Sample Handling, Analysis, and Reporting

The laboratory does not share PT samples with other laboratories, does not communicate with other laboratories regarding current PT sample results, and does not attempt to obtain the assigned value of any PT sample from the PT provider.

Proficiency Testing (PT) samples are treated as typical samples in the normal production process where possible, including the same analysts, preparation, calibration, quality control, and acceptance criteria, the sequence of analytical steps, number of replicates, and sample log-in. PT samples are not analyzed multiple times unless routine environmental samples are analyzed multiple times. Where PT samples present special

problems in the analysis process, they will be treated as laboratory samples where clients have special requests.

The type, composition, concentration, and frequency of quality control samples analyzed with the PT samples are the same as with typical samples.

Prior to the closing date of a study, laboratory personnel do not:

- subcontract analysis of a PT sample to another laboratory being run for accreditation purposes.
- Knowingly receive and analyze a PT for another laboratory being run for accreditation purposes.
- Communicate with an individual from another laboratory concerning the analysis of the PT sample.
- attempt to find out the assigned value of a PT from the PT Provider.

The laboratory institutes corrective action procedures for failed PT samples following the guidelines in Section 14 – "Corrective Action".

Retention of PT records is similar to that maintained for regular environmental samples. In addition, the lab maintains a copy of the online data entry summary when the PT results are submitted online.

27.8 Data Review

The laboratory reviews all data generated in the laboratory for compliance with the method, laboratory and, where appropriate, client requirements.

1. An initial review is performed by an analyst.
2. A second review is performed by the peer reviewer.
3. Final reports review and completion check is carried out by the program Manager or Chief Scientist/designee.

The inorganic section includes this review for checking the correctness of analyses and is applicable specifically to water samples.
These analyses include pH, conductivity, Total Dissolved Solids, and major anionic and cationic constituents.
Water Micro sample data sheets, Se, Hg and HAB data packages are relatively small. This review can be performed by entail scanning (convert to PDF) the Se, Hg, and HAB data packages and uploading them to the LIMS batch. The analyst would store the data in a binder or file cabinet. The analyst would notify the reviewer that the batch is ready for review. The reviewer would open the batch, open the PDF file, and review the data and initial the batch.

The anion and cation sums will be expressed as mill-equivalents (meq) per liter. They must balance.
The Program Manager or Chief scientists perform the final review and close the LIMS projects to report data to the clients.

The QA manager performs some of the Data reviews audits for some data packages for metal, inorganic, and organic sections and sent the report to managers and Analysts.

Section 28
REPORTING THE RESULTS

The result of each test performed is reported accurately, clearly, unambiguously, and objectively, and complies with all specific instructions contained in the test method.

Laboratory results are reported in a test report that includes all the information requested by the client, necessary for the interpretation of the test results, and required by the method used.

Data are reported without qualification if they are greater than the lowest calibration standard, lower than the highest calibration standard, and without compromised sample or method integrity.

The environmental chemistry laboratory reports reliable and accurate data of known and documented quality. This data can be used in decisions regarding Rule and Policymaking. The analysts and managers are responsible for disclosing any deviations from the methods requested by the client. Most Data is reported in the 3-significant figure from LIMs.

Sample Reanalysis:

When testing is repeated for any reason and data that has been entered in the LIMS needs to be changed to reflect a higher quality result, the access to change the previously entered results is limited to the Section Managers and Program manager. After results are initially entered the following individuals are the only ones authorized to make changes:

- Organic Chemistry – Program Manager or Organic senior chemist
- Inorganic Chemistry – Program Manager or In Organic senior chemist
- Metals – Program Manager or Metal senior chemist
- Microbiology – Program Manager senior, backup Analyst
- QA Manager

Sample re-analysis is conducted if a sufficient sample and holding time remain to repeat the analysis using an in-control system. In the case of an insufficient sample or holding time in order to repeat analysis, the data is processed and qualifiers applied to describe the sample may be deficient. The occurrence is further documented in the case narrative or communication with the customer and in the corrective action response.

28.1 Test Reports

The report format has been designed to accommodate each type of test performed and to minimize the potential for misunderstanding or misuse.

Each test report generated contains the following information:

a) a title, such as test report or test results;

b) the name and address of the laboratory, different from the address. The address and the phone number and name of a contact person should also be documented if there are any questions;

c) project identification and a pagination system;

d) the name and address of the client;

e) the identification of the method used;

f) a description of, the condition of, and unambiguous identification of the sample(s) tested, including the client identification code;

g) the date of sample receipt when it is critical to the validity and application of the results, date and time of sample collection dates the tests were performed, and the time of sample preparation and analysis if the required holding time for either activity is less than or equal to 72 hours;

h) the test results, units of measurement, an indication of when results are reported on any basis other than as received (e.g., dry weight), dilution factor, and reporting limits;

i) qualifier (See Appendix F for a list of laboratory data qualifiers);

j) the name, function, and signature or equivalent electronic identification of the person authorizing the test report and the date of issue.

28.2 Environmental Testing Obtained from Subcontractors

Utah Public Health Laboratory provides the client with the original test report from the subcontracting laboratory.

28.3 Electronic Transmission of Results

After all test requests for a sample are completed and reviewed, the results are reported to the customer. The format of results reported to the customer is determined during the consultation with the customer defining the Data Quality Objectives. These formats may take the form of hardcopy or of electronic file transfers. In no instance will data with suspect QC results be transferred without the qualifying statement.

All test results transmitted by e-mail or other electronic means comply with the requirements of the Government Records Access and Management Act (GRAMA) and associated procedures to protect the confidentiality and proprietary rights of the client. The laboratory follows UDOH privacy policy procedures on the handling of confidentiality of client data. All-State Employees are required to complete State privacy and data security policy training, Annually

28.3.1 Electronic Data Delivery (EDD)

The Divisions of Drinking Water and Water Quality require electronic data deliverables.

The Division of Drinking Water uses SDWIS format. The Division of Water Quality uses a special shared folder between it and the lab; the lab staff generates the EDD file in LIMS and copy the EDD file to the shared folder at

S:\edi\DEQ\WQX\processed

This is done after the approval and closing of the project by the Program Manager or Chief Scientist.
The DWQ retrieves the EDD file from this folder every week.

28.3.2 **Electronic Signature**
All employees' electronic signatures and initials are stored in LIMS and in the QA manager's files. All the data is reported with electronic signatures of Program Manager or chemist approving the analysis and closing the project.

28.4 Amendments to Test Reports

When any result that has been reported to the customer is changed, a comment must be added to an "Amended" report indicating the previously reported values, that the result was changed, and the initials of the individual making the change. The report must then be printed and mailed or electronically resent to the customer. Changed reports require formal corrective action and approval by the QA manager, Program Manager, and Chief Chemist

Any material amendments to a test report after it has been issued are made only in the form of another document or data transfer. All supplemental reports must meet all the requirements for the initial report and the requirements of this *Quality Manual*.

When it is necessary to issue a completely new report, the new report is uniquely identified and contains a reference to the original that it replaces.

29.1 QAP yearly updates from previous revision

QA Manual updates in Revision 3 from Previous Revision 2
QA Manual updates in Revision 4 from Previous Revision 3 in 2020

Changes from previous revision			
Section	Update	Date	Initial
25	Method 510 removed and entered 524.2	01/24/2019	AR
Electric signatures Added section	Further, address the where who and when electronic signatures are to be used. UPHL analysis Reports	01/24/2019	AR
23.1	Instrument updated for Lachat, BOD probe, Cyanide Software information LCMSMS	05/08/2019, 5/14/2019	AR
23.1	Added instrument ages/installation dates,	08/07/2019, 08/08/2019	AR

	updated instrument serial numbers, added ELISA and Atomx P&T to organic section, updated Metals instruments.		
19.1, 25.1.1, 27.5.1.3, 27.5.2.1	preservative check and manual integration	08/08/2019	Ar
Table 25.1	Removed the following inactive methods: EPA 8260 (BTEX), EPA 410.4 (COD), EPA 1110, SM4500C (Fluoride), EPA 508A, EPA 625 (Phenols), ortho-phosphate, EPA 226, EPA 900.0, EPA 160.5 (SS), EPA 351.4 (TKN), EPA 524.2 (Max THM) Added EPA 546 (ELISA) and EPA 537.1	08/08/2019, 08/09/2019	AR
Section 24	Supplies and services which affect the testing Added a stamen for supplier evaluation. Thisis evaluated by performing PT sample analysis and performance of second source QC samples results.	12/11/19	AR
25.1.2	Sampling Containers, Preservation Requirements, and Holding Times Correction made on the preservation of some inorganic methods, added 537.1, ELISA.	12/11/2019	AR
27.8	Water micro Se, Hg and HAB data packages are relatively small, Review.	12/11/2019	AR
Table 5-1, Cover page	Key personnel	12/11/2019	AR

Section 8.1, 10.2,10.3,11,20.2,28.2	Program Manager and section manager duties included. The chief scientist added in the Management section.	January 2020	AR
Page 22, 23 Page 38	Name Quartzy changed to SharePoint storage for an additional ten years	4/02/2020 04/02/2020	AR AR
Instrument list inorganic	Replaced with updated list	08/7/2020	AR
Section 28.3	Added a line privacy and security policy	9/29/2020	AR
Section 5.2.4	Updated Key personnel deputy	11/25/2020	EUO

END OF DOCUMENT