General Plan of Operations Appendix 1

Integrated Monitoring Plan (IMP)

November 2014

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Acronyms

AAC	Alaska Administrative Code
ABA	Acid Base Accounting
ADEC	Alaska Department of Environmental Conservation
ADF&G	Alaska Department of Fish & Game
ADNR	Alaska Department of Natural Resources
AP	Acid Generation Potential
ARD	Acid Rock Drainage
AWQS	Alaska Water Quality Standards
BMP	Best Management Practices
CFR	Code of Federal Regulations
EPA	Environmental Protection Agency
EPT	Aquatic insects (Ephemeropters, Phecopetra, and Trichopetra
FB	Field Blank
FL	Fork Length (tip of snout to the end of middle caudal fin rays)
Forest Service	U.S. Department of Agriculture Forest Service
FWMP	Fresh Water Monitoring Plan
GPO	General Plan of Operations
HGCMC	Hecla Greens Creek Mining Company
HDPE	High Density Polyethylene
ICP	Inductively Coupled Plasma Analysis
IDL	Instrument Detection Limit
IMP	Integrated Monitoring Plan
LCS	Laboratory Control Sample
MD	Method Blank
MDL	Method Detection Limit
MLE	Maximum Likelihood Estimate
MS	Matrix Spike
MSD	Matrix Spike Duplicate
MW	Monitoring Well
NEPA	National Environmental Policy Act
NP	Acid Neutralization Potential
NNP	Net Neutralization Potential
QAPP	Quality Assurance Project Plan
TDF	Tailings Disposal Facility
TDR	Time Domain Reflectometry
SOW	Statement Of Work
UGM	Undifferentiated Glacial and Marine
USEPA	U.S. Environmental Protection Agency

Units of Measure

ac	acre
cm	centimeter
in	inch(es)
ft	feet/foot
km	kilometer
m	meter
mm	millimeter
m^2	meter squared
ml	milliliter
µm	micrometer
oz/st	troy ounces per short ton
ppm	parts per million
st	short ton
yd^3	cubic yards

1.0 Introduction

Hecla Greens Creek Mining Company (HGCMC) prepared this *Integrated Monitoring Plan (IMP)* to meet the operational needs of the site, while addressing the goals and objectives of the federal and state regulatory agencies. This Plan was developed to meet the requirements of the Alaska Department of Environmental Conservation (ADEC) in accordance with AS 46.03.010 et. seq. and 18 AAC 60.015 et. seq. and 18 AAC 80.005 et. seq. and the U.S. Forest Service (Forest Service) implementation of 40 CFR § 1505.3 to ensure monitoring requirements identified in the National Environmental Policy Act (NEPA) documents that relate to HGCMC are met.

The Greens Creek Mine is owned and operated by HGCMC, a wholly owned subsidiary of Hecla Mining Company, Inc. The Greens Creek Mine is located near Hawk Inlet on northern Admiralty Island, in the Tongass National Forest, approximately 18 miles southwest of Juneau, Alaska (Figure 1-1). The mine site is situated partly within the Admiralty Island National Monument, and completely within the municipal boundaries of the City and Borough of Juneau. The mine site is comprised of federal and patented mining claims. The Greens Creek mine facilities are located within the Greens Creek, Zinc Creek, Tributary Creek, and Cannery Creek watersheds.

The Forest Service has issued special use permits/leases for various aspects of the operations. In addition, HGCMC holds 17 patented mining claims (7,300 acres), 645 unpatented mining claims (12,200 acres) in the area, and 17 acres in Hawk Inlet under a warranty deed with Bristol Resources, Inc.

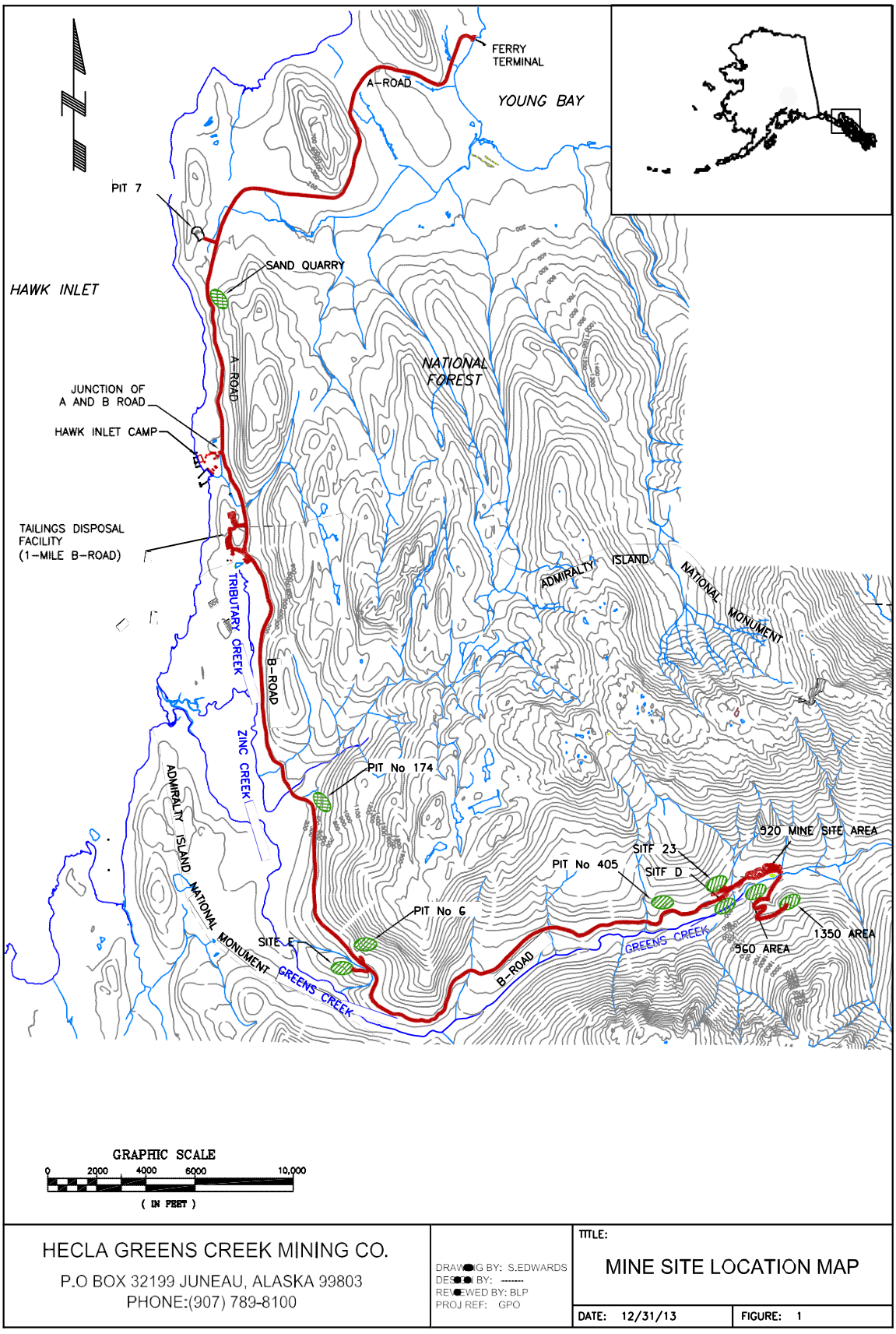
The Greens Creek Mine has been in operation since 1989, with only a short temporary cessation of operations due to low metal prices from April 1993 until July 1996. HGCMC produces three concentrates containing four payable metals (silver, zinc, lead, and gold) for shipping to smelters around the world.

1.1 Purpose

It is the goal of HGCMC to operate the mine and milling processes in a manner that will ensure the protection of the environment. This monitoring plan will assist HGCMC in the establishment and refinement of operating procedures to ensure the long-term protection of land, wildlife, and water resources. Periodic updates of the monitoring plan will coincide with regulatory changes, five-year environmental audit reviews, process modifications, or anomalies noted as a result of monitoring and sampling.

This IMP and the associated *Quality Assurance Project Plan (QAPP) of the General Plan of Operations Appendix 1 Integrated Monitoring Plan* (Appendix 1.A), are an intricate part of the environmental and operational management system for the Greens Creek Mine. The overall operation and each process component have specific management plans, which share common elements with this monitoring plan.

Figure 1-1: Greens Creek Project Location



To minimize duplication of information and rationale for specific monitoring and sampling requirements, the reviewer needs to reference the following site analytical reports and management plans:

- *Greens Creek Mine Reclamation and Closure Plan, GPO Appendix 14, April 2014*
- *Greens Creek Mine Tailings Disposal Facility Management Plan, GPO Appendix 3, February 2014*
- *Greens Creek Mine Waste Rock Management Plan, GPO Appendix 11, February 2014*
- *Greens Creek Mine Standard Operating Procedure, Construction Rock Environmental Characterization, March 2010*
- *Greens Creek Mine 2010 Site Water Balance, February 2010*
- *Greens Creek Mine Site 23/D Hydrogeology and Geochemistry Analysis, March 2004*

1.2 General Information

Location: (Mine Portal) Latitude 58° 04'58" North, Longitude 134° 37'57" West
Name of Facility: Hecla Greens Creek Mining Company – Greens Creek Mine

Type of Facility: Underground Silver, Lead, Zinc, and Gold Mine and Milling Operation

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1.3 Objectives

Compliance monitoring is undertaken to verify that the project operates within permit limitations thereby minimizing impact to the environment during operations and post closure. The objective of this document is to provide HGCMC and state/federal regulators with a clear and concise plan that lists monitoring and sampling criteria for surface/ground water quality, geochemical characterization of materials, geotechnical stability of structures, and aquatic biological resources present at the site. The relevant procedural information for sample collection, sample analysis, data analysis, and reporting are contained in Appendix 1.A.

1.4 Summary of Monitoring

This IMP presents the elements of HGCMC's monitoring and sampling program that have been initiated for operations. The monitoring and sampling area covers critical elements of the project's infrastructure, including Hawk Inlet facilities, Tailings Disposal Facility (TDF), waste rock sites, inactive

rock quarries, mill site and mine portal. This document will be updated as needed, based on regulatory changes, periodic reviews, process modifications, and the results of monitoring which indicate that further attention may be warranted.

Table 1-1 presents a summary of the water quality monitoring, biological monitoring, geochemical characterization and geotechnical monitoring activities performed during the period of active mining operations. Compliance monitoring of wastewater and storm water discharges, air emissions and other resources, such as Hawk Inlet monitoring, are addressed under specific permits and not included in this document.

Table 1-1: Summary of Monitoring Activities

Facility	Component	Method	Media	Parameters	Frequency
Project Area	Water Quality Compliance	Fresh Water Monitoring Program	Surface Water	WQ **, flow	Monthly
			Ground Water	WQ	Quarterly
	Aquatic Community Health	Biological Monitoring	Fish, macro-invertebrates, periphyton	Metals, abundance, diversity	Annually
	Const. Rock Characterization	ABA, Kinetic	Rock	NNP, ICP (metals)	As needed
Tailings Disposal Facility	Internal Water Quality Monitoring	Water sampling	Surface Water	WQ, flow	Annually
			Ground Water	WQ	Annually
			Pore Water	WQ	Annually
	Tailings Characterization	ABA, Kinetic	Tailings	NNP, ICP (metals)	Monthly, Insitu 5 years
	Stability	Visual inspection	TDF surface	Checklist	Monthly
		Compaction	Tailings	% moisture, density	Quarterly
		Wells, piezometers	GW, pore water	Water level, pressure	Monthly
	Fugitive Dust	ADP *	Dust	mass, Pb, Zn	Bi-weekly
Site 23	Internal Water Quality Monitoring	Water sampling	Surface Water	WQ, flow	Annually
			Ground Water	WQ	Annually
			Pore Water	WQ	Quarterly
	Waste Rock Characterization	ABA, Kinetic	Waste Rock	NNP, ICP (metals)	Quarterly, Insitu 5 years
	Stability	Visual inspection	Site 23 surface	Checklist	Monthly
		Survey	hubs, inclinometers	movement	Quarterly
		Wells, piezometers	GW, pore water	Water level, pressure	Monthly
Inactive Waste Rock Sites & Quarries	Internal Water Quality Monitoring	Water sampling	Surface Water	WQ, flow	Annually
			Ground Water	WQ	Annually
	Material Characterization	ABA, Kinetic	Rock	NNP, ICP (metals)	Once every 5 years
	Stability	Visual inspection	Area	cracks, sloughs	Quarterly
Pond 7	Geotechnical Stability	Visual inspection	Embankments, spillway	ADNR-Dam Safety Checklist	Monthly
		Survey	Monuments	movement	Semi-Annually

* ADP – Atmospheric Deposition Pail
** WQ-water quality

2.0 Fresh Water Monitoring Program (FWMP)

Project Background

Monitoring and sampling surface and ground water resources is an integral part of the environmental protection measures at the project.

The Hecla Greens Creek Mining Company (HGCMC) Fresh Water Monitoring Program (FWMP), in conjunction with the Quality Assurance Project Plan (QAPP) (Appendix 1.A), documents the necessary methods and procedures for sample collection, laboratory analysis, data management, and information utilization necessary to ensure that the monitoring requirements defined in the mine's Federal Environmental Impact Statement (FEIS), Record Of Decision (ROD), and Environmental Assessments (EA) are fulfilled. Both surface water and ground water monitoring are included. The FWMP and QAPP are to be reviewed and updated as needed to ensure best use of resources, appropriate quality of data, and use of the results in management decisions.

Prior to 1995, fresh water monitoring at the Greens Creek Mine was conducted under two documents; the Greens Creek Fresh Water Monitoring Operations Manual 1988; and the draft General Plan of Operations (GPO), Appendix 1 (June 1992). These documents were revised and combined into the 1995 Fresh Water Monitoring Program. The purpose of the 1995 revision was to update the information goals for monitoring, and the standard procedures for sample collection, laboratory analysis, data handling, data analysis, and information utilization. Information goals are specific quantitative and qualitative statements describing the information expectations of the monitoring program. Information utilization is defined as how the information derived from data analysis is reported and applied to management decisions.

The 2000 revision of the FWMP was a result of a Greens Creek sponsored interagency regulatory review of the Greens Creek Mine. The Project Team consisted of representatives from HGCMC and several State and Federal regulatory agencies, including the State of Alaska Department of Natural Resources (ADNR), Environmental Protection Agency (EPA), United States Forest Service (Forest Service), United States Fish and Wildlife Service (USFWS), State of Alaska Department of Fish and Game (ADFG), State Attorney General Office (AGO) and State of Alaska Department of Environmental Conservation (ADEC). The purpose of the review was to allow the State and Federal agencies having jurisdiction over the mine to ascertain overall compliance with existing authorizations and environmental laws and to implement corrective action, if needed; amend existing authorizations or plans, if necessary; and process any new authorizations necessary to provide for confidence in regulatory compliance and environmental effectiveness of the Greens Creek programs. The revision incorporated changes requested and approved by the participating regulatory agencies and HGCMC.

This 2014 revision was undertaken in conjunction with the renewal of the Waste Management permit. An environmental audit of Greens Creek Mine was required as part of the permit's renewal. SRK Consulting, Inc. conducted the audit and submitted a final report in March 2009. Recommendations from the audit have been incorporated into the IMP and QAPP.

2.1 Actions for Compliance Monitoring Directives

Implement the revised FWMP.

Conduct annual reviews of information goals, analytical data, statistical analyses, and sampling frequencies to ensure that information utilization needs are met.

Apply the information derived from data analysis and interpretation to management decisions.

2.2 Data Quality Objectives (DQOs)

DQOs are quantitative and qualitative objectives for the quality of the data used. DQOs define the quality of services requested from the laboratory, and are used in the quality assurance (QA) review by comparing the quality control (QC) data against the DQOs to qualify the data as fully usable, estimated, or rejected as unusable. Refer to the QAPP (Appendix 1.A) for additional detail on the DQOs.

2.2.1 Qualitative DQOs

Qualitative DQOs are established for representativeness and comparability.

Representativeness is a determination of how well the sample represents environmental conditions. It is addressed by monitoring site selection and sample collection and handling protocols. Requirements for blank analyses and QA review of blank data verify that samples have not been contaminated in the sampling or analytical processes.

Comparability is a determination of how well data from different sources compare to each other. It is addressed by ensuring appropriate method detection limits are achieved, and QC measures and QA data reviews are performed to verify that the data are of known and acceptable quality.

2.2.2 Quantitative DQOs

Quantitative DQOs are established for method detection limits (MDLs), minimum levels (MLs), precision, accuracy, and completeness.

MLs are established for each analyte at 90% of the Alaska Water Quality Standards (AWQS) with one exception: the ML for chromium will be the same as for chromium VI. Waters monitored under this plan are protected for all uses, and the most protective standard is applicable (18 AAC 70.020(1)). Of particular concern for these waters is protection for the growth and propagation of freshwater fish, shellfish, other aquatic life, and wildlife (18 AAC 70.020(1)(c)).

For those analytes having a hardness dependent AWQS, the hardness value used to calculate the standard for determining the ML was based on the 25th percentile of the measured hardness at surface water and groundwater sampling sites over the previous 5 years. Surface water and groundwater hardness values were summarized independently for the 25th percentile determination. Table 3 in the QAPP (Appendix 1.A) shows the MLs for each analyte evaluated by this plan.

MDLs are calculated based on the ML using certain information developed by EPA (EPA 821-B-95-002, April, 1995). For the purposes of this plan, the MDL=ML÷3.18, rounded up to the same number of significant digits as the AWQS for that analyte. Table 3 of the QAPP (Appendix 1.A) shows the MDLs for each analyte evaluated by this plan.

Precision is a measure of the ability to replicate an analysis and is expressed as the relative percent difference (RPD). The RPD criterion for water samples is ±20% and is only applicable when the analyte concentration is more than 5 times the instrument detection limit (IDL), and as long as the native amount is not greater than 4 times the spiked amount.

Accuracy is a measure of how close the analytical result is to the true concentration of the analyte, and is expressed as percent recovery (%R). The Matrix Spike/Matrix Spike Duplicate (MS/MSD) criteria are 75-125 %R for all metals. The criteria are only applicable for MS/MSD analyses as long as the native amount is not greater than 4 times the spiked amount. The accuracy limits for the Laboratory Control Sample (LCS) are method dependent, e.g. 90-110 %R for Inductively Coupled Plasma Analysis (ICP).

Completeness is a measure of how many planned analyses for all analytes actually resulted in usable data, defined as all data that is not rejected, and is expressed in percent (%). The completeness criterion is 95% for a water year, which is October 1st through September 30th.

2.3 Monitoring Sites

HGCMC has designated freshwater monitoring sites including those utilized in the FWMP. Once a site is established it is never changed and remains a site even if it becomes inactive. If a site is obliterated by construction or moved, the original site number becomes inactive and the new monitoring location is given a new site number.

Monitoring can be discontinued and a site becomes inactive for a variety of reasons. These include if the site is destroyed due to construction or natural phenomenon, was discontinued at some time in the past prior to the 2014 FWMP revision, or deemed no longer necessary by the regulatory agencies and HGCMC.

2.3.1 Description and Location of Fresh Water Monitoring Sites

Table 2-1 lists all surface and ground water monitoring sites in the current FWMP, contains a brief location description, and coordinates. Figure 2-1 depicts the approximate locations of compliance monitoring sites. These sites are considered "active." They have been determined to meet the analytical and informational needs necessary for comparison and interpretation of previous data to those of the current conditions at the site. Other sites that were previously required for monitoring are called "inactive" and are not discussed here. Details of the inactive sites can be found in previous FWMPs and annual reports.

Table 2-1: Active Monitoring Site Locations

Site #	Site Name	Location	Latitude	Longitude
6	Middle Greens Creek	The site is on Greens Creek downstream of the mine and mill. It is about 15 meters upstream of the confluence of Bruin Creek..	58°04'47.424" N	134°38'25.849" W
9	Tributary Creek	The site is on Tributary Creek, about 1 kilometer downstream of the TDF, and about a half kilometer upstream of the confluence of Zinc Creek.	58°06'22.040" N	134°44'44.100" W
13	Upper East Mine Drainage	Small drainage to the East from the 1350 adit, site is below the sediment pond in the adit area.	58°04'47.685" N	134°37'39.951" W
27	MW-2S	The site is an 8 foot deep well completed in the peat/sand unit. It is in muskeg about 250 meters south of the TDF.	58°06'48.546" N	134°44'38.365" W
29	MW-3S	The site is a 15 foot deep well completed in the peat/sand unit. It is in muskeg about 50 meters west of the TDF.	58°06'59.860" N	134°44'51.821" W
32	MW-5S	This site is a shallow well completed in the peat/sand unit. It is in the Muskeg about 50 meters west of the TDF.	58°06'57.732" N	134°44'51.225' W
46	Lower Bruin Creek	The site is on Bruin Creek downstream of waste rock areas 23 and D. It is about 20 meters upstream of Greens Creek.	58°04'46.450" N	134°38'32.580" W
48	Upper Greens Creek	The site is on Greens Creek upstream of all mining activities. It is about 300 meters upstream from the Greens Creek bridge at the 920 portal.	58°05'01.350" N	134°37'33.590" W
49	Upper Bruin Creek	The site is on Bruin Creek upstream of waste rock area 23.	58°05'04.070" N	134°38'30.410" W
54	Greens Creek below D-Pond	The site is on Greens Creek downstream of waste rock areas 23 and D. It is about 20 meters upstream of the confluence of Gallagher Creek.	58°04'41.681" N	134°38'46.529" W
57	MW-23-00-3	The site is a 68 foot deep well completed in gravel and clay. It is up gradient of waste rock area 23.	58°04'59.933" N	134°38'39.881" W
60	Lower Althea Creek	The site is on Althea Creek, about 200 meters downstream of the TDF.	58°04'41.770" N	134°45'08.432" W
61	Greens Creek Floodplain	The site is a surface water site ~ 40 meters west of D Pond in the floodplain.	58°04'43.480" N	134°38'52.910" W
62	Greens Creek Lower than 54	The site is on Greens Creek downstream of waste rock areas 23 and D. It is about 250 meters downstream of Site 54.	58°04'38.650" N	134°39'06.000" W
609	Lower Further Creek	This site is on Further Creek, about 200 meters downstream of the TDF.	58°07'05.707" N	134°45'06.332" W
711	Greens Creek above Site E	This site is on Greens Creek about 50 meters upstream of Site E.	58°04'08.425" N	134°43'27.181" W
712	Greens Creek below Site E	This site is on Green Creek about 200 meters downstream of Site E.	58°04'13.858" N	134°43'42.438" W

2.3.2 Monitoring Sites

Figure 2-1: Fresh Water Monitoring Site Location Map

2.4 Monitoring

2.4.1 Site Selection

A primary criterion for selecting a monitoring site is that it must meet the DQO for representativeness. A monitoring site must be in the appropriate location so that collected data is representative of the facility or condition (i.e., natural background) it is intended to monitor. This is determined based upon an annual review, analysis and interpretation of collected data.

The current FWMP sites listed in Table 2-1 have been demonstrated to be representative for monitoring potential water quality impacts from the mine operations, while also maintaining an efficient monitoring program. The addition and activation of any new sites would be associated with either a facility expansion and the need to establish proper up-gradient and down-gradient compliance points, or in response to a statistically significant change in water quality at an existing site and the need to better characterize the nature and extent of the change. Changes to FWMP monitoring sites must be approved by the regulatory agencies.

2.4.2 Frequency Selection

Monitoring frequency is determined based upon results of previous data analysis, planned future uses of data, and changes in mine operations. Frequency will be sufficient to detect any seasonal trends. For new monitoring sites, quarterly or monthly sampling will be sustained until sufficient samples are taken to conduct statistical trend analyses. Exceptions can be made based on site accessibility and hazards, such as brown bear activity. Unexpected events may also affect monitoring frequency.

2.4.3 Analytical Parameters for Fresh Water Monitoring

The suite of analytical parameters for samples collected at a given site in a given sample period are based upon an annual review of the information goals. The suite of analytical parameters is selected to meet those informational needs based on results from previous analysis.

Surface water sample analytical Suite P (Table 2-2) contains the shortest list of critical analytes developed over the course of the mine life. The listed parameters generally characterize constituents of concern at surface water monitoring sites.

A more comprehensive analytical profile is used for ground water analysis and periodically used for surface water, typically during months of low flows. Suite Q (Table 2-3) analytical profile contains additional dissolved metals associated with the Greens Creek ore body or waste rock that are important indicators for ground water and surface water quality during periods of low flow.

Table 2-2: Suite P (Surface Water)

Analytical Parameters	
Conductivity	pH
Temperature & Hardness	Sulfate
Total Alkalinity	
Dissolved Metals	
Arsenic	Lead
Cadmium	Mercury
Copper	Zinc

Table 2-3: Suite Q (Ground and Surface Water)

Analytical Parameters	
Conductivity	pH
Temperature & Hardness	Sulfate
Total Alkalinity	
Dissolved Metals	
Arsenic	Mercury
Barium	Nickel
Cadmium	Selenium
Copper	Silver
Chromium	Zinc
Lead	

2.4.4 **Fresh Water Quality Monitoring Schedule**

The frequency of sampling surface and ground water sites has been developed over the life of the operation with numerous adjustments as the program has been constantly re-evaluated and refined. Table 2-4 provides a general overview of annual surface and groundwater sampling.

Table 2-4: Fresh Water Monitoring Schedule

Site #	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
6	P	P	Q	P	Q	P	P	P	P	P	P	P
9		Q						Q		Q		Q
13		Q						Q			Q	
27		Q						Q		Q		Q
29		Q						Q		Q		Q
32		Q						Q		Q		Q
46		Q			Q			P			P	
48	P	P	Q	P	Q	P	P	P	P	P	P	P
49		Q			Q			P			P	
54	P	P	Q	P	Q	P	P	P	P	P	P	P
57		Q			Q			Q			Q	
60		Q						Q		Q		Q
61		Q			Q			Q			Q	
62	P	P	Q	P	Q	P	P	P	P	P	P	P
609		Q						Q		Q		Q
711								Q				P
712								Q				P

P= Suite P; Q= Suite Q

2.5 Sample Collection

In accordance with the current monitoring schedule in Section 2.4.4, water samples are collected using protocols designed to minimize bias from systematic and/or erratic contamination introduced during sample collection. Procedures for the collection of surface water and groundwater samples are provided in the QAPP (Appendix 1.A).

2.6 Sample Documentation, Packaging and Shipping

All FWMP samples are collected by HGCMC personnel, packaged, and transported off Admiralty Island for laboratory analyses. Information on the protocols for documentation, packaging and shipping of samples is provided in the QAPP (Appendix 1.A).

2.7 Sample Analyses

Independent laboratories will be used for water sample analyses. A written statement of work (SOW) defining contractual requirements, DQOs, and data deliverables for the FWMP will be prepared and sent to any laboratory selected to conduct water quality analyses. Laboratories will also be periodically audited.

2.7.1 Scope of Work for Analyses

A written SOW shall be provided to the selected laboratory(s) giving direction on the analytical work to be furnished which includes the following.

- The anticipated number of samples including QC samples, the analytes to be monitored, and the DQOs that must be met will be stated.

- The laboratory shall notify HGCMC immediately if any sample is lost due to a lab accident. This prompt notification allows HGCMC the option of re-sampling to replace the sample or taking additional samples to confirm the unusual result.

- Water quality sample analyses shall be performed within holding times and using the approved methods listed in 40 CFR § 136, Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act.

- The laboratory shall be responsible for biological sample preparation. This includes final cleaning of benthic macroinvertebrate samples of debris before analysis, and rinsing periphyton samples with DI water before analysis.

- The laboratory shall provide their latest comprehensive MDL study, done in accordance with 40 CFR § 136 Appendix B, to the third party conducting the QA review and will provide updates as they are done.

- Field Blank (FB) samples shall be analyzed for the same suite of analytes as the sample collected at the site where the FB was collected.

- For every sample group a method blank (MB) shall be analyzed for each analyte scheduled for analysis in that sample group.

- For every sample group a laboratory control standard shall be analyzed that is traceable to different source standards than the ones used for calibrations. The LCS will have a concentration for each required metal at its MDL level or, for those analytes whose MDL is

outside the range of the calibration curve, at a concentration appropriate to the curve. A duplicate analysis of this LCS will also be performed.

- For every sample group matrix spike/matrix spike duplicate (MS/MSD) analyses shall be performed for all the metals scheduled for that group. The laboratory will select the site on which MS/MSD analyses are performed and rotate it monthly to ensure all sites are included. In the laboratory the sample from the selected site will be split into thirds and two of them spiked accordingly. At least one fraction will be spiked and the laboratory will select that fraction. The spiking level should result in concentrations at or above the AWQS for each metal.

- The laboratory shall keep the complete set of raw data for the samples including sample preparation logs and instrument calibration information in easily accessible files for a period of at least 6 months

- The laboratory shall notify HGCMC immediately upon any change in certification status, personnel, equipment, or any other aspect of laboratory operations that may adversely impact the integrity of the samples or the attainment of DQOs for the analytical results.

2.7.2 Scope of Work for Data Deliverables

The written SOW provided to the selected laboratory(s) shall give direction on the data deliverables to be provided in a report to HGCMC, on laboratory letterhead, within 45 days of sample receipt, with the following information:

- Document the date samples were received by the laboratory, whether or not the shipping container was received with the seal intact, and if all samples listed on the sample inventory sheet were present.

- Document whether or not inductively coupled plasma (ICP) was used and if raw data were generated before inter-element and background corrections were applied.

- Document any problems, QC criteria exceedances, holding time exceedances, and observations affecting sample integrity and provide a detailed description.

- Provide a statement of authenticity and certification of the data with the date the report was generated and dated signature of the lab manager.

- Document the results of all sample analyses, including blind duplicates submitted at HGCMC's discretion, with HGCMC sample numbers and their corresponding laboratory number(s), date received, analyses performed (analyte and dissolved, total, or total recoverable fraction), analytical result, IDL, MDL, ML, and unit of measurement for each analyte.

- Document the results of the MB and FB analyses for each analyte.

- Document the results of the LCS analyses including the calculated %R for each analyte, and the RPD of the LCS results for each analyte.

- Document the results of the MS/MSD analyses including the calculated %R for each analyte, and the RPD of the MS and MSD results for each analyte.

- Document all analyses not meeting holding times, MDLs, or the precision and accuracy control limits by flagging them in the analytical report and provide definitions for the flags.

- Provide a compatible electronic file with the analytical results in a format compatible with the Environmental Management Database System, to reduce errors and labor required for data entry in the HGCMC database.

2.8 Quality Assurance

Data used for decision making are to be of known and acceptable quality. All data are reviewed by a qualified QA reviewer to determine if the DQOs have been met. A qualified QA reviewer has no bias about the data quality and can evaluate the possible impacts to data comparability introduced by the use of multiple labs in the analysis of samples. As a result of the QA review, data may be qualified as estimated or rejected for failure to meet the DQOs.

The requirements for field and laboratory quality control measures and methods for data verification and validation are provided in the QAPP (Appendix 1.A).

2.9 Reporting

Data specification and collection provide the foundation of a monitoring system. Review, evaluation, and reporting the data is the next essential step. Information users base decisions on the monitoring results and contents of reports.

2.9.1 Purpose of Reports

Documentation and communication of information resulting from data evaluation is the purpose of reports.

- Defined, periodic, HGCMC reports document the following:
  a) The monitoring activities.

  b) The information gained in the monitoring process.

  c) The results of information evaluation.

- Reports communicate information that is used as follows.
  a) To provide the basis for management decisions.

  b) To provide the basis for assessing the effectiveness and efficiency of the FWMP.

2.9.2 Responsibility for Reports

HGCMC is responsible for the preparation and distribution of the reports specified in this section.

2.9.3 Distribution of Reports

The reports specified in this section are to be distributed in electronic format to the Forest Service, and ADEC.

2.9.4 Reports of Exceptions

The purpose of a report of exception is to communicate changes or unanticipated problems and resulting actions. Exceptions are very short-term temporary conditions not requiring a FWMP modification. An example is the taking of additional samples for a short period of time to verify an unusual result. The report also documents the event for the historical record.

The content of a report of exception varies depending on the exception. The information provided should be clear and fully explained.

Reports of exception are made as needed and may be either an emergency or not an emergency. Emergencies are events with actual or potential significant resource damage. A report for an emergency such as a chemical spill affecting fresh water is distributed as soon as possible.

Events that are unanticipated and unscheduled but do not appear to cause or have the potential of causing significant resource damage are not time critical. They may be reported along with the next scheduled report.

2.9.5 Annual Reports

The purpose of the annual reports is to provide information which the ADEC, Forest Service, and HGCMC use to determine the following:

a) If any changes to the monitoring schedule are needed.

b) If any other changes to the FWMP are needed including any aspects of monitoring, evaluation, or reporting.

c) If any changes in best management practices (BMPs) are needed.

The content of the annual reports covers activities during a water year, October 1st to September 30th, and includes the following items:

a) A table of contents.

b) A list of interventions (procedural changes, natural phenomena and mine operation changes) that could possibly affect data during the water year and any effects detected from visual data analyses.

c) A list of any negotiated mid-year FWMP or mine BMP modifications that were made

including changes to the monitoring schedule and the problems they address.

d) A list of company and agency personnel who were involved in the FWMP during the water year and their function or job title.

e) A list of proposed program modifications including proposed revisions to the monitoring schedule, and discussion/rationale for proposed changes based on data analysis.

f) The data analyses required for each individual monitoring site include the following:

(1) An interpretive report of the conclusions drawn from the data analyses including comparisons to previous years' data, baseline data, and background data.

(2) A clarification of what data were used in the analyses and identifying any data which was not included such as data that was qualified as rejected by the QA reviewer or confirmed as an outlier based on the outlier analyses and re-sampling performed by HGCMC.

The evaluation and handling of potential outliers will be performed using the guidance found in the EPA document "Guidance for Data Quality Assessment", EPA/600/R-96/084. Section 4.4 of the EPA document provides guidance on identifying potential outliers, choosing the proper statistical test, evaluating the results and documenting the process.

The first step is to review the data to determine whether any of the points may be potential outliers. Graphical representations are the most common method. Once potential outliers are found, the data must undergo a statistical test designed to detect outliers. The statistical test chosen must be applicable to the distribution type of the data set and the number of potential outliers in the data set.

At this point, the results of the statistical outlier test must be evaluated fully to determine whether the potential outliers are a true outlier or simply an extreme value that may be part of the data set's distribution. No data points should ever be excluded solely based upon statistical testing. Any potential outliers identified by proper statistical testing must be verified. The verification of outliers must include scientific support that the data point is truly an outlier. If further checking does not suggest the point is an outlier, the results of the statistical test cannot be used to label the point as an outlier. If the support is found the data point may be identified as an outlier.

The data analysis performed on the data set to which the outlier belongs must be performed once with the outlier included and again with the outlier excluded. The results are then to be reviewed to determine the impact on the data analysis with regards to the contribution of the outlier data points.

The final step for outlier designation is documentation. The rationale for the choice of the outlier test must be given, along with the results. Then, the supporting scientific facts must be given to demonstrate the outlier is not just a statistical

anomaly, but was in fact a true outlier. Finally, the impact the outlier data point had on the statistical processing of the data must be given.

(3) A list of qualified data from the monthly QA review reports.

(4) A chronological list by site of all data collected during the water year that exceeds AWQS.

(5) A comparison of medians will be made. Data outliers shall not be used in the data set used for median comparisons. Values between the MDL and ML will be used. A notation will be included in the report that states which values used in the median comparison fall between the MDL and ML. Data values below the MDL shall be assigned a value of zero for the purposes of median comparisons. A description of applicable median comparisons follows.

Analytical results must be statistically compared to determine whether concentration changes have occurred in a geographic situation or over time. Since nearly all data is not from a normally distributed population, it is necessary to compare the medians between the data sets. Although the initial step involves difference testing of the medians, several additional steps are taken to fully evaluate the meaning of that difference testing

The first step is analysis of variance based upon the ranked data. Ranking must be used due to the nonparametric distributions. The results of the analysis of variance are evaluated to estimate what level of significance is attached to the difference testing of the means. The significance level is then compared to the project objectives to ascertain whether the two data sets differ. This significance level must receive equal attention as did the result of the difference testing.

Multiple comparisons testing is then performed so that the indications given in the earlier median testing and significance testing are confirmed. If the multiple comparisons testing does not support the conclusions of the earlier testing, then further examination is needed to rule out the possibility that false indications were given. If the multiple comparisons testing confirm the other testing, then there is a greater confidence the original results are indicative of site conditions. The multiple comparison methods chosen must be sufficiently robust as to either confirm or countermand the simpler one-on-one testing.

(6) X-Y graphs of the analytes specified and a trend analysis if indicated by visual inspection of the graphs. The scale shall be appropriate to conduct visual trend analyses, i.e., each scale will be as confined as possible based on each data range. AWQS criteria will be displayed on the graphs. Data outliers shall not be displayed on the x-y graphs. Data qualified by the QA contractor shall be labeled as such on the x-y graphs. Data values below the MDL shall be assigned a value of zero for the purposes of the x-y graphs.
Any indeterminate trend (may or may not be a trend) shall be verified using a statistical trend analysis. Data outliers shall not be used in the statistical trend analysis. Data values below the MDL shall be assigned a value of zero for the purposes

of the trend analysis. Trend analyses must be performed on the data sets such that the appropriate level of confidence is achieved. This level is based upon the traditional false positive / false negative rate (related to α) that can be tolerated. Also, the statistical test chosen must be powerful enough to conclude whether a trend is present or not. In other words, the test cannot be so weak that no conclusion is reached, even on data where clear trends are evident.

Also, the test must be selected and the test parameters chosen such that the distribution of the data is either properly matched or is non-parametric. If the data are tested and proven to be normally distributed, then normal statistical tests shall be utilized. If the data distributions cannot be matched, then non-parametric testing is needed.

Once these two issues are resolved, the statistical test must be able to handle a seasonality component. The first step in the process is to choose a proper technique to determine whether the data have a seasonality component. If they do, the trend test must have a seasonality parameter to adjust for this component in the data. Further, the data set must contain enough data within the periodicity of the season to allow for this testing. This means that a seasonality component cannot be identified unless there are frequent enough data points within each season to allow for this conclusion to be reached. An example, would be that a seasonal component of about 6 months (one wet and one dry season per calendar year) cannot be tested if the data were only obtained quarterly or semi-annually, unless independent proof of the seasonal component can be provided.

2.10 Data Management

This section documents information storage, access, and archive practices for both hardcopy and electronic information.

2.10.1 Reports

- Access to records is controlled by the remoteness of the location and the limited access to mine premises.
- All incoming original hardcopy laboratory reports and associated QA review reports are filed chronologically at the mine.
- Electronic copies of HGCMC's reports are stored on a local server, which is backed up and maintained by the information technology department.
- Original hardcopies never leave the premises. They are photocopied as needed for distribution and satisfying information requests.
- Hardcopy reports may be archived 6 years after the date of creation. They may be moved to a less accessible location provided the previous five years of hardcopy are kept readily accessible.

2.10.2 Electronic Data

- A relational database containing all the FWMP data is maintained by HGCMC at the mine. Copies or partial copies of the database may be distributed to others as needed to facilitate data analysis.

- Data security is maintained by limiting access rights to the database files through network login IDs and passwords. Passwords are changed as needed.

- Laboratory data are electronically imported or manually entered into the HGCMC database. Associated qualifiers are manually entered after the QA review report is finalized and received by HGCMC.

- Personnel will be trained in reading the data sheets, electronic data transfer, and using the database before data entry is performed.

- All data (100%) entered into the database manually, and a sample (5%) of the data imported into the database electronically, are verified against the hardcopy before the data are used for analysis.

- Data produced before January 1989 may be archived to maintain processing speed and reduce the size of the backups.

- If data is archived it must be reloaded before database upgrades or enhancements are made to ensure it remains accessible and compatible. After the changes are completed it may be archived again.

- Changes to the database structure or utilities may be needed as a result of changes to the FWMP, data analysis protocols, or other reasons. A log of database changes, enhancements, problems, and fixes is kept to aid in troubleshooting.

2.11 Program Audits

Program audits provide an evaluation of the efficiency and effectiveness of the QA functions of the FWMP. This feedback loop provides the information needed for continuous improvement of the FWMP. The audit procedures below evaluate how well the information goals and DQO's are being met.

2.11.1 Responsibilities

HGCMC has the primary responsibility for ensuring that the data are of known and acceptable quality and the FWMP has been implemented as designed and thus has primary audit responsibility.

The Forest Service and ADEC have regulatory oversight responsibility and may perform independent audits on a random and/or as needed basis. Other agencies may also perform audits.

2.11.2 Data Acquisition Audits

A review of the data collection system will evaluate whether or not the QC procedures in the FWMP are being followed and if documentation of these activities is sufficient to establish the quality of the information collected. Findings may be used to make improvements to the FWMP or to initiate corrective action by HGCMC for lapses in execution or documentation.

- HGCMC will perform one audit per year. The results of this audit will be included with the yearly report.

a) The laboratory and QA review reports for a randomly selected month in conjunction with the FWMP and the current monitoring schedule are reviewed for the following determinations:

b) The completeness of the laboratory data versus what was planned in the monitoring schedule and if the correct analytical fractions were analyzed.

c) Whether or not analyses were performed within holding times.

d) Whether or not a QA review of the data was performed and the amount of data qualified as estimated or rejected.

2.11.3 Data Management Audits

A review of data management evaluates whether or not the procedures for data management in the FWMP are being followed and if data integrity is being maintained. If lapses in data management are found corrective action will be taken by HGCMC and documentation kept on file at the mine site.

- HGCMC will perform one audit per year. The results of this audit will be included with the yearly report.
- The data management specifications of the FWMP are reviewed for the following determinations:

a) Whether all reports were received within the specified time and copies forwarded as required.

b) Whether hardcopy and electronic data are stored such that unauthorized access is minimized.

c) Whether or not laboratory data have been QA reviewed and qualified if necessary, which is documented with a report.

d) Whether laboratory report and QA review report originals are in the files where expected.

e) Whether the laboratory data with appropriate qualifiers have been accurately entered into the database.

f) Whether statistical analysis of the data is being appropriately performed and reports are found in the files where expected.

g) Whether the FWMP has been reviewed and updated as needed.

h) Whether previous copies of updated versions of the FWMP are retained and found in the files where expected.

2.11.4 Laboratory Audits

A review of the laboratory's facility, equipment, personnel, organization, and management will evaluate the data reliability the laboratory is capable of producing. The laboratory as a system is verified against the documentation provided in their QA manual, their MDLs, and the SOW defining the services to be provided to HGCMC. A complete and thorough audit may be done through contractual services. HGCMC may choose to accept the results of a third party audit done for other purposes, such as drinking water certification or national accreditation programs such as A2LA, instead of performing their own audit.

- Laboratory audits should be performed at least every five years.
- Guidelines for laboratory audits are available from the USEPA or ASTM Standard Practice E548. The basic elements are summarized below.

a) Organization:
Well Organized
Duties/Responsibilities Clearly Defined
Supervision/Inspection/Audit/Self-Appraisal Program

b) Staff:
Technical Competence Qualifications Documented
Training/Maintenance/Upgrading of Competence Sufficient Supervision
Adequate Number of Staff

c) Equipment:
Adequate in Kind and Quality Maintained

d) Calibration/Reference Standards

e) Test Methods/Standard Operating Procedures

f) Environment/Facilities:
Space
Physical/Chemical Control Housekeeping

g) Samples:
Handling
Storage
Integrity/Chain of Custody

h) Analytical Reports and Record Keeping

i) QA program with specified QC activities

- A copy of the letter of certification or accreditation may be used as the documentation of an audit. Otherwise, the auditor will prepare a report listing the items reviewed and the conclusions of the review with any recommendations. Copies will be provided to the Forest Service and HGCMC and kept on file at the mine site.

3.0 Internal Monitoring of Mine Waste Rock

The Greens Creek Mine has one active waste rock facility (Site 23) and multiple inactive waste rock sites. Characterization and monitoring of active and inactive mine waste rock is ongoing and will continue over the active life of the mine. Classification and segregation of characterized waste rock provides the basis for ongoing management at active and inactive sites. Geochemical characterization and geotechnical stability monitoring of Site 23 is required by the Waste Management Permit 2014DB0003.

The geochemical characterization programs for the Greens Creek Mine are well established. Waste rock from the mine is visually and geochemically characterized and managed accordingly. Representative samples for characterization of mine waste are based on operational and geological records identifying materials mined.

Material characterization is performed using one or more of the established analytical procedures: multi-element ICP analysis, Acid Base Accounting (ABA) using the Modified Sobek Method to determine acid Neutralization Potential (NP), Acid generation Potential (AP) and Net Neutralization Potential (NNP), and kinetic testing (40-weeks). These analytical tools are used to accurately classify the material and their potential to affect water quality.

Sites where characterized materials have been placed for either permanent or temporary disposal are monitored for water quality and stability. The water quality monitoring is an internal monitoring program and not part of the FWMP. The sampling is of contact water (i.e., pore water, leachate or seepage) within the waste rock facility boundaries and is therefore not expected to be compliant with AWQS. The objective of the monitoring is to track water quality trends to support predictions regarding geochemical weathering processes and effects on water quality. The results from the internal monitoring may be used to refine facility specific management or reclamation plans.

The following subsections provide an overview of the monitoring schedules, and type of characterization testing for active and inactive sites.

3.1 General Classification of Mine Waste Rock

Due to its variable geochemical properties and acid generation potential, mine waste rock is managed on the basis of the following classification system. The waste rock classification by an experienced geologist at the underground blast face or muck pile is based on visual characteristics as verified through analytical testing.

Waste Rock Types:

- **Class 1:** This material has a Net Neutralization Potential (NNP) greater than 100 tons calcium carbonate ($CaCO_3$)/1000 tons. No special handling is required.
- **Class 2:** This material has a NNP value between 100 and -100 tons $CaCO_3$/1000 tons and is placed at least two feet from final pile surfaces.
- **Class 3:** This material has a NNP value between -100 and -300 tons $CaCO_3$/1000 tons. It is placed at least two feet from final pile surfaces.
- **Class 4:** This material has a NNP value less than -300 tons $CaCO_3$/1000 tons and is kept underground as fill.

Waste rock at Greens Creek has two general conditions; fresh waste rock from the mine and weathered waste rock from inactive waste rock sites. Fresh waste rock is generally alkaline (pH 7-9). Weathered waste rock from inactive sites is either near neutral (pH 6-8) or acidic (pH <6).

3.2 Characterization and Monitoring of Mine Waste Rock

The schedule for the monitoring and required analytical testing of the active waste rock site, inactive waste rock sites, and rock used in the construction of facilities are listed in Table 3-1. Analytical suites are listed in Table 3-2.

Table 3-1: Monitoring: Active / Inactive Waste Rock Sites & Quarries

Site Name	Monitoring Type	Parameters	Frequency
Site 23 (Active)	site	visual inspections	monthly
	surface water, spring	C1 or C2	annual
	ground water	C1 or C2	annual
	water levels (wells, piezometers)	depth to water, pressures	semi-annually, some sites monthly or quarterly
	leachate - drains	C1 or C2, flow	quarterly
	suction lysimeters	L1	annually
	rock characterization	ABA: ICP (chemistry), paste pH*	quarterly: annually
	rock characterization - insitu	paste pH, ICP, ABA	once every 5 years
	survey hubs, inclinometers	stability, movement	quarterly or annually
	composite soil cover	moisture probes, water levels, tipping buckets (WQ), lysimeters	quarterly or annually
Inactive Waste Rock	site	visual inspections	quarterly
	surface water	C1 or C2	annual
	ground water	C1 or C2	annual
	rock characterization - insitu	paste pH, ICP, ABA	once every 5 years
Construction Rock**	rock characterization	paste pH, ABA	as necessary – prior to use

* Paste pH, ABA, multi-element ICP from outer pile slope or quarry wall at least every five years, one sample site per acre at a depth deep enough to encounter Class 2/Class 3 waste rock if less than five feet.

** Five samples per lithologic unit should be considered the minimum number of samples necessary to represent a potential source area or volume of rock less than 100,000 tons. For larger tonnages collect at least 10 samples per 100,000 tons of rock produced in an individual campaign or over multiple years.

ABA = Acid Base Accounting determines NP, AP, NNP
ICP= Multi-element Inductively Coupled Plasma
VI = Visual Inspection
LY = Lysimeter (Suite L1)
pH= Paste pH

Table 3-2: Analytical Suites: Active/Inactive Waste Rock Sites & Quarries

Sampling Suite C1	Parameters		
	Arsenic	Zinc	Alkalinity
	Barium	Antimony	Silica
	Cadmium	Mercury	Chloride
	Chromium	Aluminum (total)	Sulfate
	Copper	Calcium	Orthophosphate
	Iron	Magnesium	Thiosulfate
	Lead	Sodium	Total Dissolved Solids
	Manganese	Potassium	Total Suspended Solids
	Molybdenum	Hardness	Bicarbonate
	Nickel	DOC	Alkalinity
	Silver	Thallium	Acidity
	Selenium	Ammonia, TKN	

Sampling Suite C2	Parameters		
	Arsenic	Thallium	Alkalinity
	Cadmium	Nickel	Acidity
	Chromium	Zinc	Chloride
	Copper	Calcium	Sulfate
	Iron	Magnesium	Thiosulfate
	Lead	Sodium	Total Dissolved Solids
	Manganese	Potassium	Total Suspended Solids

Sampling Suite L1	Parameters		
	Aluminum	Manganese	Sodium
	Arsenic	Magnesium	Potassium
	Barium	Molybdenum	DOC
	Cadmium	Nickel	Amonia
	Calcium	Silver	Chloride
	Chromium	Zinc	Sulfate
	Copper	Antimony	Thiosulfate
	Lead	Selenium	Orthophosphate

All metals are dissolved unless otherwise noted

3.2.1 Mine Waste Rock Characterization and Monitoring

Greens Creek uses the numerical system described in Section 3.1 for production waste rock classification and placement. Waste rock classification is based on rock type and pyrite content. Interpretation of development and exploration drilling information allows mine geologists and engineers to estimate the quantities of argillite and phyllite anticipated during mining. Where practical the mine plan tries to minimize development in high pyrite rock, although mining potentially acid producing rock is unavoidable. Production geologists visually inspect the active mining face and muck piles to determine the waste rock lithology and pyrite content, estimate the NNP value, and assign the material a Classification Number. Chip samples of the material are collected and sent to the in-house lab for ABA analysis. The ABA results help document the types of material produced and validates the visual classification system.

Waste rock disposal management follows the following criteria:[1]

- Mixing of Class 2 and Class 3 is allowed to avoid physical discontinuities in the waste rock dump;
- Priority use of Class 1 is of higher beneficial use at Site 23 and the TDF area as an outer slope encapsulating layer;
- Place Class 1 as a two 2 foot layer at Site 23 and the TDF.

3.2.2 Site 23 Characterization and Monitoring

Class 1, 2, and 3 waste rock is brought to the active waste rock Site 23 by underground haul trucks and placed in stockpiles. The designated placement zones linked to the three classes of rock are marked on the active lift area prior to placement of production rock and are sampled quarterly. Quantities of Class 1 and Class 2/3 waste rock placed at Site 23 will be tracked and included in the quarterly reports to ADEC, as required by WMP 2014DB0003, Section 2.3.1.8.

Active Areas:

- Two composite samples from each stockpile of Class 1 and Class 2/3 quarterly for ABA. Samples are collected from the top 12-inches within active placement areas.
- Outer side slopes will be sampled at least every five years, at a depth deep enough to encounter Class 2/3 waste rock if less than five feet. Samples will be analyzed for ABA and paste pH. The location (coordinates and elevation) of each sample will be recorded.
- Groundwater/leachate samples will be collected quarterly from the finger drains and curtain drains when flow is greater than 1 liter per minute (Suite C1 or C2).
- Groundwater wells (EDMS Site #: 50, 51, 326, 1263) will be sampled annually (Suite C1 or C2).
- Site 23 will be visually monitored for signs of damage or potential damage from settlement, ponding, leakage, instability, frost action, erosion, thawing of the waste, or operations at the site. Monitoring will be performed weekly and documented monthly as required by WMP 2014DB0003, Section 2.3.1.1.

3.2.3 Inactive Waste Rock Sites Characterization and Monitoring

Water quality monitoring is conducted at several inactive waste rock dump sites on a semi-annual or annual basis. Geochemical samples are taken once every five years for paste pH and ABA. This monitoring is conducted until the waste rock is removed, the site is reclaimed, and stabilized. Once all the material is removed from an inactive waste rock site, that site can be removed from the sampling program.

Site E is an example of an inactive waste rock site. It is located 4.6 miles up the B Road between the Hawk Inlet port facility and the 920 mill site. Approximately 365,000 cubic yards (yd^3) of waste rock and glacial till were placed at the site from 1988 to 1994. Waste rock removal from the site and co-disposal of the material with tailings at the tailings facility is expected to significantly improve water quality in the small drainages between Site E and Greens Creek, while also improving pore water chemistry and geotechnical stability of the TDF.

[1] ADEC approved this change to the Greens Creek disposal method in a letter dated May 13, 2004.

- The frequency of monitoring of ground water and surface water is dependent upon the yearly activity at the site; greater activity results in increased monitoring frequency. Minimally sites are monitored annually.
- Outer side slopes of the exposed production waste rock will be sampled at least every five years. Samples will be analyzed for ABA and paste pH. The location of each sample will be recorded on a map.

3.2.4 Construction Rock Characterization

All construction rock currently used on site outside of containment is shipped in from quarries not associated with the Greens Creek operation. Construction rock originating from offsite is sampled by personnel from the surface operations, environmental or geology departments (or consultants) who are familiar with acid rock drainage (ARD) and metals leaching principles. The number of samples required depends on the compositional variability of the rock and the amount of rock or aggregate to be quarried:

- Five (5) samples per lithologic unit are considered the minimum number of samples necessary to represent a potential source area or volume of rock less than 100,000 tons.
- At least 10 samples per 100,000 tons of rock or greater produced in an individual campaign or over multiple years are collected.

Samples of non-weathered rock are to be collected from outcrops or through drilling and should represent the range of compositional variability of the source area. Five to ten pounds of rock per sample is generally sufficient for routine geochemical characterization. The sample may be a composite of several pieces of rock from an area or zone representing a single rock type. Composites of mixed rock types should be avoided.

Depending on the intended use of the rock and the results of the ABA and ICP analyses, additional testing may be warranted. Additional tests may include:

- Whole rock assay for major and trace elements, reported as oxides;
- Mineral content determined by X-Ray diffraction;
- Abrasion tests to determine rock durability;
- Kinetic leach tests (40 week humidity cell) to determine potential for metals and sulfate mobility.

4.0 Internal Monitoring of Tailings

The Internal Monitoring of Tailings describes monitoring within the tailings pile area, in contrast to the compliance monitoring (under the Fresh Water Monitoring Program) at peripheral facility boundary sites. As such, data generated by the Internal Monitoring Plan effort are not for compliance purposes, but provide a continuing perspective on in-pile geochemical processes.

There are three principal issues that affect potential ARD and metal leaching from the Greens Creek tailings facility including the setting and design of the individual facility, the operation of the facility, and reclamation and closure. Aspects of the facility design, operation, and closure that serve to minimize ARD and metal leaching risk are described in Tailings, Appendix 3 and the Reclamation Plan, Appendix 14 of the General Plan of Operations.

4.1 Summary of Characterization Monitoring

Monitoring is conducted to confirm the following:

- The site is constructed according to the approved construction plans;
- The site is maintained in a stable condition over the short and long term;
- Water management system components are effective and maintained as designed;
- Geochemical and hydrologic processes are defined and meet expectations with respect to limiting oxidation and leaching and minimizing the effects on the receiving environment; and,
- The effectiveness of Best Management Practices to control fugitive dust from escaping the facility.

Inspections and monitoring requirements for the tailings facility, including water levels, water quality and geochemical testing of the tailings and production rock, are described in this section and summarized in Table 4-1.

4.1.1 Tailings Characterization and Monitoring

During the period the mine is active samples of mill tailings are collected prior to transport to the TDF and post-placement samples are collected at the TDF. These samples are analyzed for ABA.

- Composite samples are collected monthly from the mill tailings filter press.
- Six (6) samples are collected annually from active placement areas.

Every five years until final closure of the tailings facility, older inactive portions of the TDF are sampled to determine the NP and AP values as a proactive measure to further characterize the TDF material. Sample locations are aerially distributed across the facility and represent the top 6 inches of tailings, not argillite or other interim cover material.

- A minimum of six (6) samples are collected from the oldest pile surfaces for analysis of NP, AP and NNP.

The intent of this sampling is to monitor the consumption of buffering capacity of tailings near exposed surfaces of the pile.

4.1.2 **Water Monitoring**

See Table 4-1 for a summary of monitoring activities for the tailings facility. Visual observations and material sampling are used to ensure that construction of the facility is according to approved construction plans. Visual observations and routine maintenance ensure that the water management system is functioning as designed. Water quality data, flow and level monitoring, material sampling and information from site meteorology stations are used to define geochemical and hydrologic processes occurring at the site. This information is evaluated with respect to design expectations, and modifications are made, if necessary, to minimize effects on the receiving environment in the short and long term.

The number and location of water samples collected each year may vary due to the constantly changing conditions within this active facility. Efforts are made to extend and protect monitoring wells as the height of the tailings pile increases, but occasionally wells get damaged or destroyed. Suction lysimeters buried within the pile can also lose their functionality due to deterioration of the tubing over time. New suction lysimeters are installed each year as the pile grows. The number of wells and lysimeters located within the tailings facility ensures that sufficient data can be collected to satisfy the monitoring objectives.

Table 4-1: Summary of Monitoring and Sampling Activity – Tailings Facility

Site Name	Monitoring Type	Parameters	Frequency
Tailings Facility	site	visual inspections	monthly
	surface water	C1 or C2	annually
	ground water	C1 or C2	annually
	water levels (wells, piezometers)	depth to water, pressures	semi-annually, some sites monthly or quarterly
	drains, wet wells	C1 or C2, flow	annually
	suction lysimeters	L1	annually
	tailings characterization	ABA: ICP (chemistry), paste pH	monthly: annually
	tailings characterization - insitu	ABA	annually
	compaction	percent moisture, wet density	quarterly or annually
	Fugitive dust - ADP	mg/m^2, lead, zinc	Bi-weekly

ADP = atmospheric deposition pail
ABA determines AP, NP and NNP
C1, C2 and L1 sampling suite parameters are listed in Table 3-2

4.1.3 **Fugitive Dust Monitoring**

The control of fugitive dust from the tailings facility is a required mitigation measure in the 2013 Final Environmental Impact Statement and Record of Decision for the Tailings Disposal Facility expansion. Monitoring of fugitive dust emissions is a requirement of the WMP 2014DB0003. Deposition of dust to the west, south and southwest of the tailings facility is believed to be the source of elevated (above background) lead concentrations that have been recorded at some of the water quality monitoring sites.

Visual observations and operational experience indicate that dust loss from the tailings pile occurs when dry, windy conditions persist at the site. These conditions typically occur for short periods between mid-

November and late March when high pressure systems produce cold, dry weather and strong northerly winds.

A variety of Best Management Practices (BMPs), including engineering controls and operational controls, are being utilized to minimize the amount of fugitive dust escaping the facility. Engineering controls include the use of wind fencing in active placement areas and the application of water to the exposed surface of the pile when weather conditions are favorable for dusting. The use of polymer is also planned to be pilot-tested for its ability to prevent dusting. Operational controls include capping inactive portions of the pile with argillite and selective placement of tailings in portions of the pile based on weather conditions.

HGCMC researched methods for lead loading analysis and is evaluating a passive monitoring system. This passive system involves the use of a 10 liter Atmospheric Depositional Pail (ADP) mounted approximately 1.3 meters off the ground. Since January 2011 five ADP systems have been deployed 50-100 meters from the base of the dry stack tailings pile. Four of the ADPs loosely correlate to the cardinal points on a compass, with the fifth system in the southwest position. On a two week cycle the ADPs are collected and filtered through a pre-weighed 47 mm glass fiber filter with a 1.5 micron pore size. The filters are then dried and weighed in order to measure the total loading. Following this process the filters are analyzed for total lead and total zinc. Results from the analysis equate to the amount of material that passes through the opening of the ADP over a two week period. Therefore it is possible to calculate the average daily load per given area. HGCMC accepts that there are some limitations and possible artifacts introduced into the data using the ADP systems, however the consistency of the trends between the five ADP systems suggest that this is a very effective tool for monitoring loading. Along with the ADP systems HGCMC also monitors and records the hourly meteorological conditions near the dry stack Tailings Facility. These measurements include wind direction, wind velocity, relative humidity, rainfall, air temperature, and barometric pressure. Furthermore the surface operations department maintains a log of where in the Tailings Facility they have been placing and working. One final piece of data being collected is the temperature of the tailings pile at depth.

The results from the ADP monitoring are routinely evaluated in context with the meteorological data and surface operations data to determine the effectiveness of BMPs. The goal is to continuously improve the BMPs to minimize fugitive dust emissions from the tailings facility. The monitoring data, including an analysis and interpretation of the results, will be presented in the Annual report.

5.0 Biological Monitoring

The role of biological monitoring is to ensure the continued use of Greens Creek and its tributaries by fish and other aquatic species, and to document the continued health of all levels of the biological community: primary productivity, invertebrate communities, and fish. Biological monitoring will also detect early changes to the aquatic community that may result from changes in water chemistry, either through surface or groundwater inputs to the system.

Results from biological monitoring are compared to baseline conditions, or if baseline data are unavailable, to a reference site that is unaffected by the mine. There were few baseline studies conducted before development of the Greens Creek Mine using current state-of-the-art protocols. The existing biological monitoring program is designed to compare present conditions to future conditions, with consideration given to any previous monitoring. HGCMC contracts with the ADF&G for the monitoring and reporting for this activity. This document serves as the quality assurance plan for biological monitoring.

5.1 Elements of the Biological Monitoring Program

The biological monitoring program for the Greens Creek Mine addresses the following factors:

1. Abundance and condition of juvenile fish;
2. Whole body concentrations of Cd, Cu, Hg, Pb, Se, Ag, and Zn in juvenile fish;
3. Periphyton biomass, estimated by chlorophyll-a concentrations;
4. Abundance and community structure of benthic invertebrates;

5.2 Summary for Biological Monitoring

Table 5—1 summarizes the sites to be sampled, factors sampled at each site, and sampling frequency.

Table 5-1: Summary of Biological Monitoring Sites

Site Name	Monitoring Objective	Compare to:	Frequency	Factors	Time to Sample
Middle Greens Creek (Site #6 – site discontinued in 2012)	Baseline		Sample on 5 year schedule, unless indication of WQ exceedance	FA, FM, P, MI	mid-late July
Upper Greens Creek (Site #48)	Routine, control		Annually for 5 years, then review	FA, FM, P, MI	mid-late July
Greens Creek Below D-Pond (Site #54)	Routine, treatment	Control	Annually for 5 years, then review	FA, FM, P, MI	mid-late July
Tributary Creek (Site #9)	Baseline	Change over time	Annually for 5 years, then review	FA, FM, P, MI	mid-late July

KEY:
WQ - water quality
FA - fish abundance
FM - fish metals content
P - periphyton biomass
MI - macroinvertebrate abundance, community
Baseline - the conditions at the beginning of the biological monitoring program

Table 5-2: Suite R (Biological Monitoring Parameters)

Juvenile Fish	Periphyton	Aquatic Invertebrates
1. Relative abundance and condition. 2. Subsample from each sample site will be analyzed for whole body concentrations of; • Cadmium, • Copper, • Mercury (added in 2012) • Lead, • Selenium, • Silver • Zinc. (Metals are to be reported as total per dried weight of tissue). 3. The laboratory shall also report the percent moisture of the samples so that wet weight values can be calculated. 4. Water temperature will be measured.	1. Samples will be collected for estimates of Chlorophylls a, b, and c.	1. Samples will be collected to determine abundance and community structure.

Biological monitoring parameters identified in Suite R further augments the surface and groundwater monitoring and sampling program to accurately track the viability of the aquatic environment in Greens Creek and its tributaries.

5.2.1 Description of Sample Locations

Upper Greens Creek: FWMP Site 48

Site 48 is located upstream of all mine and mill facilities, except for exploratory drilling, and serves as the control reach for comparing data collected downstream at Sites 6 and 54. Site 48 is at approximately 265 m elevation, and about 0.8 km upstream from the concrete weir in Greens Creek, which blocks upstream fish passage.

Greens Creek below D-Pond: FWMP Site 54

Site 54 is located approximately 25 meters downstream of production rock storage areas 23 and D and monitored to detect potential effects from the rock storage areas and treatment ponds, in addition to the mine, mill and shop facilities upstream. Site 54 is at about 225 m elevation and 0.4 km downstream of Site 6.

Tributary Creek: FWMP Site 9

This site was previously monitored for water quality under the former Fresh Water Monitoring Plan (FWMP) from 1981 through 1993. It was reactivated in 2001 for inclusion in the biological monitoring program. Site 9 is located 1.2 km downstream of the dry-stack tailings facility at about 25 km elevation and is monitored to detect potential effects from the tailings facility. This is the closest free-flowing stream reach suitable for biomonitoring to the TDF. As these disposal facilities were situated on the hydrographic divide, there is no comparable upstream site.

5.3 Periphyton Biomass

5.3.1 Rationale

Many fish species are highly migratory and their presence or absence does not adequately describe the health of a specific reach of stream. Periphyton, or attached algae, is sensitive to changes in water

quality. Their abundance confirms that productivity is occurring at specific locations within a water body. Algae generally have short life cycles; therefore monitoring biomass provides an ideal indicator to detect short-term effects (Barbour et al. 1999).

5.3.2 Sample Collection and Laboratory Analysis

The protocol for collecting and analyzing stream periphyton is derived from Freshwater Biological Sampling Manual, Resources Inventory Committee, Province of British Columbia (1997), Alaska Department of Fish and Game (1998), and Barbour et al (1999). Periphyton sampling should not occur in-stream near minnow traps that are soaking as this violates the conditions necessary for depletion trapping.

Ten rocks are collected from the streambed of the creek in each study reach for sampling. A 5 by 5 cm square of high-density foam is placed on each rock; material around the foam square is removed by scrubbing with a toothbrush, and then rinsed away using a spray bottle containing stream water. The foam square is removed and the isolated area scrubbed with a toothbrush. Loosened periphyton is rinsed onto a 1 µm (47 mm diameter) glass fiber filter attached to a vacuum pump. After extracting as much water as possible from the sample on the glass fiber filter, approximately 1 ml saturated $MgCO_3$ is added to the filter to prevent acidification and conversion of chlorophyll to phaeophytin. The glass fiber filter is wrapped in a large paper filter to absorb additional water, and placed in a sealed, labeled plastic bag with desiccant. The samples are frozen on site in a light-proof cooler with additional desiccant and transported to laboratory for analysis. Samples are kept frozen until laboratory analyses are conducted by Division of Habitat staff.

Periphyton sampling at Site 9 will occur after fish sampling to avoid disturbing juvenile fish, though biologists must work carefully to avoid disturbing stream substrate which could affect periphyton results. Alternatively, samples could be collected upstream or downstream of the fish sample reach.
Laboratory analysis requires extraction of chlorophyll pigments and measurement of chlorophyll concentrations on a fluorometer or spectrophotometer. Measurements on a spectrophotometer require a centrifuge. Laboratory analysis follows established protocol (USEPA and standard methods).

5.4 Benthic Macroinvertebrate Density and Richness

5.4.1 Rationale

Benthic macroinvertebrates classified in the Orders Ephemeroptera (mayflies), Plecoptera (stoneflies), and Trichoptera (caddis flies), collectively known as EPT taxa, are sensitive to changes in water quality and an important food source for fish. Most benthic macroinvertebrates have a complex one-year (or more) life cycle and limited mobility, therefore, benthic macroinvertebrates provide an ideal indicator to detect short-term and long-term effects within local aquatic communities (Barbour et al. 1999). An abundant and diverse group of EPT taxa indicate a healthy local aquatic community and results can be used to assess overall stream health with other local studies (e.g. periphyton biomass).

5.4.2 Sample Collection and Laboratory Analysis

Eight benthic macroinvertebrate samples are to be collected from each site using methods modified from Barbour et al (1999). More than eight can be collected to improve calculated mean densities. There is flexibility with respect to which invertebrate sampling equipment is used as long as is it consistent with the methods described in Barbour et al. (1999) (e.g. Surber or Hess sampler). In the

past, samples were collected from each site with a Hess sampler using a random sample design. Samples are to be collected exclusively from riffle habitats where the greatest amount of taxonomic richness and density are usually observed. This sample design eliminates the variability from sampling pools or other habitats where pollution-sensitive taxa are less likely to be present. The sample collection methods should be standardized throughout the year by having one biologist collect all invertebrate samples, spend the same amount of time collecting each sample (e.g. 5 minutes), and dig to the same depth at each sample site (10-15 cm).

For sample collection, the Hess sampler is pushed into the stream bottom, encompassing 0.086 m^2 of substrate, to define the sample site. The substrate is manually disturbed and rocks are brushed within the sample area and then removed. Fine gravels are disturbed to about 10–15 cm depth to collect buried individuals. Macroinvertebrates are collected using a 363 μm mesh net, then relocated to a pre-labeled 500 mL Nalgene® bottle and preserved in 80% denatured ethanol and shipped to the laboratory for processing. Macroinvertebrate samples are later sorted from debris and identified to the lowest practical taxonomic level by a taxonomist.

Macroinvertebrate sampling at Site 9 should occur after fish sampling to avoid disturbing juvenile fish distribution. Alternatively, samples could be collected upstream or downstream of the fish sample reach.

5.5 Juvenile Fish Populations

5.5.1 Rationale

Salmonids are highly migratory, predators, and good indicators of long-term effects and habitat conditions (Barbour et al. 1999), therefore monitoring fish populations affords another biological level to detect change within the aquatic community and assess overall stream health.

5.5.2 Sample Collection

Fish populations are sampled using a modification of a three-pass removal method described by the Forest Service (Bryant 2000). Fish are collected using 0.635 cm (¼ inch) square mesh galvanized Gee's minnow traps baited with salmon roe that was previously treated with Betadine® disinfectant solution. Approximately 25 minnow traps are deployed within each sample reach; the final number of traps used are dependent on stream conditions and habitat availability during field sampling. Natural features such as shallow riffles or small waterfalls are used to help define the upper and lower reach boundaries, in order to minimize fish migration into the sample reach, where possible. To assist with meeting the closed-reach assumption of the three-pass removal method, baited "block" traps are also set upstream and downstream of each sample reach to capture potential migrants.

Sample reaches are identified by aluminum tree tags and flagging set during previous years' sampling. Reach lengths varied between sites, depending on available habitat for minnow trapping. At Upper Greens Creek Site 48, the reach is 50 m; at Greens Creek Site 54, the sample reach is 50 m; and at Tributary Creek Site 9, the sample reach is 50 m.

Minnow traps are placed throughout each sample reach focusing on pools, undercut banks, bank alcoves, under root-wads or logjams, and other habitats where fish are likely to be captured. In higher velocity sites, rocks are placed in the traps to increase trap weight and provide cover for fish. In each fish sample reach, the traps are set for about 1.5 hours, and then retrieved and captured fish are

transferred to perforated plastic buckets. The buckets are placed in the creek to supply dissolved oxygen and to reduce stress on captured fish. Fresh bait is added to the traps, and all are reset for a second 1.5 hour period. While the second set is fishing, fish captured during the first set are counted, identified to species, measured to FL, and placed in a mesh holding bag in the stream. The procedure is repeated for the third 1.5 hours trapping period.

Block traps are set for the entire 4.5 hours sampling period. Fish captured in block traps are counted and identified to species, but not included in further analyses. Ten Dolly Varden from the first trapping period at each site are to be retained for laboratory analysis of whole body metals concentrations. Fish not retained for the metals analyses are returned to the stream reach immediately after sampling is completed.

Each salmonid captured is weighed to investigate mean fish condition between sites and years for each species.

5.5.3 Data Analyses and Presentation

Fish population estimates are calculated using the multiple-pass depletion method developed by Lockwood and Schneider (2000), an iterative method that produces a maximum likelihood estimate (MLE), *N*, of fish with a 95% confidence interval.

Let *X* represent an intermediate sum statistic where the total number of passes, *k*, is reduced by the pass number, *i*, and multiplied by the number of fish caught in the pass, $C_{i,}$, for each pass,

$$X = \sum_{i=1}^{k} (k - i) C_i$$

Let *T* represent the total number of fish captured in the minnow traps for all passes. Let *n* represent the predicted population of fish, using *T* as the initial value tested. Using *X*, the MLE, *N*, is calculated by repeated estimations of *n*. The MLE is the smallest integer value of *n* greater than or equal to *T* which satisfies[2] the following:

$$\left[\frac{n+1}{n-T+1}\right] \prod_{i=1}^{k} \left[\frac{kn - X - T + 1 + (k-i)}{kn - X + 2 + (k-i)}\right]_i \leq 1.000$$

The probability of capture, *p*, is given by the total number of fish captured, divided by an equation where the number of passes is multiplied by the MLE and subtracted by the intermediate statistic, *X*,

$$p = \frac{T}{kN - X}$$

The variance of *N*, a measure of variability from the mean, is given by,

[2] Lockwood and Schneider (2000) suggest the result should be rounded to one decimal place (1.0). We use three decimal places (1.000), which is an option in Carle and Strub (1978).

$$\frac{N(N-T)T}{T^2 - N(N-T)\left[\frac{(kp)^2}{(1-p)}\right]}$$

We determined the standard error (SE) of *N* by calculating the square root of the variance of *N*, and the 95% confidence interval for the MLE using: $\pm$ 2(SE). Small 95% confidence intervals result when fewer captures steadily occur with each pass; large confidence intervals result when captures do not steadily decrease or when the number of fish captured on the second or third pass exceed the number of fish captured on the previous pass. In addition, a MLE cannot be generated from samples from small populations if few fish are captured during the three sample events; in these cases, we present the number of fish captured as the result and do not include a MLE.

Calculating a MLE using three-pass depletion data relies heavily on equal capture probability among passes (Bryant 2000, Carle and Strub 1978, Lockwood and Schneider 2000). To evaluate equal capture probability, we use the goodness of fit test in White et al. (1982), recommended by Lockwood and Schneider (2000), which follows the χ^2 test form. If the goodness of fit test indicates we did not achieve equal capture probability, the MLE will be biased low. We first calculate expected numbers of fish captured for each pass (C_1, C_2, C_3) using variables previously described:

$$E(C_1) = N(1-p)^{i-1}p$$

Then we calculate χ^2,

$$\chi^2 = \frac{[C_1 - E(C_1)]^2}{E(C_1)} + \frac{[C_2 - E(C_2)]^2}{E(C_2)} + \frac{[C_3 - E(C_3)]^2}{E(C_3)}$$

5.6 Metals Concentrations in Juvenile Fish

5.6.1 Rationale

Monitoring whole body metals concentrations in juvenile fish assesses metal loading in aquatic communities near the Greens Creek mine. Current year data are compared to previous years' data to detect change over time and water quality data can be compared as well to examine relationships. Weber, Scannell, and Ott (2001) documented metals accumulation in juvenile fish tissues within two months of migration into mineralized tributaries, therefore results can detect both short-term and long-term changes in tissue metals concentrations.

5.6.2 Sample Collection and Laboratory Analysis

Ten juvenile Dolly Varden within the size range 85–125 mm FL are captured in the minnow traps collected from each site for whole body metals analyses. The specified size range improves the likelihood of sampling only resident fish, assuming the age of fish in that size class is 2–3 year Dolly Varden that have not migrated to sea. Sample fish are measured to FL, individually packed in clean, pre-labeled bags and frozen on-site until transport to the laboratory. Biologists handling the fish wear VWR Certiclean Class 100 Nitrile gloves to reduce the risk of metal contamination.

At the laboratory, the fish are weighed without removal from the bags, and correction made for the weight of the bag. The fish are submitted to a private analytical laboratory (Columbia Analytical Services, Inc. in Kelso, Washington), where they are digested, dried, and analyzed for silver (Ag), arsenic

(As), cadmium (Cd), chromium (Cr), copper (Cu), mercury (Hg), lead (Pb), selenium (Se), and zinc (Zn) on a dry-weight basis, with percent total solids also reported.

5.6.3 **Reporting**

- Periphyton Biomass

  Periphyton samples will be analyzed on either a fluorometer or a spectrophotometer.

  Chlorophylls a, b, and c will be calculated from samples measured on the spectrophotometer.

  Periphyton biomass will be reported as mg chlorophyll-a / m^2 of stream substrate. Comparisons will be made among the control and treatment sample sites, and between , years at each site using appropriate statistical methods. Data will be presented graphically, and the data values will be contained in appendices to biomonitoring reports.

- Benthic Macroinvertebrates

  Data compilation and analyses for benthic samples should follow the protocol of the Alaska Stream Condition Index (Major and Barbour 1999), as described below and with modifications.

  List of Metrics:

  Abundance Measures

  Total invertebrates counted per subsample

  Total aquatic invertebrates per subsample

  Total terrestrial invertebrates per subsample

  Estimated total aquatic invertebrates per sample

  Estimated total terrestrial invertebrates per sample

  % sample terrestrial

  % sample aquatic

  Taxonomic Richness Measures

  Total aquatic taxa Average taxa/sample

  No. of Ephemeroptera taxa

  No. of Plecoptera taxa

  No. of Trichoptera taxa

  Community Measures (estimate of total sample)

Est. number Ephemeroptera

Est. number Plecoptera

Est. number Diptera

Percent Ephemeroptera

Percent Plecoptera

Percent Diptera

Richness Measures

Composition Measures

% EPT

% Chironomidae

% Dominant Taxon

The metrics are calculated from the data collected and recorded on the laboratory bench sheet after the laboratory identification and analysis.

- Abundance of Rearing Fish

Analysis of fish population estimates should include graphical display of fish abundance trends at all bio-monitoring sites, and a statistical comparison of means (or medians) between populations at control and treatment sites.

Data analysis should include graphical displays of annual fish population trends by species for each bio-monitoring site. Graphs displaying species/length distribution by year should also be provided.

Potential change in juvenile fish abundance between the Greens Creek control and treatment bio-sites will be analyzed. Results of this analysis should be compared with similar statistics for water quality, metals content, periphyton biomass, macroinvertebrate indices and toxicity collected at these monitoring sites for the same time periods. This information will be used to evaluate and document potential cause-effect relations between changes in water quality, and aquatic biota abundance, distribution and community structure.

- Metals Concentrations in Rearing Fish

The median, maximum, and minimum concentrations of each metal will be reported for each sampling site. Comparisons will be made among sampling sites. Metals concentrations also will be compared to metals concentrations in whole body juvenile fish of similar species from other regions of Alaska (e.g. Weber Scannell et al., 1995, 1998, 2000b; Snyder-Conn et al. 1992, 1993).

6.0 Geotechnical Monitoring and Inspections

The Greens Creek Mine has two waste rock areas and the TDF Pond 7 that require geotechnical monitoring for stability and structural integrity. The waste rock disposal sites are monitored for potential movement and long-term stability as part of the general plan of operations. Site 23 and Site D, as part of the standard operating procedures, are monitored for overall stability using a number of instrumentation readings to assess potential movement.

Pond 7 at the TDF is a permitted facility by ADNR-Dam Safety (#AK00307) Class 3 low hazard potential dam that complies with the monitoring and inspections criteria identified in Attachment A – Special Conditions of the Certificate of Approval to Operate a Dam.[3]

One of the Special Conditions associated with the Pond 7 permit is the development and periodic updating of *Pond 7 Operation and Maintenance Program Manual*, which specifies the details of operating, monitoring, and inspection guidelines pertinent to geotechnical stability and reporting.[4] Those routine monitoring and inspection provisions are listed within this IMP, but to ensure full compliance with all provisions of the Dam Safety Permit, it should be referenced.

Table 6-1 provides a summary of monitoring and inspection requirements to verify the geotechnical stability of specific waste rock sites and the TDF Pond 7 embankment. Monitoring activities include visual inspections, pneumatic piezometers, vibrating wire piezometers, inclinometers, stand pipe water level, and survey monuments. Surface water, groundwater, and pore water monitoring and sampling for these facilities are covered in Section 3.2.

Table 6-1: Waste Rock Sites and TDF Geotechnical Monitoring and Inspection

Site Name	Daily	Weekly	Monthly	Quarterly	Semi-Annual	Annually	5-Year
Site 23/D	VI		VI, PP	IC, SL		SM	
TDF	VI VW	SI	VI	SL	SM	SM	
Pond 7	VI SP VW	SI	VI		SM	SM	DSI

KEY:
DSI = 5-year Dam Safety Inspection
IC = Inclinometer
PP = pneumatic piezometers
SI = Safety Inspection
SM = Survey Monument – embedded in concrete
SL = Stand Pipe Water Level
SP = Seepage return flow rate
VI = Visual Inspection
VW = Vibrating wire piezometer (4x daily recorded on data logger)

[3] Alaska Department of Natural Resources- Dam Safety Certificate No. FY2009 -10-AK00307
[4] Hecla Greens Creek Mining Company Pond 7 – AK00307 Operation and Maintenance Program, October 15, 2008

7.0 Quality Assurance/Quality Control Program

The *Quality Assurance Project Plan (QAPP) of the General Plan of Operations Appendix 1 Integrated Monitoring Plan* (Greens Creek 2014) found in Appendix 1.A presents the rational and technical requirements for the monitoring and methodologies that are presently used at the site to further improve site wide monitoring.

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Appendix 1.A
Quality Assurance Project Plan (QAPP) of the General Plan of Operations Appendix 1 Integrated Monitoring Plan

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List of Appendices

Acronyms

AAC	Alaska Administrative Code
ABA	Acid Base accounting
ADEC	Alaska Department of Environmental Conservation
ADNR	Alaska Department of Natural Resources
AGO	Attorney General's Office
ANILCA	Alaska National Interest Land Conservation Act
APDES	Alaska Pollution Discharge Elimination System
ASTM	Alaska Sampling and Testing Methods
AWQS	Alaska Water Quality Standards
CFR	Code of Federal Regulations
CH	Clean Hands
CV	Casing Volume
CWA	Clean Water Act
DH	Dirty Hands
DI	Deionized
DOW	ADEC, Division of Water
DQO	Data Quality Objective
DW	Depth to Water
EA	Environmental Assessment
EPA	Environmental Protection Agency
EIS	Environmental Impact Statement
FWMP	Fresh Water Monitoring Plan
HGCMC	Hecla Greens Creek Mining Company
ICP	Inductively Coupled Plasma Analysis
IWMMP	Integrated Waste Management and Monitoring Plan
IDL	Instrument detection limit
LCS	Laboratory Control Standard
MAG	Management Information Goals
MDL	Method Detection Limit
MIG	Monitoring Information Goals
MQO	Measurement Quality Objective
ND	Non-Detect
NEPA	National Environmental Policy Act
NIST	National Institute of Standards and Technology
NP	Acid Neutralization Potential
NNP	Net Neutralization Potential
PQL	Practical Quantification Limit

QA	Quality Assurance
QAP	Quality Assurance Plan
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Practice
RL	Reporting Limit
RPD	Relative Percent Difference
RIG	Regulatory Information Goals
RS	Reference Standard
SIG	Statistical Information Goals
SOP	Standard Operating Procedure
SRM	Standard Reference Material
TD	Total Depth
TDF	Tailings Disposal Facility
TDR	Time Domain Reflectometry
USDOT	United States Department of Transportation
XRD	X-Ray Diffraction

Units of Measure

ac	acre
cm	centimeter
in	inch(es)
ft	feet/foot
km	kilometer
m	meter
mm	millimeter
m^2	meter squared
ml	milliliter
µg	microgram
oz/st	troy ounces per short ton
ppm	parts per million
st	short ton
yd^3	cubic yards

A PROJECT MANAGEMENT ELEMENTS

A.1 Title and Approvals

Title: Quality Assurance Project Plan (QAPP) of the General Plan of Operations Appendix 1 Integrated Monitoring Plan (IMP)

Name: Scott Hartman
General Manager, Vice President

Organization Name:

Hecla Greens Creek Mining Company

Signature: _____ **Date**: _____

Name: Christopher Wallace
Project QA Officer

Organization Name:

Hecla Greens Creek Mining Company

Signature: _____ **Date**: _____

Name: Tim Pilon
ADEC DOW Project Manager
Organization
ADEC DOW-Wastewater D/C Auth Pgms

Signature: _____ **Date**: _____

Name: Richard Heffern
Section Manager, QA Officer

Organization Name:

ADEC DOW WQSAR Program

Signature: _____ **Date**: _____

A.2 DISTRIBUTION LIST

This list includes the names and addresses of those who receive copies of the approved QAPP and subsequent revisions.

Table 1 Distribution List

NAME	POSITION	AGENCY/ COMPANY	DIVISION/ BRANCH/SECTION	CONTACT INFORMATION
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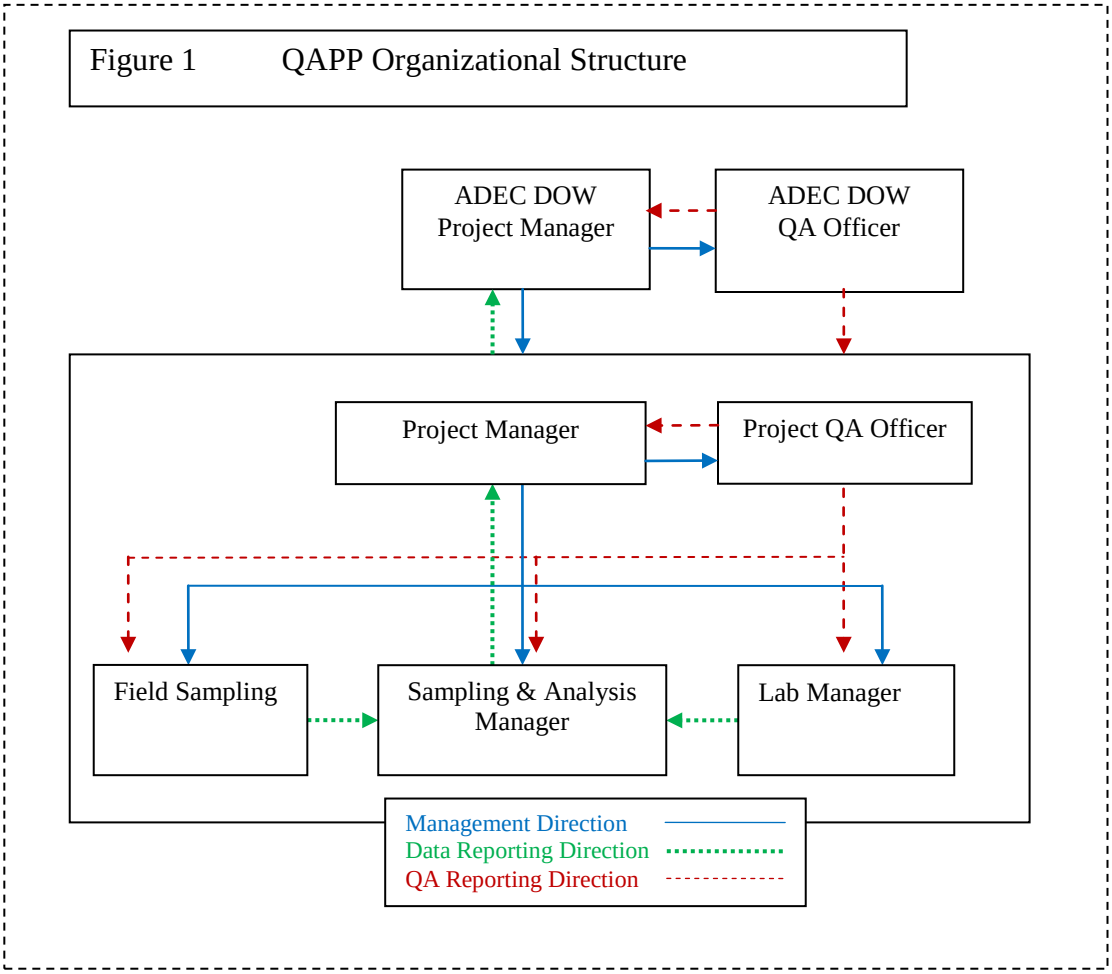
A.3 PROJECT/TASK ORGANIZATION

Duties and responsibilities of key individuals are listed below and summarized in Figure 1:

- Project Manager – Vice President and General Manager of the Hecla Greens Creek Mining Company.
- Project QA Officer – Environmental Affairs Manager responsible for permitting, regulatory compliance, and oversight of all aspects of implementing the Quality Assurance Project Plan (QAPP) and Field Procedures Manual.
- Sampling & Analysis Manager – This individual will maintain the quality of field activities, sample collection, sample handling, laboratory analysis and data analysis, and document the quality of data at each processing level. The manager identifies major aspects of the project requiring specific quality control and demonstrates that quality control is a major focus for this project.
- Data Manager – This individual identifies the procedures to be used to verify that sample and field monitoring data is accurately entered and available for analysis.
- Laboratory Manager – Responsible for the overall review and approval of contracted laboratory analytical work, responding to sample result inquiries and method specific details.
- ADEC Project Manager - Responsible for overall technical and contractual management of the project. For Permit related monitoring projects, responsible for ensuring the permit complies with permit required water quality monitoring as specified in the approved QAPP.
- ADEC Quality Assurance Officer - Responsible for QA review and approval of plan and oversight of QA activities ensuring collected data meets project's stated data quality goals.

Figure 1 QAPP Organizational Structure



A.4 BACKGROUND AND PROJECT OBJECTIVES

A.4.1 Problem Definition

The Greens Creek Mine is a lead, zinc, silver and gold mine and mill located on the northwest portion of Admiralty Island, approximately 18 miles southwest of Juneau, Alaska. The facility has been in operation since 1989, with one temporary cessation of operations from 1993 to 1996. The mine's current production rate is 2,200 to 2,400 tons of ore per day. Major site facilities include the underground mine, mill, waste rock storage areas, dry tailing disposal facility, port facilities, and roads connecting these components. The facilities are located within the Greens Creek, Zinc Creek, Tributary Creek and Cannery Creek drainages, which flow into Hawk Inlet.

Routine monitoring is performed as described in the Greens Creek Mine Integrated Monitoring Plan (IMP) to fulfill monitoring requirements defined in the mine's Environmental Impact Statements (EIS), Records of Decision, Environmental Assessments (EA) and ADEC Waste Management Permit 2014DB0003. The data generated from monitoring activities must be of appropriate quantity and quality to satisfy the project objectives.

A.4.2 Project Objective(s)

The objectives of the QAPP are:

- Ensure that monitoring requirements in the National Environmental Policy Act (NEPA) documents that relate to HGCMC are met. 40 CFR § 1505.3 states that agencies may provide for monitoring to assure their decisions are carried out.
- Ensure that Alaska Water Quality Standards (AWQS) are met. The State of Alaska, Department of Environmental Conservation has promulgated water quality standards to protect all uses of a water body.
- Ensure the intent of the Clean Water Act (CWA) is met. While this plan does not address discharges authorized by the mine's discharge permit under the CWA, some procedures described in this plan are similar to those described in 40 CFR § 136. This CFR referenced document describes guidelines that were established for test procedures for the analysis of pollutants discharged under Section 402 Alaska Pollution Discharge Elimination System (APDES) and Section 401 (State Certification) of the CWA.
- Ensure monitoring of surface water and groundwater and corrective actions will be in accordance with State regulations 18 AAC 60.820 – 18 AAC 60.860.
- Ensure test procedures for the analysis of water samples shall conform to the parameters, methods and procedures in the IMP and in 18 AAC 60.820 – 18 AAC 60.860.
- Ensure that the intent of the Alaska National Interest Land Conservation Act (ANILCA) is met.
- Evaluate the effectiveness of the IMP and QAPP annually.
- Collect information for specific reclamation needs and additional resource protection requirements as needed.
- Ensure the economic efficiency of the IMP and QAPP.
- Add and/or delete monitoring sites as needed; and modify schedules, protocols and methods as needed to ensure that all the goals of the IMP and QAPP are met.

This QAPP will be used to maintain the quality of field activities, sample collection, sample handling, laboratory analysis and data analysis, and to document the quality of data at each processing level. The QA/QC program identifies major aspects of the project requiring specific quality control and demonstrates that quality control is a major focus for this project.

A.5 PROJECT / TASK DESCRIPTION and SCHEDULE

A.5.1 Project Description

The Greens Creek Mine Integrated Monitoring Plan (IMP) documents the required material characterization, stability, freshwater samples, and biological samples which are collected at the prescribed frequency to ensure that the monitoring requirements defined in the mine's Environmental Impact Statements (EIS), Records Of Decision, Environmental Assessments (EA) and ADEC Waste Management Permit 2014DB0003 are fulfilled. The IMP will be periodically reviewed and updated as necessary to coincide with regulatory changes, five-year environmental audit reviews, process modifications, or anomalies noted as a result of monitoring and sampling. Refer to the most current

agency approved version of the IMP for a detailed description of monitoring. Table 2 shown below provides a general overview monitoring activities.

A.5.2 Project Implementation Schedule

Table 2 Project Implementation Schedule

Product	Media	Sampling Site	Parameters	Frequency	Time Frame
QAPP Preparation					
Monitoring	Surface Water	Project Area	Water quality, flow	Monthly/ Quarterly	Year-round
	Groundwater	Millsite, Site 23/D, and TDF	Water quality, static water level	Quarterly	Year-round
	Tailings Characterization	Mill Tailings	ABA*, Kinetic	Annually	Year-round
	Waste Rock Characterization Dump Stability Interstitial Water	Site 23	ABA*, Kinetic Inclinometer Lysimeter	Quarterly, Annually Annually Annually	Year-round
	Bio-monitoring	Greens Creek and Tributary Creek	WQ, FA, FM, P, MI**	Mid-late July	Year-round
Lab Analysis	All Media	All sites		Analyses within sample holding time requirements	Year-round
Field Audit	Audit of field monitoring operations	All sites		< 30 days of project start-up	1/project
Reports	All Media	All sites		Quarterly Annually	May, Sep., Nov. April 15

* ABA - Acid Base Accounting

** WQ - water quality, FA-fish abundance and distribution, FM-fish metals content, P-periphyton biomass, MI-macroinvertebrate abundance

A.6 DATA QUALITY OBJECTIVES AND CRITERIA FOR MEASUREMENT DATA

A.6.1 Data Quality Objectives (DQOs)

Data Quality Objectives (DQOs) are qualitative and quantitative statements that:

- Clarify the monitoring objectives; and,
- Define the appropriate type of data needed.

The IMP describes the various types of monitoring performed throughout the project area, locations and frequency of monitoring (where applicable), and the data generated from the monitoring. Each type of monitoring has different DQOs based on the purpose for, and intended application of, the data.

The project's overall DQOs are to collect appropriate data to:

- Determine if water resources are protective of the applicable AWQS at compliance monitoring locations and identify water quality trends;
- Document the condition and long-term health of aquatic biological resources;
- Demonstrate that mine waste rock and tailings facilities are being managed in accordance with approved plans and permits; and,
- Determine if facility specific management and reclamation plans are adequate to protect the environment during operations and post-closure.

A.6.2 Measurement Quality Objectives (MQOs)

Measurement Quality Objectives (MQOs) are a subset of DQOs. MQOs are derived from the monitoring project's DQOs. MQOs are designed to evaluate and control various phases (sampling, preparation, and analysis) of the measurement process to ensure that total measurement uncertainty is within the range prescribed by the project's DQOs. MQOs define the acceptable quality (data validity) of field and laboratory data for the project. MQOs are defined in terms of the following data quality indicators:

- Detectability
- Precision
- Bias/Accuracy
- Completeness
- Representativeness
- Comparability

Detectability - is the ability of the method to reliably measure a pollutant concentration above background. ADECs Division of Water uses two components to define detectability: method detection limit (MDL) and practical quantification limit (PQL) or reporting limit (RL).

- The MDL is the minimum value which the instrument can discern above background but no certainty to the accuracy of the measured value. For field measurements the manufacturer's listed instrument detection limit (IDL) can be used.
- The PQL or RL is the minimum value that can be reported with confidence (usually some multiple of the MDL).

Sample data measured below the MDL is reported as ND or non-detect. Sample data measured ≥ MDL but ≤ PQL or RL is reported as estimated data. Sample data measured above the PQL or RL is reported as reliable data unless otherwise qualified per the specific sample analysis.

The detectability criterion is addressed by specifying to the analytical laboratory the analytical methods and associated MDL and PQL required for each type of monitoring. For water quality monitoring the MDL and PQL are based on the applicable AWQS.

Precision - is a measure of the ability to replicate an analysis and is expressed as the relative percent difference (RPD). The RPD criterion for water samples is ±20% and is only applicable when the analyte concentration is more than 5 times the IDL, and as long as the native amount is not greater than 4 times the spiked amount. The RPD criterion for biological samples is ±35% due to the greater degree of variability in samples.

Bias (Accuracy) - is a measure of confidence that describes how close a measurement is to its "true" value and is expressed as %R. Methods to determine and assess accuracy of field and laboratory measurements include instrument calibrations and various types of QC checks (e.g., sample split measurements, sample spike recoveries, matrix spike duplicates, continuing calibration verification checks, internal standards, external standards, and sample blank measurements). Bias/Accuracy is usually assessed using the following formula:

$$Accuracy = \frac{MeasuredValue}{TrueValue} \times 100$$

The Matrix Spike/Matrix Spike Duplicate (MS/MSD) criteria are 75-125 %R for all metals. The criteria are only applicable for MS/MSD analyses as long as the native amount is not greater than 4 times the spiked amount. The accuracy limits for the Laboratory Control Sample (LCS) are method dependent, e.g. 90-110 %R for Inductively Coupled Plasma-Mass Spectrometry (ICP-MS).

Completeness - is a measure of the percentage of valid samples collected and analyzed to yield sufficient information to make informed decisions with statistical confidence. Project completeness is determined for each pollutant parameter using the following formula:

$$\frac{T - (I+NC)}{T} \times (100\%) = \text{Completeness}$$

Where T = Total number of expected sample measurements.
I = Number of invalid sample measured results.
NC = Number of sample measurements not produced (e.g. spilled sample, etc).

The Fresh Water Monitoring Program (FWMP) is the only monitoring program for which completeness is a stated DQO. The completeness criterion is 95% for a water year (October 1 – September 30).

Representativeness - assigns what parameters to sample for, where to sample, type of sample (grab, continuous, composite, etc.) and frequency of sample collection. The IMP specifies these criteria for each type of monitoring.

Comparability - is a measure that shows how data can be compared to other data collected by using standardized methods of sampling and analysis. HGCMC utilizes standardized methods for the

collection and analysis of water quality samples to ensure comparability of data generated. Metals concentrations in water samples are measured in the dissolved fraction (filtered samples) to limit potential variability caused by mineralized sediments in surface and ground water. This enables comparison of surface water and ground water data, from both the internal monitoring program for tailings and waste rock sites and the FWMP compliance monitoring sites, to help explain water quality trends or data anomalies. Data collected from the FWMP sites is compared to the applicable AWQS.

Different laboratories are used for analysis of FWMP samples and samples from the internal monitoring of tailings and waste rock sites. HGCMC frequently collects split samples and submits them to both laboratories for analyses of the same constituents. This QA/QC check of the laboratories validates the comparability of the data.

The Measurement Quality Objectives for the FWMP compliance monitoring are shown in Table 3. The laboratory may achieve lower MDLs than specified but not higher.

Table 3 Measurement Quality Objectives (MQOs)

Analyte	Method	MDL[1]	PQL[2]	AWQS[3]	Precision[5,7]	Accuracy[6,7]	Complete
Total Alkalinity, mg/L	2320	1.0	18	20	+/- 20 RPD	75-125 %R	95%
Hardness, mg/L	2340B	1.0	None	None	+/- 15 RPD	75-125 %R	95%
Conductivity, µmhos/cm	2510	10	None	None	+/- 10%	+/- 10%	95%
pH, s.u.	4500-H+			6.5 - 8.5	+/- 0.2	+/- 0.1	95%
Arsenic, diss., µg/L	1638m	2	9	10	+/- 20 RPD	75-125 %R	95%
Barium, diss., µg/L	1638m	280	900	1000	+/- 20 RPD	75-125 %R	95%
Cadmium, diss., µg/L	1638m	0.15 / 0.11	0.47 / 0.34	0.52 / 0.38	+/- 20 RPD	75-125 %R	95%
Chromium, diss., µg/L	1638m	3.1	9.9	100	+/- 20 RPD	75-125 %R	95%
Copper, diss., µg/L	1638m	1.4 / 1.0	4.6 / 3.2	5.1 / 3.6	+/- 20 RPD	75-125 %R	95%
Lead, diss., µg/L	1638m	0.25 / 0.15	0.81 / 0.49	0.90 / 0.54	+/- 20 RPD	75-125 %R	95%
Mercury, diss., µg/L	1631e	0.0003	0.011	0.012	+/- 20 RPD	75-125 %R	95%
Nickel, diss., µg/L	1638m	12.7 / 9.4	40.4 / 30.0	44.9 / 33.3	+/- 20 RPD	75-125 %R	95%
Selenium, diss., µg/L	1638m	1.42	4.5	5.0	+/- 20 RPD	75-125 %R	95%
Silver, diss., µg/L	1638m	0.21 / 0.10	0.66 / 0.33	0.73/0.37[4]	+/- 20 RPD	75-125 %R	95%
Sulfate, mg/L	M300.0-IC	70	225	250	+/- 20 RPD	75-125 %R	95%
Zinc, diss., µg/L	1638m	12.9 / 9.3	41.0 / 29.4	45.6 / 32.7	+/- 20 RPD	75-125 %R	95%

1. MDL=PQL÷3.18, rounded up to the same number of significant digits as the AWQS for that analyte. If AWQS for this constituent is hardness dependent, two numbers are listed. First number listed is for surface water sites, the second is for groundwater sites.
2. PQL based on AWQS x 0.9. If AWQS for this constituent is hardness dependent, two numbers are listed. First number listed is for surface water sites, the second is for groundwater sites.
3. If AWQS is hardness dependent, two numbers are listed for the purposes of calculating the MDL and PQL. First number listed is based on a hardness value of 37 to represent the 25th percentile of surface water hardness values, the second number listed is based on a hardness value of 25 to represent the 25th percentile of groundwater hardness values. AWQS is for chronic conditions unless otherwise noted. The actual hardness dependent AWQS for that constituent will depend on the actual hardness of the sample, not on the number that appears in this table.
4. AWQS is a 24 hour average (acute).
5. The precision DQO is only applicable when the analyte concentration is more than 5 times the IDL.
6. Listed accuracy is for MS/MSD only. The accuracy DQO for the LCS QC sample is method dependent.
7. The precision and accuracy DQOs for MS/MSD analyses are only applicable as long as the native amount is not greater than 4 times the spiked amount.

A.7 SPECIAL TRAINING REQUIREMENTS/CERTIFICATION

All personnel collecting samples will be thoroughly trained in protocols currently used for collection of water quality, geochemical characterization of materials, geotechnical stability of structures, and aquatic biological samples. Written record must be made for training of all new personnel in either field notes/notebook or sampling sheets. Training of personnel collecting samples will be provided and documented by senior staff of HGCMC.

Contracted laboratories performing analytical work must have the requisite knowledge and skills in execution of the analytical methods being requested. Information on laboratory staff competence is usually provided in each lab's Quality Management Plan (QMP) and/or Quality Assurance Project Plan (QAPP). The QMP for PNNL Marine Sciences Laboratory (FWMP) is included as Appendix 1.A.C, and the QAP for ACZ Analytical Laboratories, Inc. (internal monitoring) is included as Appendix 1.A.D.

Table 4 Training Requirements

Specialized Training/Certification	Field Staff	Lab Staff	Monitoring Supervisor	Lab Supervisor	Project QA Officer
Safety training	X	X	X	X	X
Water sampling techniques	X		X		X
Instrument calibration and QC activities for field measurements	X		X		X
Instrument calibration and QC activities for laboratory measurements		X		X	X
QA principles			X	X	X
QA for water monitoring systems			X		X
Chain of Custody procedures for samples and data	X	X	X	X	X
Handling and Shipping of Hazardous Goods	X	X	X	X	X
EPA Approved Field Measurement Method Training	X		X		X
Specific EPA Approved Lab Analytical Method Training		X		X	X

A.8 DOCUMENTS AND RECORDS

A.8.1 Documentation of Measurements, Sampling, and Inspections

For each measurement or sample taken, the following information is recorded:

- Place, date, and time of inspection, observation, measurement, or sampling;
- Person(s) who inspected, observed, measured, or sampled;
- Dates the analyses were performed and by which analytical facility;
- Analytical techniques or methods used;
- Accuracy of the analytical method (detection limits); and,
- Results of all required analysis.

Chain of Custody forms accompany all samples to assure sample holding times and handling procedures are met throughout the sample and analytical process.

A.8.2 Retention of Records

During operation, closure, and reclamation all records of monitoring activities and results, calibrations, and maintenance are retained for a period of at least three years from the date that the permit expires and as long as necessary to comply with applicable laws.

A.8.3 Monitoring Reports and Submission Schedules

The ADEC Waste Management Permit 2014DB0003 requires submission of quarterly reports summarizing inspection and monitoring results. Reports for the first three calendar quarters are due within 60 days after the end of the quarter. These reports are submitted to ADEC to specifically satisfy the reporting requirements of the Waste Management Permit, with courtesy copies provided to the USFS and ADNR. The quarterly reports address the following:

- Summaries of inspections and monitoring results;
- Analytical results for monitoring performed at the FWMP compliance sites during the corresponding quarter, with comparisons to historical data;
- Quantities and disposition of tailings and waste rock; and,
- Summary of water flow and management monitoring and meteorological data during the quarter.

The report for the fourth calendar quarter will be submitted by April 15 of the following year and serve as an Annual Report. The Annual Report will satisfy the reporting requirements of the ADEC, USFS and ADNR. In addition to the information provided in the quarterly reports, the Annual Report will address the following:

- Geochemical monitoring of tailings, waste rock and construction rock;
- Geotechnical stability monitoring of the tailings disposal facility, Site 23 and Pond 7;
- Internal water quality monitoring of the tailings disposal facility and Site 23;
- Monitoring of fugitive dust from the tailings disposal facility; and,
- An assessment of the adequacy of the reclamation surety bond.

All work associated with the annual aquatic bio-monitoring is performed by an independent outside entity with expertise in that field. This includes data collection, analysis, interpretation of results, and preparation of a technical report. Currently, the aquatic bio-monitoring is performed by the Alaska Department of Fish and Game, Division of Habitat, under annual contract to HGCMC. The technical report on the bio-monitoring is submitted by April 15 of the following year.

In addition to the quarterly and annual reports, Waste Management Permit 2014DB0003 stipulates conditions which require notification to ADEC not later than 5:00 p.m. of the next regular work day. These conditions include:

- Wildlife casualties associated with facility activities;
- When a statistically significant increase in a constituent concentration above a WQS is discovered at a surface or ground water monitoring location; or,
- Any non-compliance with a permit condition.

If a statistically significant increase in a constituent concentration above a WQS or a non-compliance condition is discovered, HGCMC shall:

- Determine the extent of the exceedance or non-compliance;
- In consultation with ADEC and documented in writing, implement a plan to restore compliance and determine the cause of the exceedance or non-compliance;
- Submit to ADEC, within seven working days after an exceedance or non-compliance is verified by HGCMC, a plan for corrective actions to prevent adverse environmental impacts and avoid future exceedances of a similar nature; and,
- Implement the corrective action plan as approved by ADEC.

Below is a table of all documents and records that will be produced and their disposition, including location and retention time.

Table 5 Project Documents and Records

Categories	Record/Document Types	Location	Retention Time
Site Information	Network Description	On Site	
	Site characterization file		
	Site maps		
	Site pictures		
Environmental Data Operations	QA Project Plan		
	Field Method SOPs		
	Field Notebooks		
	Sample collection/measurement records		
	Sample Handling & Custody Records		
	Chemical labels, SDS sheets		
	Inspection/Maintenance Records		
Raw Data	Lab data (sample, QC and calibration) including data entry forms		3 years after permit expires
Data Reporting	Discharge Monitoring Reports (DMRs, for permitted facility)		3 years after permit expires
	Progress reports		
	Project data/summary reports		
	Lab analysis reports		
	Investigation summary (CATS)		
	Inspection Report		
Data Management	Data management plans/flowcharts		
	Data algorithms		
Quality Assurance	Control charts		
	Data quality assessments		
	DMRQA and PE samples		3 years after permit expires
	Site audits		
	Lab audits		
	QA reports/corrective action reports		
	Response		
	Performance Evaluation Samples		

B DATA GENERATION AND ACQUISITION

B.1 SAMPLING

See the Integrated Monitoring Plan for specific sampling processes and designs.

Water samples are collected using protocols designed to minimize bias from systematic and/or erratic contamination introduced during sample collection. Water quality protocols are performance based and were developed from prior HGCMC sampling protocols incorporating selected procedures from EPA and U.S. Geological Survey methods. These protocols are applicable to the analytes being monitored, and the MDLs and MLs required assuring appropriate comparisons to AWQS. While these water quality sampling protocols are not required to be used, they are recommended. If other water quality sampling protocols are used, they should be based on proven methodologies such that the required MDLs and MLs can be achieved without experiencing false positive constituent levels due to introduced contamination.

B.2 SAMPLING METHOD REQUIREMENTS

B.2.1 Sampling Containers

The following applies to water samples collected under the FWMP:

- Sample containers are supplied by the laboratory conducting the analyses (PNNL Marine Sciences Laboratory).
- Sample containers will be pre-cleaned and pre-labeled at the laboratory prior to shipment to HGCMC. Filters and tubing used in the sample collection are also provided by the laboratory. They will be stored in a dry, dust free environment to avoid contamination on the outside of the bottles that could be inadvertently transferred to the sample during collection.
- Each bottle for trace metal analyses is placed within its own set of double re-sealable bags. Each bottle for the measurement of general wet chemistry analytes is placed within a single re-sealable bag. The individually bagged bottles for each site are placed together into a large clear plastic bag designated for that site.
- If a pre-cleaned bottle becomes uncapped during shipment or storage it will be returned to the laboratory and not used.
- Containers are supplied without chemical preservative. Collected samples are delivered to the laboratory within 24 hours and proper chemical preservation is performed at the laboratory.

The following applies to water samples collected under the internal monitoring program:

- Sample containers are supplied by the laboratory conducting the analyses (ACZ Laboratories, Inc.).
- Sample containers requiring chemical preservation will be pre-preserved at the laboratory prior to shipment to HGCMC. They will be stored in a dry, dust free environment to avoid contamination on the outside of the bottles that could be inadvertently transferred to the sample during collection.
- HGCMC is responsible for procuring filters and tubing that are certified as appropriate for use in the collection of environmental samples.
- HGCMC will print and affix the appropriate labels to the containers.
- All bottles for each site will be placed together into a large clear plastic bag.

The table below lists specific analyte/method criteria for parameter holding times and preservation methods. For parameters not listed in this table, see 40 CFR 136.6 for EPA-approved preservation methods and containers. 40 CFR 136.6 is available at: http://www.gpoaccess.gov/cfr/index.html

Table 6 Preservation and Holding Times for the Analysis of Samples

Analyte		Matrix	Container	Volume	Sample Preparation	Maximum Holding Time
Hardness		Water	poly	500 mL	0.2% HNO_3	180 days
pH		Water	poly	500 mL	Field filter; unpreserved	24 hours[1]
Conductivity		Water	poly	500 mL	Field filter; unpreserved	14 days
Bicarbonate		Water	poly	500 mL	Field filter; unpreserved	14 days
Alkalinity		Water	poly	500 mL	Field Filter; unpreserved	14 days
Ca, Mg, Na, K		Water	poly	250 mL	Field Filter, 0.2% HNO_3	180 days
Sulfate, chloride		Water	poly	60 mL	Field Filter; unpreserved	28 days
Nitrate-Nitrite		Water	poly	250 mL	Unfiltered; H_2SO_4 to pH < 2	28 days
Hardness		Water	poly	100 mL	HNO_3 to pH < 2; < 4°C	180 days
Mercury Total		Water	poly	250 mL	Unfiltered; 0.5% HCL	90 days
Dissolved Metals	Silver Ag	Water	poly	500 mL	Field Filter, 0.2% HNO_3	180 days
	Arsenic As	Water	poly	500 mL	Field Filter, 0.2% HNO_3	180 days
	Barium Ba	Water	poly	500 mL	Field Filter, 0.2% HNO_3	180 days
	Cadmium Cd	Water	poly	500 mL	Field Filter, 0.2% HNO_3	180 days
	Chromium Cr	Water	poly	500 mL	Field Filter, 0.2% HNO_3	180 days
	Copper Cu	Water	poly	500 mL	Field Filter, 0.2% HNO_3	180 days
	Nickel Ni	Water	poly	500 mL	Field Filter, 0.2% HNO_3	180 days
	Lead Pb	Water	poly	500 mL	Field Filter, 0.2% HNO_3	180 days
	Selenium Se	Water	poly	500 mL	Field Filter, 0.2% HNO_3	180 days
	Zinc Zn	Water	poly	500 mL	Field Filter, 0.2% HNO_3	180 days

[1]From sample receipt

B.2.2 Sampling Methods

B.2.2.1 General Procedures

All personnel collecting samples will be thoroughly trained in protocols currently used for collection of water quality samples. For all FWMP sampling, and whenever possible for internal monitoring, sampling will be done by teams of at least two trained people. Two people provide additional safety and overall efficiency while collecting samples in the field.

The following procedures apply regardless of the site type (ground water or surface water). Contamination will be minimized by paying strict attention to the work being done, awareness of potential contaminant sources, and minimizing atmospheric dust and debris from roads, vehicles, sampling locations, and the general environment.

a) Assemble all requisite supplies for the samples scheduled to be collected that day, place them in the vehicle, and drive to the sample location(s) parking a safe distance away when the sample site is near a roadway to minimize contamination by airborne particulate.

b) Open the storage cooler and remove the appropriate site bag containing the sample bottles and any QC sample bottle(s) scheduled for that site. Gather all ancillary supplies in a heavy clear plastic bag or cooler.

c) Walk to the sampling location and set up to take samples.

d) At each site samplers involved in collecting samples will put on a new set of clean gloves. Only disposable, non-powdered latex gloves will be used during sample collection.

e) For FWMP sampling, one member of the sampling team will be designated as "clean hands" (CH) and the second member as “dirty hands" (DH). CH may touch only the innermost re-sealable bag and the sample bottle and cap. DH is responsible for all other activities that do not involve direct contact with the innermost re-sealable bag or the sample bottle and cap. DH should not touch metal surfaces or extremely sediment-laden objects. The CH/DH protocol should be followed for all sampling when at least two team members are present.

B.2.2.2 Surface Water Sample Collection Procedures

At each location the following information is to be recorded in a field log book: sample team, date, time, site name, sample ID, analytical suite, field parameters (pH, conductivity and temperature), flow measurement or estimate (if practicable), weather conditions, and any other information that will aid in the interpretation of the data.

Samples are collected facing upstream to minimize the potential for contamination by disturbed bottom sediments.

For each unpreserved sample bottle to be filled when conditions exist to completely submerge the sample bottle without disturbing sediments:

- Completely submerge the bottle and remove the cap. Hold the cap so that the liner is facing upstream allowing flushing of the cap interior, and partially fill the bottle.
- While the bottle is still submerged, replace the cap and remove the bottle from the water.
- Shake the bottle several times and empty the bottle downstream and/or away from the site.
- After two more rinses, submerge the bottle entirely allowing the bottle to completely fill with sample leaving as little air space as possible.
- Replace the cap and place the sample in the plastic site bag.

For collecting samples in pre-preserved bottles, samples that require filtering in the field, or from sites where conditions do not exist to completely submerge the bottle without disturbing sediments, either:

- Utilize a clean, triple rinsed, and appropriately sized sample bottle as a transfer device to fill the required sample bottle; or,
- Use a peristaltic pump with new, clean tubing to draw directly from the stream exercising care to not disturb sediments.

B.2.2.3 Ground Water Sample Procedures

Ground water samples are collected using a variety of methods that are based on the depth of the well, and whether it is artesian/flowing, has a rapid recharge rate, or a slow recharge rate. Artesian/flowing

wells do not require purging prior to sample collection. Wells that recharge rapidly are purged to remove a minimum of three (3) casing volumes and until the pH, conductivity and temperature stabilize. Wells that recharge slowly are purged until dry, and then allowed to recover until there is sufficient volume to collect the samples. For shallow wells, purging and sampling are performed using a peristaltic pump. For deep wells where pumping is not possible, a disposable bailer is used for purging and sample collection. Artesian/flowing wells are sampled using a peristaltic pump to draw water from the top of the well casing.

At each location the following information is to be recorded in a field log book: sample team, date, time, site name, sample ID, static water level (before purging), total depth, purge volume, analytical suite, field parameters (pH, conductivity and temperature), flow measurement or estimate (if artesian), weather conditions, and any other information that will aid in the interpretation of the data.

After properly purging the well, groundwater samples are collected as follows:

- *If using an electric pump:* DH will attach a length of new tubing to the well's discharge tubing and the pump. DH will operate the pump and flush the tubing prior to sample collection. Both team members are careful not to touch the end of the tubing, or to let it touch anything.
- *If using a manual bailer:* DH will retrieve water from the well by slowly lowering the bailer into the well, minimizing the suspension of sediment if present. When practicable, retrieve and discard at least one bailer volume to rinse the bailer prior to sample collection. DH will pour/dispense water from the bailer into the sample bottles.
- Unpreserved sample bottles will be rinsed with water from the well by partially filling the bottle, replacing the cap, shaking vigorously to also rinse the cap, and emptying the bottle away from the site. Repeat two more times to triple rinse each bottle prior to sample collection.
- Pre-preserved bottles are not rinsed prior to sample collection.
- CH collects the samples by holding the bottles under the end of the tubing or bailer, avoiding contact between the bottle and tubing or bailer. CH secures the cap and places the sample bottle into the inner bag (if applicable) and re-seals it.

B.2.3 Sample Bottle Labeling

Each sample container requires a label large enough to record the information needed to readily identify the sample. The information recorded on each label will include the project name, sample point, date/time collected, filtered or unfiltered, preservation, and sampler's initials. Permanent waterproof ink or permanent marker should be used for all labeling purpose. The following are general guidelines to bottle labeling:

1 Put on a pair of clean gloves (new gloves should be used for each sample set).

2 Pull the sample set out, and fill out the necessary sections (site, date, time, and sampler) on the label, for each sample bottle.

3 To maintain consistent record keeping and to aid in efficient computer data processing, it is important to record the exact sample station identification on the sample label, corresponding to sample points contained in the IMP.

B.3 SAMPLE HANDLING AND CUSTODY REQUIREMENTS

B.3.1 Sample Custody Procedures

All water quality samples are collected by HGCMC personnel, packaged, and transported off Admiralty Island for laboratory analyses. This section describes the steps necessary to properly document the sample shipment, package the samples for shipment, and to arrange for and coordinate shipment of the samples from the mine site to the laboratory.

A chain of custody form and a bill of lading are filled out for each sample shipment. A copy of each is kept by sampling personnel to properly document and track the sample shipment. Example chain of custody forms are provided in Appendix 1.A.B. Documentation will be filed at the HGCMC mine site.

A bill of lading is completed for the shipping carrier to be used. HGCMC has accounts with Alaska Airlines Gold Streak Service and Federal Express. The carrier used is based on their ability to deliver samples to the laboratory's location, and the carrier's flight schedule. The account number is put on the bill of lading.

The samples and documentation are inspected and reviewed for accuracy, completeness, and legibility. The reviewer by initialing the chain of custody form documents the review as complete. The items to be reviewed are as follows:

1 The monitoring schedule is referenced to ensure all sample bottles including the QC samples are present.
2 The preprinted sample bottle labels and the chain of custody are reviewed.
3 The bill of lading is reviewed to ensure the correct delivery address.

B.3.2 Sample Packaging and Shipping Requirements

Packaging, marking, labeling, and shipping of samples will comply with all regulations promulgated by the U.S. Department of Transportation (USDOT) in 49 CFR 171-177. Staff should receive the necessary training for shipping samples or consult with the sub-contracted laboratory for shipping instructions.

Packaging

For the testing laboratory to generate valid test results, the integrity of field samples must be intact upon receipt at the laboratory. Protocols ensuring proper integrity of field samples from the time of collection to the time of receipt at the testing lab include:

- packing samples to prevent breakage or leakage;
- immediately cooling and maintaining unpreserved samples at 39°F (4°C);
- delivering samples to the lab in a time frame that allows analysis within the parameters' recommended holding times (see Table 6); and
- confirming the receipt and integrity of field samples with documentation generated by the shipper and the testing lab.

Packaging the samples is facilitated by the laboratory shipping empty bottle sets in the coolers that will be used for shipping the samples back to the laboratory. Coolers protect the sample containers, and

provide the necessary environmental conditions (cleanliness, temperature, etc.) during transport. Blue Ice or frozen water in appropriate containers is used to maintain a temperature of 4°C +/- 2°C within the coolers during sample shipment to the laboratory, and it is HGCMC's responsibility to freeze Blue Ice or water-filled containers prior to use. Below is a checklist of procedures for packaging water samples for shipment:

1 In a clean place without removing bottles from their resealable bag(s) ensure each sample bottle lid is tight, the bottle is properly labeled, and the cooler is clean to help minimize any contamination.

2 Ensure each sample bottle for metals analyses is within a set of double resealable bags, each sample bottle for the measurement of physical analytes is within a single resealable bag, and both are within the large clear heavy plastic bag designated for each site.

3 Place all site bags into the cooler. Set the bottles snugly in the cooler using clean packing material as necessary to prevent the sample bottles from moving within the cooler during transportation.

4 Place sufficient previously frozen Blue Ice or water filled bottles in the cooler with the samples to maintain the cooler temperature at 4°C +/- 2°C during transportation.

5 Copy the chain of custody form, seal the original in a resealable plastic bag, and place the bag within the cooler. Retain the copy for HGCMC's files.

6 Place strapping tape around the cooler as necessary to ensure the lid does not open during transportation and to confirm the cooler has not been tampered with during transportation. Tape should be applied over the cooler lid lock mechanism if present.

7 Secure the shipping label to the top of the cooler.

8 Transport the cooler to a secure storage area or to the shipping agent.

Schedule of Shipment

Shipment of samples is coordinated between sampling personnel, laboratory personnel, and the transportation carrier(s) to be used. Samples are shipped expeditiously to the laboratory, and should arrive in less than 2 days from the sample collection date. Holding time limitations must be considered when decisions are made regarding sampling and shipping times.

Notes:

- Sample shipments are not scheduled when it would result in expected delivery on late Friday afternoons, weekends, or holidays. Samples must be unpacked, logged, and preserved immediately upon receipt at the laboratory.
- Shipments are scheduled in consideration of the ability to get samples to town in time to meet the carrier's flight schedule. The carrier's schedule is checked beforehand for changes due to holidays or other reasons which could result in delayed delivery.
- The sample cooler(s) is brought to the drop-off point or common carrier in town and a copy of the bill of lading is returned to the mine for filing.
- A copy of the bill of lading is faxed to the Laboratory or they are called with the air bill number confirming to them the expected shipment and delivery time.

B.4 QUALITY CONTROL REQUIREMENTS

Quality Control (QC) is the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the monitoring project's data quality objectives.

B.4.1 Field Quality Control Measures

Quality Control measures in the field include but are not limited to:

- Proper cleaning of sample containers and sampling equipment.
- Maintenance, cleaning and calibration of field equipment/ kits per the manufacturers and/or laboratory's specifications, and field Standard Operating Procedures (SOPs).
- Chemical reagents and standard reference materials are used prior to expiration dates.
- Proper field sample collection and analysis techniques.
- Correct sample labeling and data entry.
- Proper sample handling and shipping/transport techniques.
- QA/QC Samples (should generally be equal to 15% of the total field and/or lab measurements or at least 1/sampling event, whichever is greater), including:
    - Field Blank (to the laboratory) samples
    - Field Replicate samples
    - Field Replicate measurements

B.4.2 Laboratory Quality Control (QC) Measures

Consistency in the use of fundamental laboratory techniques and practices over time is essential for creating a useful, reliable, and technically defensible database of analytical test results. Monitoring shall be conducted in accordance with EPA-approved analytical procedures and in compliance with 40 CFR Part 136, Guidelines Establishing Test Procedures for Analysis of Pollutants.

Quality Control in laboratories includes the following:

Calibration - Initial calibration ensures that the instruments are set up and adjusted properly to generate acceptable quantitative and qualitative test results. Initial instrument calibration procedures for most analyses require a minimum of three calibration standards and a blank. The associated calibration curve is required to have a linearity of 0.995 to be acceptable for sample analysis for most methods. Verifying the calibration ensures that acceptable sample test results are initially and continually produced throughout the analytical test run. Calibration verification (CV) standards are analyzed after completion of initial calibration and at required frequencies (typically every 10 to 20 samples) during and at completion of analytical testing. CV test results must meet acceptance criteria (typically 90-110% recovery for most methods) in order to generate valid sample test results.

Blanks - Calibration blanks and preparation blanks or method blanks are used to monitor the background associated with the analysis and preparation procedures. Blanks are required to be analyzed as a component of the initial instrument calibration and/or at a minimum frequency of 5% of the test sample quantity analyzed during each test run or one per batch, whichever is greater. Test results on all blanks must meet acceptance criteria (typically +/- reporting limit) in order to generate valid sample test results.

Laboratory Control Standards (LCS) - Analysis of LCSs are used to monitor the overall performance of the laboratory, including both sample preparation and analysis procedures. A certified SRM also

referred to as a reference standard (RS), is typically used as an LCS in most analytical laboratories. SRMs must be analyzed for all applicable test methods at a minimum frequency of 5% of the test sample quantity analyzed during each test run or one per batch, whichever is greater. Test results on all LCSs are required to meet acceptance criteria for accuracy (typically 75-125% recovery) in order for sample test results to be valid.

Matrix Spikes - These are used to monitor analytical performance with regard to accuracy within a specific sample matrix. Analysis of matrix spikes for all applicable methods is required at a minimum frequency of 5% of the test sample quantity analyzed during each test run or one per batch, whichever is greater. Test results on all matrix spikes are required to meet acceptance criteria for accuracy (typically 75-125% recovery) in order for sample test results to be valid.

Duplicates - Duplicates are used to monitor analytical performance with regard to precision. Analysis of sample duplicates for all applicable methods is required at a minimum frequency of 5% of the test sample quantity analyzed during each test run or one per batch, whichever is greater. Test results on all sample duplicates are required to meet acceptance criteria for precision (typically ≤20-25% RPD) in order for sample test results to be valid.

Sample Analysis – Sample analysis must be performed within the recommended holding times for each parameter tested (See Table 6). Sample preparation and analysis must correctly follow prescribed methodology. Reported test results must be derived from data that falls within the calibration range for each test parameter.

Contracted laboratories will provide analytical results after verification and validation by the laboratory QA Officer. The laboratory must provide all relevant QC information with its summary of data results so that the Project QA Officer or his/her designee can perform field data verification and validation, and review the laboratory reports. It is understood that Synectics is contracted to HGCMC to conduct the lab data review for the FWMP. The Project QA Officer or his/her designee (Synectics) reviews these data to ensure that the required QC measurement criteria have been met. If a QC concern is identified in the review process, the Project Sampling & Analysis Manager and Project QA Officer will seek additional information from the sub-contracted laboratory to resolve the issue and take appropriate corrective action/s.

Table 7 Laboratory Quality Control Samples

Field/Lab Quality Control Sample	Measurement Parameter	Frequency	QC Acceptance Criteria Limits
Lab Blank	All parameters	1:20	<5x MDL
Lab Fortified Blank	All ICP-MS (1638) and ICP-OES (200.7) Metals and Hardness	1:20	75-125%
	Mercury, Alkalinity, pH and Conductivity	NA	NA
Initial Calibration Verification Check Standard	All parameters	1 at beginning of analytical run	±10%
Continuing Calibration Verification Check Standard	All parameters	1:10	±15%
Matrix Spike/Matrix Spike Duplicate	All ICP-MS (1638) and ICP-OES (200.7) Metals and Hardness	1:20	75-125%
	Mercury, Alkalinity, pH and Conductivity	NA	NA
Lab Duplicate Sample	All parameters	1:20	RPD <20%
External QC Check Standard	All parameters	1:20	75-125%

B.5 EQUIPMENT TESTING, INSPECTION AND MAINTENANCE REQUIREMENTS

This section describes the procedures and criteria used to verify that all instruments and equipment are acceptable for use.

Field equipment used for sample collection and field measurements requires a program of control, calibration, adjustment, and maintenance. Portable water quality instruments in good working order are used for the field measurement of a standard set of field parameters summarized in Table 8. Note: The make and model of these instruments may vary over time.

Table 8 Field Testing Equipment

Equipment	Parameter
Solinst model 101 Depth to Water Tape	Water Level (groundwater wells)
Global Water FP111 Flow Probe	Stream Flow
Hydrolab Quanta Multi-Probe System	pH Water temperature Dissolved oxygen Oxidation/reduction potential (ORP/Eh) Electrical conductivity Turbidity
Hach 2100P Portable Turbidimeter	Turbidity
Oakton pH/Con 10 Series	pH Electrical Conductivity Water Temperature
YSI EC 300	Electrical Conductivity
YSI 30	Electrical Conductivity
Solinst Model 408 Double Valve Pump Solinst Model 464 Pump Control Unit	Groundwater

All field measurement data are recorded in field log books then input into an electronic database. Field crews may use field instrumentation and equipment maintained at the project site and/or instrumentation and equipment brought in from off-site.

Calibration, Operational Checks, Maintenance, and Record Keeping

Monitoring staff will document that required acceptance testing, inspection and maintenance have been performed. Records of this documentation should be kept with the instrument/equipment kit in bound logbooks or data sheets.

Field instrument preparations, calibration, and/or operational checks typically are performed at the beginning of each day's sampling activities. These tasks are performed following instrument manufacturer's recommended procedures or the procedures contained in this manual. A check of field instrument calibration is conducted initially (before sampling), at the completion of the day's field measurements, and as needed throughout the day, to establish and document that instruments are operated within specified tolerances.

Documentation of calibration measurements for field instruments must be completed every day prior to use and recorded in a field note book. Standards used for instrument calibration, operational checks, and calibration verification must be in accordance with applicable criteria such as the National Institute of Standards Technology (NIST), American Society for Testing and Materials (ASTM) standards, or other accepted procedures outlined in the instrument manufacturer's specifications.

Prior to use, maintenance procedures must be conducted on field instruments failing to meet acceptable operating specifications during calibration and calibration verification procedures. A record should be

maintained of field instruments' make(s)/model(s), status of parts needed, working status, deficiencies (if any), instrument maintenance records, and any additional pertinent information.

Contracted and sub-contracted laboratories will follow the testing, inspection and maintenance procedures required by EPA Clean Water Act approved methods and as stated in the respective laboratory's QAP and SOPs.

Field Instrument Handling Procedures

The Greens Creek site location is subject to varying climatic conditions over the course of a typical calendar year. During the fall, winter, and spring months, air temperatures may be below freezing for extended periods of time. Electrodes used for measuring pH, oxidation reduction potential (ORP/Eh), dissolved oxygen, and conductivity may be ruined or rendered inoperable if allowed to freeze. Procedures must be followed to protect field instrumentation from freezing out in the field during water quality monitoring events. Prior to beginning field activities:

- select a cooler/insulating box of adequate size to hold all of the field instruments and associated equipment needed for performing field measurements
- equip the inside of a cooler with padding such as "bubble wrap" (sample protection)
- when freezing conditions occur, add an adequate amount of a heat source to the cooler (heat packs/hand warmers or other) to maintain temperatures above freezing inside the cooler while in the field.

Field Equipment and Instrument Decontamination Procedures

All sample collection equipment and field instrumentation that comes into contact with a sample must be decontaminated following sampling. Decontamination procedures differ depending on the instrument or equipment, as described below:

- For the water level meter, portable submersible pump, and peristaltic pump, the following procedure should be followed:

    1 rinse in water
    2 wash with an anionic detergent
    3 rinse in deionized water (DI)
    4 air dry
    5 dispose of cleaning agent at the proper waste facility.

The purpose of the water and detergent wash is to remove particulate matter and other potential contaminants. The purpose of the final DI rinse is to remove detergent and any residual contaminants.

- Hydrolab Quanta (refer to the Hydrolab Procedures Manual):

    1 thoroughly rinse all probes three times with tap water

    2 place in storage/transport cup, which should have ¼ inch of tap water or pH 4 buffer (if preferred), before traveling to the new site or for short-term storage.

If traveling to another site for sampling:

    1 rinse the probe with site water at new location, to remove any residual water from the previous site.

2 between sites place probe in the transfer cup..

Using deionized water for storage purposes causes the pH probe to malfunction and require immediate replacement. Between sampling locations, the steps outlined above are recommended.

If the Quanta Multi-purpose probes appear to contain deposits or contaminants that cannot be removed from the rinse steps above, and a "drift" in parameter readout is observed, the Quanta meter can be sent into the nearest vendor for repair, or the simple cleaning methods described below can be done weekly or as needed for removing stubborn deposits:

1 Spray probes with the over-the-counter cleaning agent, "Scrubbing Bubbles," making sure that the lenses are sprayed over well, OR use Alconox solution.

2 Allow bubbles to sit for a couple of minutes.

3 Using the small tube brush is included in the maintenance kit; carefully scrub around all the probes to remove debris and build-up.

4 Rinse well with tap water, making sure to remove all the suds.

5 Dispose of any diluted cleaning agents and water at the proper waste facility.

B.6 INSPECTION / ACCEPTANCE OF SUPPLIES AND CONSUMABLES

Field staff are responsible for ensuring that supplies and consumables (e.g., standard materials and solutions, filters, pumps, tubing, sample bottles, glassware, reagents, calibration standards, electronic data storage media, etc.) are inspected and accepted for use in the monitoring project.

All reagents, calibration standards, and kit chemicals are to be inspected to ensure that expiration dates have not been exceeded prior to use in the monitoring project. No standard solutions, buffers, or other chemical additives should be used if the expiration date has passed. It is the responsibility of the sampling manager or his/her designee to keep appropriate records, such as logbook entries or checklists, to verify the inspection/acceptance of supplies and consumables, and restock these supplies and consumables when necessary.

All sample collection devices and equipment will be appropriately cleaned prior to use in the monitoring project. All sample containers, tubing, filters, etc. provided by a laboratory or by commercial vendor, will be certified clean for the analyses of interest. Contracted and sub-contracted laboratories will follow procedures in their laboratory's Quality Assurance Plan (QAP) and SOPs for inspection/acceptance of supplies and consumables.

B.7 DATA MANAGEMENT

The success of a monitoring project relies on data and their interpretation. It is critical that data be available to users and that these data are:

- Of known quality;
- Reliable;
- Aggregated in a manner consistent with their prime use; and
- Accessible to a variety of users.

Quality Assurance/Quality Control (QA/QC) of data management begins with the raw data and ends with a defensible report, preferably through the computerized messaging of raw data.

Data management encompasses and traces the path of the data from their generation to their final use or storage (e.g., from field measurements and sample collection/recording through transfer of data to computers (laptops, data acquisition systems, etc.), laboratory analysis, data validation/verification, QA assessments and reporting of data of known quality to the respective ADEC Division of Water Program Office). It also includes/discusses the control mechanism for detecting and correcting errors.

Various people are responsible for separate or discrete parts of the data management process:

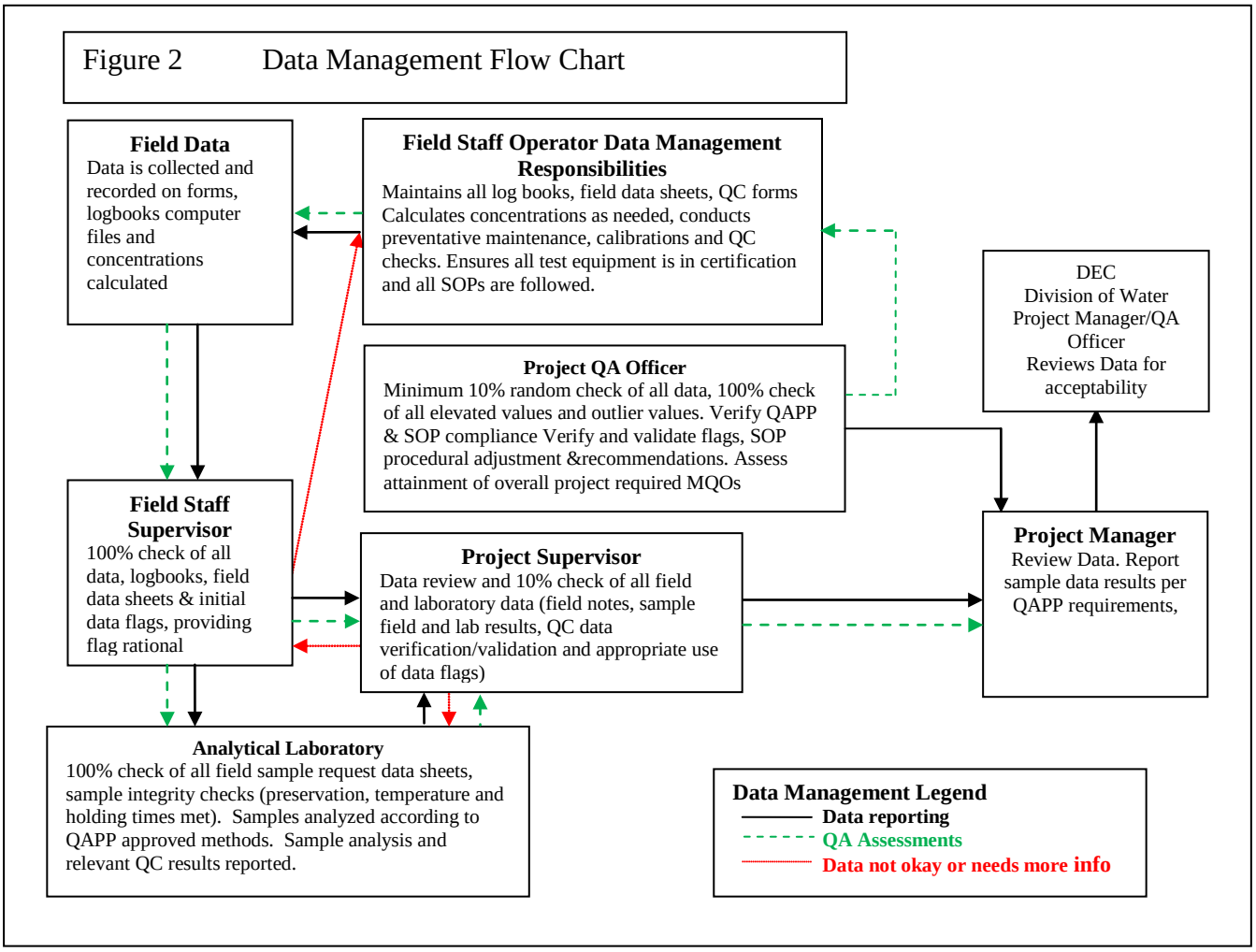
- The field samplers are responsible for field measurements/sample collection and recording of data and subsequent shipment of samples to laboratories for analyses. They assemble data files, which includes raw data, calibration information and certificates, QC checks (routine checks), data flags, sampler comments and meta data where available. These files are assembled and forwarded for secondary data review by the sampling supervisor.
- Laboratories are responsible to comply with the data quality objectives specified in the QAPP and as specified in the laboratory QAP and method specific SOPs. Validated sample laboratory data results are reported to the sampling coordinator/supervisor/project supervisor.
- Secondary reviewers (lab manager/sampling & analysis manager/project QA officer) are responsible for the review, verification and validation of field and laboratory data, and reporting validated data to the Project Manager.
- The Project QA Officer is responsible for performing routine independent reviews of data to ensure the monitoring projects data quality objectives are being met. Findings and recommended corrective actions (as appropriate) are reported directly to project management.
- The Project QA Officer is responsible for final data certification.
- ADEC DOW Project Manager/QA Officer/AQS data entry staff conducts a final review (tertiary review) and submits the validated data to STORET, AQMS, ICI-APDES, DROPS as appropriate.

The Data Management Flow Chart at the end of this section provides a visual summary description of the data flow/management process for environmental data collected in support of ADEC's Division of Water decision making processes.

Data Storage and Retention

A relational database containing all water quality data is maintained by HGCMC at the mine. Copies or partial copies of the database may be distributed to others as needed to facilitate data analysis. Data security is maintained by limiting access rights to the database files through network login IDs and passwords. Passwords are changed as needed. Laboratory data are electronically imported or manually entered into the HGCMC database. Associated qualifiers are manually entered after the QA review report is finalized and received by HGCMC. All data (100%) entered into the database manually, and a sample (5%) of the data imported into the database electronically, are verified against the hardcopy before the data are used for analysis. Laboratory Records will be retained by the contract laboratory for a minimum of five years. Project records will be retained by HGCMC at the mine site through final reclamation.

Figure 2 Data Management Flow Chart



C ASSESSMENT AND OVERSIGHT

C.1 ASSESSMENTS AND RESPONSE ACTIONS

The following QA assessment activities are provided to serve as a guideline of activities to be performed by the Project's QA Officer or his/her designee to evaluate the overall monitoring system (data collection, analysis, and reporting).

Field Assessments (each pollutant)

- Precision (replicate) sample measurements. Project should have minimum of 1 paired measurements/sampling event or 20% of project samples, whichever is greater. Replicate measurements should be evenly spaced over project timeline. Precision criteria to be specified in the project's Measurement Quality Objectives (MQO) table, see section A.6.2.

Field samples collected for subsequent laboratory analysis (each pollutant)

- Field blank samples for each analyte to be measured. Project should have minimum of 1 field blank measurement/sampling event or 20% of project samples, whichever is greater.
- Sample splits (one split sent to lab analyzing project samples, other split sent to a reference lab).
- Matrix spike duplicates (MSD) (assesses total measurement bias for project – both precision & accuracy). Frequency of MSDs usually specified by analytical method. Accuracy and precision of criteria for each pollutant and analytical method to be specified in the project's MQO table see section A.6.2.

Note: It is the responsibility of the laboratory to enroll itself in these blind PT studies with the results mailed/emailed directly to the ADEC DOW Water Quality Assurance Office and the Monitoring Project's QA Officer. Routine laboratory performance in the blind PT sample studies will be used to assess overall laboratory data quality as well as monitoring project data quality.

On-Site Assessments

- Inspection of field monitoring operations for compliance with QAPP requirements.
- Laboratory Audit (if concerns arise regarding laboratory data quality)
- Audit of project field measurement data results.

Project Data Assessments

- Audits of Monitoring Data for reproducibility of results from recalculation/reconstruction of field/lab unprocessed data.
- Calculation of monitoring project's overall achieved precision, accuracy and data completeness compared to QAPP defined precision, accuracy and data completeness goals.

C.2 REVISIONS TO QAPP

Annually the QAPP will be reviewed and revised as needed. Minor revisions may be made without formal comment. Such minor revisions may include changes to identified project staff (but not lead project staff: QA project officer, project manager, sampling manager, contracted laboratories), QAPP distribution list and/or minor editorial changes.

Revisions to the QAPP that affect stated monitoring Data Quality Objectives, Method Quality Objectives, method specific data validation *"critical"* criteria and/or inclusion of new monitoring methods must solicit input and pre-approval by ADEC DOW QA Officer/ADEC Project Management before being implemented.

C.3 QA REPORTS TO MANAGEMENT

The following table describes assessment types, frequency, content, responsible individual/s, and distribution of assessment reports to management and other recipients and actions to be taken.

Table 9 QA Reports to Management

QA Report Type	Contents	Presentation Method	Report Issued by	Reporting Frequency	
				As Required	Year
On-site Field Inspection Audit Report	Description of audit results, audit methods and standards/equipment used and any recommendations	Written text and tables, charts, graphs displaying results	Project QA Officer/auditor	✔	
Field Split Sample Report	Evaluation/comparison of result of split sample results from different laboratories, audit method.	Written text and tables, charts, graphs displaying results	Project QA Officer/auditor	✔	
On-site Laboratory Audit Report	Description of audit results, audit methods and standards/equipment used and any recommendations	Written text and tables, charts, graphs displaying results	Project QA Officer/auditor	✔	
3rd Party PT (DMRQA, etc.) Audit Report	Description of audit results, methods of analysis and any recommendations	Written text and charts, graphs displaying results	Project QA Officer/auditor	✔	✔
Corrective Action Recommendation	Description of problem(s); recommended action(s) required; time frame for feedback on resolution of problem(s)	Written text/table	Project QA Officer/auditor	✔	
Response to Corrective Action Report	Description of problem(s), description/date corrective action(s) implemented and/or scheduled to be implemented	Written text/table	Project Manager overseeing sampling and analysis	✔	
Data Quality Audit	Independent review and recalculation of sample collection/analysis (including calculations, etc.) to determine sample result. Summary of data audit results; findings; and any recommendations	Written text and charts, graphs displaying results	Project QA Officer	✔	
Quality Assurance Report to Management	Project executive summary: data completeness, precision, bias/accuracy	Written text and charts, graphs displaying results	Project QA Officer	✔	✔

D DATA VALIDATION AND USABILITY

D.1 DATA REVIEW, VERIFICATION AND VALIDATION REQUIREMENTS

D.1.1 Data Validation

Data validation means determining if data satisfy QAPP defined user requirements; that is, that the data refer back to the overall data quality objectives. Data validation is an analyte and sample-specific process that extends the evaluation of data beyond method, procedural, or contractual compliance (i.e., data verification) to determine the analytical quality of a specific data set to ensure that the reported data values meet the quality goals of the environmental data operations (method specific data validation criteria). It is important that the data reviewers be familiar with the specific methods and QA/QC requirements associated with the Greens Creek project in order to properly review and validate associated analytical data. Water quality monitoring data is used for establishing baseline conditions, predicting water quality at various project facilities, and developing water quality discharge limitations. For these reasons, and because the data may also be the basis for future closure and reclamation decisions and strategies, it is critical that sample analyses and associated data meet method requirements and project specifications.

D.1.2 Data Verification

Data Verification is the process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual requirements.

D.1.3 Data Review

Data Review is the process that evaluates the overall data package to ensure procedures were followed and that reported data is reasonable and consistent with associated QA/QC results.

D.2 VALIDATION AND VERIFICATION METHODS

D.2.1 Validation Methods

All data generated shall be validated in accordance with the QA/QC requirements specified in the methods and the technical specification outlined in this QAPP. Raw field data will be maintained by the Program staff who collect it. Raw laboratory data shall be maintained by the laboratory. The laboratory may archive the analytical data into their laboratory data management system. All data will be kept a minimum of 3 years.

Field data is first reviewed by field personnel performing the field measurement procedures. As with laboratory data, the field personnel have primary responsibility for the technical quality of field data, and for ensuring that field methods are properly performed and instrumentation is in good working order.

Analytical data generated by the laboratory is first reviewed by the testing laboratory and then reported to the Sampling and Analysis Manager. The laboratory has primary responsibility for correctly identifying and quantifying analytes and compounds of interest, for identifying matrix interferences, and for identifying and correcting instrument anomalies when possible. The laboratory is also responsible for the technical quality of the data, for meeting all quality control parameters by correctly following the analytical methods, and for using instrumentation that is in proper working order for the given method.

All laboratory data will be validated according to the laboratory's QAP. The rationale for any anomalies in the QA/QC of the laboratory data will be provided to the Project Manager with the data results. Completed Chain-of-Custody forms will be sent back from the laboratory to the Sampling and Analysis Manager. Data will be qualified as necessary.

The Project QA Officer or his/her designee is responsible for reviewing field log notebooks for accuracy and completeness. Synectics is contracted to HGCMC to conduct the lab data review for the FWMP. The Project QA Officer or his/her designee (Synectics) will fill out a Laboratory Data Review and Validation Checklist (example in Appendix 1.A.E) to be included with the permanent files and the monitoring report. The Laboratory Data Review and Validation Checklist will verify and validate the following items:

- Compare sample information from the field data sheets with the laboratory analytical results to ensure no transcription errors have occurred;
- Verify and validate sample results from the laboratory;
- Verify project QC criteria have been met (i.e., Blind Duplicates, Blanks, Matrix Spikes, Standards, and Completeness).

Unacceptable data (i.e., data that do not meet the QA measurement criteria of precision, accuracy, representativeness, comparability and completeness) will not be used or if used, the problems with the data will be clearly defined, flagged appropriately and data use clearly delimited and justified. Sampling may need to be repeated. Any actions taken to correct QA/QC problems in sampling, sample handling, and analysis must be noted. Under the direction of the Project QA Officer, project staff will document any QA/QC problems and QA/QC corrective actions taken.

D.2.2 Verification Methods

The primary goal of verification is to document that applicable method, procedural and contractual requirements were met in field sampling and laboratory analysis. Verification checks to see if the data were complete, if sampling and analysis matched QAPP requirements, and if Standard Operating Procedures (SOPs) were followed.

The Project QA Officer is responsible for the verification of the data and should verify at least 10% of the generated project data. The field data sheets are compared with the SOPs, sampling requirements and sample sites identified in the Greens Creek Integrated Monitoring Plan.

D.3 RECONCILIATION WITH USER REQUIREMENTS

The Project QA Officer and Sampling & Analysis Manager will review and validate data against the Project's defined MQOs prior to final reporting stages. If there are any problems with quality sampling and analysis, these issues will be addressed immediately and methods will be modified to ensure that data quality objectives are being met. Modifications to monitoring will require notification to ADEC and subsequent edits to the approved QAPP.

Only data that have been validated and qualified, as necessary, shall be provided to ADEC Division of Water.

APPENDICIES

Appendix 1.A.A

Geotechnical Visual Inspection Checklist

ALASKA DAM SAFETY PROGRAM
VISUAL INSPECTION CHECKLIST

NID ID#_____
SHEET __ OF __

GENERAL INFORMATION

NAME OF DAM:	POOL ELEVATION:
NATIONAL INVENTORY OF DAMS ID#:	TAILWATER ELEVATION:
OWNER:	CURRENT WEATHER:
HAZARD POTENTIAL CLASSIFICATION:	PREVIOUS WEATHER:
SIZE CLASSIFICATION:	INSPECTED BY:
PURPOSE OF DAM:	INSPECTION FIRM:
O & M MANUAL REVIEWED:	DATE OF INSPECTION:
EMERGENCY ACTION PLAN REVIEWED:	

ITEM	YES	NO	REMARKS
RESERVOIR			
1. Any upstream development?			
2. Any upstream impoundments?			
3. Shoreline slide potential?			
4. Significant sedimentation?			
5. Any trash boom?			
6. Any ice boom?			
7. Operating procedure changes?			

DOWNSTREAM CHANNEL			
1. Channel			
a. Eroding or Backcutting			
b. Sloughing?			
c. Obstructions?			
2. Downstream Floodplain			
a. Occupied housing?			
b. Roads or bridges?			
c. Businesses, mining, utilities?			
d. Recreation Area?			
e. Rural land?			
f. New development?			

EMERGENCY ACTION PLAN			
1. Class I or Class II Dam?			
2. Emergency Action Plan Available?			
3. Emergency Action Plan current?			
4. Recent emergency action plan exercise?			**DATE:**

INSTRUMENTATION			
1. Are there			
a. Piezometers?			
b. Weirs?			
c. Observation wells?			
d. Settlement Monuments?			
e. Horizontal Alignment Monuments?			
f. Thermistors?			
2. Are readings			
a. Available?			
b. Plotted?			
c. Taken periodically?			

NID ID#_____
SHEET __ OF __

ALASKA DAM SAFETY PROGRAM
VISUAL INSPECTION CHECKLIST

SAFETY

ITEM	YES	NO	REMARKS
SAFETY			
1. ACCESS			**TYPE:**
a. Road access?			
b. Trail access?			
c. Boat access?			
d. Air access?			
e. Access safe?			
f. Security gates and fences?			
g. Restricted access signs?			
2. PERSONNEL SAFETY			
a. Safe access to maintenance and operation areas?			
b. Necessary handrails and ladders available?			
c. All ladders and handrails in safe condition?			
d. Life rings or poles available?			
e. Limited access and warning signs in place?			
f. Safe walking surfaces?			
3. DAM EMERGENCY WARNING DEVICES			
a. Emergency Action Plan required?			
b. Emergency warning devices required by EAP?			**TYPE(S):**
c. Emergency warning devices available?			
d. Emergency warning devices operable?			
e. Emergency warning devices tested?			
f. Emergency warning devices tested by owner?			**WHEN:**
g. Emergency procedures available at dam?			
h. Dam operating staff familiar with EAP?			
4. OPERATION AND MAINTENANCE MANUAL			
a. O & M Manual reviewed?			
b. O & M Manual current?			**DATE:**
c. Contains routine inspection schedule?			
c. Contains routine inspection checklist?			

NID ID#_____
SHEET __ OF __

ALASKA DAM SAFETY PROGRAM
VISUAL INSPECTION CHECKLIST

EMBANKMENT DAMS

ITEM	YES	NO	REMARKS
EMBANKMENT DAMS			**TYPE:**
1. CREST			
a. Any settlement?			
b. Any misalignment?			
c. Any cracking?			
d. Adequate freeboard?			
2. UPSTREAM SLOPE			
a. Adequate slope protection?			
b. Any erosion or beaching?			
c. Trees or brush growing on slope?			
d. Deteriorating slope protection?			
e. Visual settlement?			
f. Any sinkholes?			
3. DOWNSTREAM SLOPE			**TYPE:**
a. Adequate slope protection?			
b. Any erosion?			
c. Trees or brush growing on slope?			
d. Animal burrows?			
e. Sinkholes?			
f. Visual settlement?			
g. Surface seepage?			
h. Toe drains dry?			
i. Relief wells flowing?			
j. Slides or slumps?			
4. ABUTMENT CONTACTS			
a. Any erosion?			
b. Seepage present?			
c. Boils or springs downstream?			
5. FOUNDATION			**TYPE:**
a. If dam is founded on permafrost			
(1) Is fill frozen?			
(2) Are internal temperatures monitored?			
b. If dam is founded on bedrock			**TYPE:**
(1) Is bedrock adversely bedded?			
(2) Does rock contain gypsum?			
(3) Weak strength beds?			
c. If dam founded on overburden			**TYPE:**
(1) Pipeable?			
(2) Compressive?			
(3) Low shear strength?			

NID ID#_____
SHEET __ OF __

ALASKA DAM SAFETY PROGRAM
VISUAL INSPECTION CHECKLIST

TIMBER DAMS

ITEM	YES	NO	REMARKS
TIMBER DAMS			**TYPE:**
1. CREST			
a. Any settlement?			
b. Any misalignment?			
c. Adequate freeboard?			
d. Deck timbers sound?			
2. ABUTMENT AND FOUNDATION CONTACTS			
a. Any erosion?			
b. Seepage present?			
c. Boils or springs downstream?			
d. Exposed bedrock?			
e. Is bedrock deteriorating?			
f. Visible displacements?			
3. STRUCTURAL AND CRIB TIMBERS			**TYPE:**
a. Any deterioration?			
b. Are ends broomed or checked?			
c. Are timbers preservation treated?			
d. Are timbers pinned or bolted?			
4. CRIBS			
a. Are cribs filled with rock fill?			
b. Is rock fill sound rock?			

NID ID#_____
SHEET __ OF __

ALASKA DAM SAFETY PROGRAM
VISUAL INSPECTION CHECKLIST

SPILLWAYS

ITEM	YES	NO	REMARKS
SPILLWAYS			**TYPE(S):**
1. CREST			**TYPE(S):**
a. Any settlement?			
b. Any misalignment?			
c. Any cracking?			
d. Any deterioration?			
e: Exposed reinforcement?			
f. Erosion?			
g. Silt deposits upstream?			
2. CONTROL STRUCTURES			
a. Mechanical equipment operable?			
b. Are gates maintained?			
c. Will flashboards trip automatically?			
d. Are stanchions trippable?			
e. Are gates remotely controlled?			
3. CHUTE			
a. Any cracking?			
b. Any deterioration?			
c. Erosion?			
d. Seepage at lines or joints?			
4. ENERGY DISSIPATERS			
a. Any deterioration?			
b. Erosion?			
c. Exposed reinforcement?			
5. METAL APPURTENANCES			
a. Corrosion?			
b. Breakage?			
c. Secure anchorages?			
6. EMERGENCY SPILLWAY			
a. Adequate grass cover?			
b. Clear approach channel?			
c. Erodible downstream channel?			
d. Erodible fuse plug?			
e. Stable side slopes?			
f. Beaver dams present?			

NID ID#_____
SHEET __ OF __

ALASKA DAM SAFETY PROGRAM
VISUAL INSPECTION CHECKLIST

LOW LEVEL OUTLET

ITEM	YES	NO	REMARKS
LOW LEVEL OUTLET			**TYPE**
1. GATES			
a. Mechanical equipment operable?			
b. Are gates remotely operated?			
c. Are gates maintained?			
2. CONCRETE CONDUITS			
a. Any cracking?			
b. Any deterioration?			
c. Erosion?			
d. Exposed reinforcement?			
e. Are joints displayed?			
f. Are joints leaking?			
3. METAL CONDUITS			
a. Is metal corroded?			
b. Is conduit cracked?			
c. Are joints displaced?			
d. Are joints leaking?			
4. ENERGY DISSIPATERS			
a. Any deterioration?			
b. Exposed reinforcement?			
5. METAL APPURTENANCES			
a. Corrosion?			
b. Breakage?			
c. Secure anchorages?			

NID ID#_____
SHEET __ OF __

ALASKA DAM SAFETY PROGRAM
VISUAL INSPECTION CHECKLIST

INTAKES

ITEM	YES	NO	REMARKS
INTAKES			
1. EQUIPMENT			
a. Trash racks			
b. Trash rake?			
c. Mechanical equipment operable?			
d. Intake gates?			
e. Are racks and gates operable?			
f. Are gate operators operable?			
2. CONCRETE SURFACES			
a. Any cracking?			
b. Any deterioration?			
c. Erosion?			
d. Exposed reinforcement?			
e. Are joints displaced?			
f. Are joints leaking?			
3. CONCRETE CONDUITS			
a. Any cracking?			
b. Any deterioration?			
c. Erosion?			
d. Exposed reinforcement?			
e. Are joints displaced?			
f. Are joints leaking?			
4. METAL CONDUITS			
a. Is metal corroded?			
b. Is conduit damaged?			
c. Are joints displaced?			
d. Are joints leaking?			
5. METAL APPURTENANCES			
a. Corrosion?			
b. Breakage?			
c. Secure anchorages?			
6. PENSTOCKS			**TYPE MATERIAL:**
a. Material deterioration?			
b. Joints leaking?			
c. Supports adequate?			
d. Anchor blocks stable?			

NID ID#_____
SHEET __ OF __

ALASKA DAM SAFETY PROGRAM
VISUAL INSPECTION CHECKLIST

CONCRETE DAMS

ITEM	YES	NO	REMARKS
CONCRETE DAMS			**TYPE OF DAM:**
1. CREST			
a. Any settlement?			
b. Any misalignment?			
c. Any cracking?			
d. Any deterioration?			
e. Exposed reinforcement?			
d. Adequate freeboard?			
2. UPSTREAM FACE			
a. Spalling?			
b. Cracking?			
c. Erosion?			
d. Deterioration?			
e. Exposed reinforcement?			
f. Displacement?			
g. Loss of joint fillers?			
h. Damage to membranes?			
i. Silt deposits upstream?			
3. DOWNSTREAM FACE			**TYPE:**
a. Spalling?			
b. Cracking?			
c. Erosion?			
d. Deterioration?			
e. Exposed reinforcement?			
f. Inspection gallery?			
g. Foundation drains?			
h. Foundation drains clear and flowing?			
i. Seepage from joints?			
j. Seepage from lift lines?			
4. ABUTMENT & FOUNDATION CONTACTS			
a. Exposed bedrock?			
b. Erosion?			
c. Visible displacement?			
d. Seepage from contact?			
e. Boils or springs downstream?			

Appendix 1.A.B

Example Analytical Lab Chain of Custody Forms

Lab Set To:
ACZ

Chain of Custody Record / Analysis Request

Company Name:	**HGCMC**	Project Name:	**Tails Area**
Company Address:	P.O.Box 32199 Juneau, AK 99803	Report To: Jennifer Saran / jsaran@hecla-mining.com	
		Sampler:	# containers
		P.O.Number: X11034	
Telephone: (907) 790-8472 T. Morales / 8461 R. Jung 9473 C. Wallace / 8474 J. Saran / 8420 S. Williamson Fax: (907) 790-8478			

Sample I.D.	Date Collected	Time Collected	Matrix Water / Soil	250ml. White Poly	250ml Red Poly	250ml Yellow Poly	250ml Amber Glass	250ml Red Poly		Suite C1									RUSH (see below)

Comments:

e-mail: tmorales@hecla-mining.com / rjung@hecla-mining.com
cwallace@hecla-mining.com / swilliamson@hecla-mining.com

Deliverables

- ☐ Level 1
- ☐ ADEC Format
- ☐ ACOE
- ☐ Other:_____
- ☐ EDD-Format:_____Specify

Turnaround Time

- ☐ 2 Business Days
- ☐ 5 Business Days
- ☐ 10-15 Business Days
- ☐ Other:_____# Business Days

RELINQUISHED BY SAMPLER:	RECEIVED BY:	RELINQUISHED BY:	RECEIVED BY:	Condition of Sample Containers:
Signature:	Signature:	Signature:	Signature:	Temp Received: _____ °C
Printed Name:	Printed Name:	Printed Name:	Printed Name:	# of Coolers: _____
Firm: *HGCMC*	Firm:	Firm:	Firm:	Seals Intact: _____
Date / Time:	Date / Time:	Date / Time:	Date / Time:	Page _____ of _____

SAMPLE CUSTODY RECORD

(SOP#: MSL-A-001 & MSL-A-002)

Date: _____

Battelle
. . . Putting Technology To Work
Pacific Northwest Division
Marine Sciences Laboratory
1529 West Sequim Bay Road
Sequim, Washington 98382

Project Name: _____
Project Manager: _____
Phone Number: _____

Shipment Method: _____
Preservation: _____

Line	Field Sample ID	Collection Date/Time	Matrix	No. of Containers	Test Parameters					Laboratory ID	Observations/Comments
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											
15											

Relinquished By:	Company:	Received By:	Company:
Signature/Printed Name	Date/Time	Signature/Printed Name	Date/Time
Relinquished By:	Company:	Received By:	Company:
Signature/Printed Name	Date/Time	Signature/Printed Name	Date/Time

Distribution: White - Laboratory, Project Files Yellow - Laboratory, Client Pink - Sampler

Appendix 1.A.C

PNNL Marine Science Laboratory Quality Assurance Management Plan (QAMP)

PNNL Marine Sciences Laboratory Quality Assurance Management Plan (QAMP)

PNNL Marine Sciences Laboratory
1529 West Sequim Bay Road
Sequim, Washington 98382
(360) 681-4550

January 2014

INTRODUCTION

The purpose of the PNNL Marine Sciences Laboratory (MSL) Quality Assurance Management Plan (QAMP) is to describe the Quality Program implemented at the facility. This plan summarizes the elements of the quality assurance program and discusses the quality control activities routinely used. The objective of the Quality Program is to obtain accurate and precise data consistent with project objectives. The Quality Assurance (QA) Program has evolved over time to meet client needs, but its roots are from the U.S. Environmental Protection Agency's (EPA's) document EPA QA/R-2, "EPA Requirements for Quality Management Plans". This QAMP also addresses the required elements of The NELAC Institute (TNI). While this plan sets forth Quality Program requirements, work plans and QA project plans are used to define project-specific client requirements.

Implementation of the policies and requirements specified in the QAMP and the associated procedures will provide defensible and credible data enhancing the quality of products and services.

CONCURRENCES AND APPROVALS

01/10/2014
Date

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12/18/2013
Date

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Date

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Table of Contents

1.0 INTRODUCTION

The Pacific Northwest National Laboratory (PNNL) is operated by Battelle Memorial Institute, Pacific Northwest Division for the Department of Energy (DOE). For the purpose of this Quality Assurance Management Plan (QAMP), Battelle and PNNL will hereafter be referred to in general as PNNL, except in instances when specifically referring to Battelle as the Battelle Memorial Institute or "Battelle" is in a cited reference title.

Since PNNL consists of research and regulated analytical work, requirements of this document are applied to projects on a risk based graded approach. As a result, requirements of this document may not be applicable for some projects and/or may generally be used as guidance as a result of the graded approach.

1.1 QUALITY ASSURANCE MANAGEMENT PLAN

This QAMP describes the Quality Assurance (QA) Program policies, procedures and accountabilities established and implemented at the PNNL Marine Sciences Laboratory (MSL). This QAMP summarizes elements of QA and the quality control (QC) activities used to perform work by collecting accurate, precise and reliable data consistent with project objectives. Detailed methodologies and practices are written in MSL Standard Operating Procedures (SOPs) or project planning documents.

This QAMP is designed to be an overview of MSL operations and to meet the requirements of many clients. It is also intended to address elements of the Environmental Protection Agency's (EPA) document EPA QA/R-2, "EPA Requirements for Quality Management Plans", the Navy QA Program and the requirements for The NELAC Institute (TNI). While this plan establishes the QA program requirements, QA Project Plans (QAPP), sample analysis plans, and/or "kits" assembled at the time of sample receipt are used to define any project specific quality requirements not contained in or superseding this plan.

A copy of the QAMP is available on the intranet or upon request. All applicable personnel are expected to be aware of and perform their assignments in accordance with the QA requirements described in the QAMP. The signature page at the front of the QAMP indicates management's review, consensus, and approval.

To ensure that the QAMP remains current, it is reviewed annually and updated as needed. If only minor changes are needed, red-line changes are applied to the current version. If major changes are needed, the entire document is revised and the effective date is updated.

1.2 POLICY STATEMENT

The MSL is committed to maintaining the highest ethical and professional standards. All personnel shall conduct themselves in accordance with these standards and in their relationships with each other, with clients, with the public, and with PNNL.

- All personnel shall document calculations, analyses, tests and software required to substantiate results and processes used to develop products/solutions.
- All personnel shall ensure that the scientific and technical information that results from PNNL research is available for maximum possible future use by the scientific community and the public unless contrary to PNNL's interests or the client's requirements.

- All personnel shall identify and appropriately control items and materials affecting scientific results.
- All personnel shall use equipment of known accuracy for process monitoring and data collection.
- All personnel shall maintain records necessary to substantiate results and processes of research or administrative activities, protect records from loss or damage, refer requests from non PNNL personnel for access to records to the Records Manager, and retire records to approved record storage areas.
- All personnel shall be fair and ethical in business operations and not request or make unauthorized business disclosures.
- Research involving human subjects shall be conducted in a manner that will fully protect the subjects.

All personnel must be free of any influence, interest, or relationship that actually or potentially conflicts with the best interests of PNNL or its clients.

- All personnel shall be free of any influence, interest, or relationship that:
  - conflicts, potentially conflicts, or appears to conflict with the best interests of PNNL or its clients
  - could cause embarrassment or public criticism of PNNL
  - could interfere with personnel's ability to perform job duties

All personnel shall comply with all laws, regulations, and contractual obligations and with the conditions imposed by the will of PNNL and PNNL policy.

- All personnel shall comply with applicable PNNL policies, standards, work flows, procedures, permits, and other work instructions. Any deviation from compliance with Laboratory work flows requires a documented variance.
- All personnel shall conduct work within the facility-specific operational boundaries specified in Facility Use Agreements.
- Management system owners shall develop their management systems, standards, and work flows with appropriate input from personnel enabling them to effectively conduct work activities in compliance with applicable requirements.
- Management system owners shall base their work flows on an evaluation of external requirements documents and applicable non-government standards, e.g., orders; directives; federal, state, and local laws; and PNNL policy.

In accordance with these principles, a QA Program was developed to assure that all activities affecting the quality of data or products produced for clients are thoroughly planned and coordinated by project teams. The MSL will ensure that all data generated, processed, or used in completing each task are scientifically valid, legally defensible, and of known and acceptable quality. As part of PNNL, the MSL is committed to the corporate policy of providing quality products and services and committed to their clients to ensure that sampling and analytical procedures are properly executed, sample integrity is not compromised, all QC procedures are implemented and recorded, and only valid data is reported. To attain this goal, the MSL has implemented the QA Program summarized in this QAMP.

1.3 OVERVIEW OF PROGRAM

The MSL works to business, management and quality practices specified by PNNL under the "How Do I" (HDI) system (a web-based system of policies, forms and procedures encompassing

safety and QA). This system provides an infrastructure for performing day-to-day work, which includes QA activities. The PNNL system provides documentation of training, reminders for updating training, issuing of formal laboratory record books, a records archive, the chemical ordering and tracking system, and a system for tracking quality problems. The MSL has developed its own QA program as discussed in this QAMP to direct MSL-specific work and address client requirements. The goal is for the MSL QA Program to complement and agree with the HDI system, while meeting MSL needs.

The objective of the MSL's QA Program is to provide clients with quality products and services. A critical element in providing quality products is the maintenance of a QA Program that provides for conducting activities in a planned and controlled manner, thereby permitting the verification of quality performance. The consistent delivery of products of acceptable and documented quality requires commitment and adherence to QA and QC principles and procedures throughout the performance of each task. A commitment to quality is an integral part of every person's job. In addition, the MSL recognizes that formal functions are necessary to assure PNNL Management and its clients that the work performed and the technical products produced meet client needs and conform to their specific data quality objectives and requirements. These formal functions are QA and QC. Since PNNL consists of research and regulated analytical work, QA and QC are applied to projects on a risk based graded approach.

- QA includes all systems designed to assure management and the client that data were collected, processed, and interpreted in accordance with the requirements of the planning documents; that all aspects of work performance, including data generation and analysis are adequately documented; and that all data are accurate and fully traceable. For this system to be effective, each individual must understand his or her role in implementing the program. The responsibilities, authorities, and accountabilities with the MSL QA Program are defined in this QAMP.
- QC functions include all activities that are designed to assess or control precision and accuracy of measurements and data. QC functions involve performance of procedures necessary to attain and document the prescribed standards of performance in all measurement and data collection processes.

One of the first steps of the planning process is the development of data quality objectives (DQOs). DQOs provide the criteria needed to design a project or study (hereafter referred to as project when discussed for general purposes), and once determined, become part of the project planning documents. In addition to the objectives, the project planning documents define the methods, personnel, schedule, and deliverables associated with the project. The project planning documents may be supported by SOPs, which are detailed documents that describe the approved methods for instrument calibration, data collection, processing, reduction and reporting. Planning also involves ensuring that personnel are fully qualified and trained to perform their responsibilities and that facilities and equipment are adequate and appropriate for their use. Procurement of qualified subcontractors is also a key consideration during the project planning stage.

A major component of the work performed by the MSL involves the collection and analysis of samples for chemical, biological, and physical parameters. A sample control system is essential to ensure that the history of each sample is documented and verifiable. QC activities are implemented during the performance of the work to measure and control the quality of the product. Additional methods of quality assessment are data validation and document reviews and QA verification activities. Deficiencies noted during the assessment process are reported to

management who take the necessary remedial action to bring the system into compliance. Quality improvement processes are implemented to ensure that problems identified are solved, and do not recur.

1.4 SCOPE

The MSL comprises various technical groups. These groups provide a wide range of contract research services in support of environmental programs, primarily those related to the marine environment. The QA program defined in this document generally may be applied to any project performed by the MSL, as required by accreditations/certifications, projects, external clients and other components of PNNL.

The services and products provided by the MSL are used for a variety of purposes, including defining baseline environmental conditions, assessing environmental effects, as evidence in litigation, and as the basis for regulatory decisions. The diversity of projects demands a flexible QA program that is cost-effective, yet meets the needs of the client and the standards of the MSL. This document describes the framework of the MSL's QA Program and defines the minimum standards that apply to projects on a risk based graded approach. This QAMP is supplemented by SOPs and project planning documents (i.e., QAPPs, work plans, toxicity testing plans). SOPs provide detailed descriptions of QA activities, as well as the QC requirements for routine technical procedures. Project planning documents define the specific quality objectives for projects and describe the procedures necessary to attain those objectives.

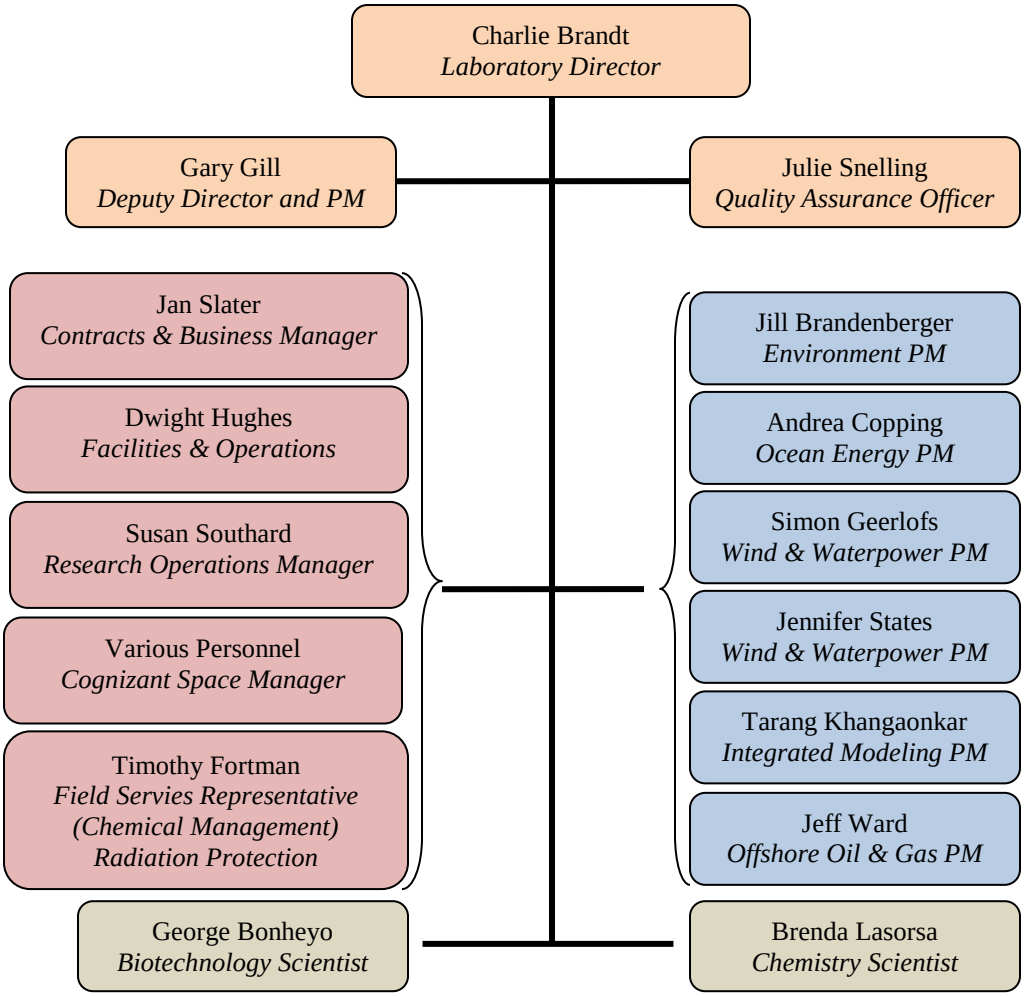
2.0 ORGANIZATION AND PERSONNEL

This section describes the organization of the MSL and defines the associated responsibilities, authorities, and accountabilities.

2.1 ORGANIZATION

QA at the MSL is an interdisciplinary line management function. The MSL's responsibility assignments are that 1) quality is achieved and maintained by those who have been assigned responsibility for performing work, and 2) quality achievement is independently verified by those not directly responsible for performing the work. The organization and Key Personnel of the MSL is illustrated in Figure 2.1.

FIGURE 2.1: Organization and Key Personnel



The Quality Assurance Officer (QAO) has the authority and organizational freedom to identify quality problems, to initiate, recommend or provide solutions, and to verify implementation. All verification activity reports are made available to line and project management. Line and project

management are responsible for identifying and assuring implementation of corrective action to all deficiencies.

Any personnel can initiate a stop work on the basis of a safety concern. In the case of a quality concern, the supervisor (which could be the Project Manager (PM), QAO, project supervisor, etc.) shall be immediately notified of the concern and then shall initiate investigative activities or initiate implementation of corrective actions. If the nature of the concern is such that the immediate manager cannot be approached, other avenues are also available for raising concerns. It is recommended that personnel seek resolution through the successive levels of management for their organization or through their Human Resource Manager. If personnel do not believe this will lead to resolution of the concern, they may go to a member of management with whom they are comfortable and trust, or any functional director.

2.2 RESPONSIBILIES

➢ Laboratory Director

The Laboratory Director provides overall management and has responsibility for all research operations.

The Laboratory Director is ultimately responsible for ensuring that appropriately qualified personnel are hired, resources for training are allocated, and that appropriate training and professional growth are provided, and records of training are maintained.

➢ Project Manager

The PM has overall responsibility for the management of project activities. Specific responsibilities include:

- Defining DQOs and QA/QC requirements for a project
- Ensuring a project work plan and QAPP or both is prepared prior to work initiation and that it meets the requirements of the client, and any applicable regulations.
- Ensuring, when applicable, that PNNL, local, state and federal notifications are given, permits obtained and standards/regulations followed.
- Administering and supervising all project tasks to ensure that all project objectives are met, on time, within budget, and of appropriate quality
- Preparing project planning documents, ensuring that the plans are reviewed and approved according to policies and ensuring that the planning documents are made available to participating project personnel.
- Assigning personnel to project tasks in accordance with their experience and skill.
- Identifying project specific personnel training needs, ensuring personnel receive necessary training to perform his/her assigned tasks and ensuring the training is documented.
- Ensuring that the project objectives are communicated to project personnel and that project personnel are trained to perform any procedures unique to the project
- Reviewing all project reports and deliverables for scientific validity (completeness, accuracy, and appropriate qualifiers)
- Addressing project-specific deficiencies that are identified during verification activities

➢ Quality Assurance Officer

The QAO provides overall direction to, and oversight of, all QA activities. The QAO is part of the Quality & Assurance Services Department and reports to the manager of that Department, located in Richland, WA. The QAO does not report to anyone at the Sequim facility and thereby maintains independence. Specific responsibilities include:

- Developing the QAMP and updating it, as needed, to reflect policies and procedures
- Assisting Project Managers (PMs), when applicable, reviewing project planning documents for conformance to relevant policies, procedures, regulations and requirements and defining QA and QC requirements and budgets at the proposal stage
- Assisting PMs in defining the QA and QC procedures to be used during a project
- Administering a training program related to QA policies and procedures
- Scheduling, planning, and conducting verification activities (assessments, data audits) of projects and facilities
- Data package QA reviews
- Preparing written reports summarizing the results of verification activities for distribution to PMs and management
- Participating in, or coordinating, inspections and audits conducted by clients and regulatory agencies
- Preparing periodic status reports of QA activities and verification results for management
- Reviewing and providing comments on the QA aspects of technical procedures, project planning documents, and reports
- Preparing SOPs of exclusive QA activities, also adding input for the quality sections of all SOPs
- Scheduling triennial SOP reviews, distributing SOPs, maintaining an SOP log, and archiving historical SOPs
- Notifying applicable management of any concerns or conditions that could impact activities or operations and stop-work when applicable.

➢ **Cognizant Space Manager (CSM)**

The CSM is responsible for providing day-to-day oversight activities of the laboratory spaces. Specific responsibilities include:

- Identifying and mitigating hazards from activities and operations in their assigned workspaces
- Conducting periodic assessments of their assigned workspaces and acting to correct any deficiencies observed
- Restricting access to their assigned workspaces when appropriate
- Notifying applicable management of any concerns or conditions that could impact activities or operations within their assigned workspaces and stop-work when applicable..

➢ **Personnel**

- Performing work in conformance with specified procedures, project planning documents and policies and procedures, including ethical and legal responsibilities.
- Notifying applicable management of any deviations to the procedures/methods specified in the planning documents or of any circumstances that could affect the quality or integrity of the data.

- Notifying applicable management of any concerns or conditions that could impact personnel safety and stop-work when applicable.
- Communicating to the appropriate manager any deviation from established procedures or issues requiring corrective action
- Defining appropriate QA requirements for purchased items and services

➢ **Contracts and Business Manager**

- Providing acquisition, contracts, and related business support that assists in meeting the strategic goals and objectives of the MSL and its clients
- Assisting personnel in ensuring that the proposal preparation process meets MSL goals
- Ensuring that QA requirements are specified in procurement documentation
- Ensuring that the proper review of requests for contracts/projects has been completed. The HDI system work flow "Project Review and Approval" describes the process in detail.

➢ **Operations Manager**

- Overseeing and implementing core Environmental Safety and Health (ES&H) support services to ensure laboratory and personnel compliance with regulations
- Ensuring and assessing that proper waste handling, safety measures, and training are being performed by and for personnel in conjunction with work performed

➢ **Environmental and Safety Engineer and Radiation Safety Officer**

- **Environmental and Safety Engineer (ESE):** Support environmental protection and safety aspects of facility services including ventilation and wastewater control systems, local exhaust systems, and drinking water systems. Maintain facility environmental and safety permits and ensure that facility environmental and safety requirements are met. Detailed responsibilities of the ESE regarding wastewater are documented in the MSL Wastewater Management Plan (EM-MSL-01), which is available on the PNNL intranet (https://wwwi.pnl.gov/emsd/em/msl/documents/EM-MSL-01.stm). Detailed responsibilities of the ESE regarding the drinking water system are documented in: Water System Management Program.

2.3 PERSONNEL QUALIFICATIONS AND EXPERIENCE

The quality of products depends, in part, on the competence and expertise of the personnel involved. The MSL will ensure that all individuals involved in the conduct or supervision of projects (including laboratory technicians, field personnel, toxicologists, analysts, data-processing personnel, supervisors, PMs and QA personnel) have the necessary education, training, and experience to perform their assigned tasks. This objective is achieved by hiring personnel with the appropriate qualifications and providing continual training and opportunities for professional growth.

Education, work experience and other applicable qualifications are documented and maintained in personnel files. The MSL home page (http://marine.pnl.gov/) provides a list of some key personnel, including a biography and education when applicable.

2.3.1 Responsibilities

The Laboratory Director is ultimately responsible for ensuring that appropriately qualified personnel are hired, resources for training are allocated, and that appropriate training and professional growth are provided, and records of training are maintained.
Each individual's supervisor is responsible for identifying specific training needs, ensuring that the personnel receives the necessary training to perform his/her assigned tasks, and assigning personnel to project tasks in accordance with their experience and skill.

Each individual is responsible for completing required training and submitting training records and certificates to their supervisor, for updating their training file as needed, and for identifying and completing additional training that may be required, but was not assigned.

2.3.2 Training

Specific training requirements are prescribed in procedure MSL-A-006, Marine Sciences Laboratory Training. Training begins the first day of service and continues throughout a personnel's term of employment. Introductory seminars on policies and organization, QA, ethical and legal responsibilities, and ES&H are presented during an orientation program. Technical training begins prior to work being performed, through reviews of procedural documents and demonstrations by experienced personnel. Introductory courses are augmented by general and project-specific training that is conducted periodically. All personnel assigned to projects receive training to acquire the necessary skills to perform their responsibilities. Technical training is accomplished through a variety of approaches, including

- Direct hands-on training. Training is accomplished by reviewing procedural documents (e.g., SOPs, project work plans), proficiency testing, and supervision by experienced personnel. Each SOP includes the training requirements associated with that procedure, including any proficiency tests.
- Project kickoff meetings. Kickoff meetings ensure that all project personnel are aware of the project objectives and the methods to be used to accomplish the objectives. This also includes field safety training at the beginning of each sampling period.
- Technical seminars. These seminars, which are available to all personnel, are conducted by PNNL personnel or guest speakers and generally cover current projects or related research programs.
- Continuous education through a tuition reimbursement program.
- Attendance at professional meetings and outside workshops.

ES&H training is monitored and provided using Integrated Operations System (IOPS) and Enterprise Learning, bot available on-line. Training includes chemical, physical, biological, radiological, and mechanical hazards.

QA training is administered by the QAO. Briefings and one-on-one training on general or project-specific topics related to QA (e.g., sample custody, data validation, and data narration) are conducted as needed. PNNL's on-line training modules are available. The personnel complete the training activity and print a training completion form that must be signed and submitted to the training department to obtain credit. The signed form is evidence that the personnel has read; acknowledges, and understands their personal QA responsibilities.

2.3.3 Documentation

Records of training and qualifications include the following:

- PNNL Integrated Operations System (IOPS) training
- PNNL Enterprise Learning training
- MSL specific training assignments
- Certificates attesting to the attendance or completion of external courses
- Resumes and biographies

Records of training and qualifications are maintained in personnel files at the MSL, the PNNL on-line computer training system, the MSL home page (http://marine.pnl.gov/), or the intranet. These files are secure with limited approved access, when applicable.

2.3.4 Improper, Unethical or Illegal Actions

Training courses in ethical and legal responsibilities including the potential punishments and penalties for violations are provided initially and annually thereafter via on-line computer training. The applicable annual refresher course number and title is 002351, “PNNL Refresher Training”. Topic areas include Business Ethics, Electronic Time Reporting, Human Resources, Property Management, Sustainability and Operational Excellence, Safety and Health, Emergency Preparedness, Safeguards and Security, and Unclassified Cyber Security. Upon completion of the course, a form is signed (manually or electronically) to obtain credit. The signed form is acknowledgement that the personnel have read and understand their personal and legal responsibilities including potential punishments and penalties for violations.

3.0 FACILITIES AND EQUIPMENT

The MSL, located in Sequim, Washington, is part of the Pacific Northwest National Laboratory (PNNL). The PNNL is operated by Battelle Memorial Institute, Pacific Northwest Division for the Department of Energy (DOE). Battelle Memorial Institute is a non-profit research and development organization.

The MSL campus is on 140 acres fronting Sequim Bay in the Salish Sea, near Puget Sound, making an excellent location for marine based research. The MSL campus consists of two separate areas; the beach area and the upland area. In addition to general office space, the MSL consists of:

- Over 8,000 square feet of general purpose laboratory space
- Over 6,000 square feet of wet laboratory space
- A research dock and outdoor experimental tanks
- State-of-the-art water supply and treatment system
- Research boats and scientific divers

The MSL supports various researchers, scientists and support personnel, including university students, graduates and post docs.

3.1 WET LABORATORIES

Two wet laboratories provide over 6000 square feet of space for studies requiring flowing freshwater, filtered seawater, and raw seawater through several separate distribution systems. High quality, Class AA seawater is obtained from Sequim Bay through an all- Polyvinyl Chloride (PVC) system with two independent intakes. A redundant system of various pumps provides a continuous supply of filtered and unfiltered seawater to experimental tanks. An emergency diesel generator ensures continuous seawater supply and other essential services in the event of electrical failure. A 14,000-gal reserve tank provides filtered seawater to the laboratories for up to 18 hours (dependent on flow rates required) in the event of failure of all three pumps. Raw seawater at ambient temperature (9-11°C) can be provided at a rate of 250 GPM, and up to 20 GPM of filtered seawater or freshwater can be supplied at various temperatures.

Holding and breeding facilities for a variety of fish, shellfish, and freshwater, estuarine, and marine plants are provided in these laboratories and in outdoor tanks. All water used in testing is passed through a regulated treatment system to ensure no impact is made on the receiving environment.

Two isolation rooms within one of the wet labs provide the capability to isolate pathogens. The isolation rooms share a common waste sump and pumping system and disinfection system on the discharge to the main water treatment system.

3.2 GENERAL PURPOSE LABORATORIES

➢ Beach Facility

General purpose laboratories in the Beach facility consist of chemistry and bioassay laboratories and support rooms (e.g., wash rooms, preparation labs, and microscopy labs).

➢ Upland Facility

General laboratories in the Upland facility consist of ten fully-equipped chemistry laboratories, including a Class-100 Clean Laboratory Facility, each occupying 600 ft^2. The chemistry laboratories are equipped with an array of instrumentation, support equipment and supplies.

Specific styles of clean rooms include: Ultra Trace Hg and Methyl Hg clean rooms for preparing sampling equipment; trace metals grade supplies are stored in clean rooms. The MSL contains a general organic chemistry laboratory for preparation of sample extracts for gas chromatography and mass spectroscopy, and analysis for physical properties of sediment. A high performance liquid chromatography (HPLC) system, with variable wavelength Ultraviolet (UV) light detector, fluorescence detector, auto injector, fraction collector, integrator, and data reduction system is available for specialized sample preparation.

The Upland facility is also equipped with secure sample login, sample holding/acclimation, sample staging/preparation/digestion/extraction. It has the capacity and ergonomic set up to address the specific style of testing to be accomplished. Equipment cleaning stations necessary to provide the level of cleanliness required to support the data generated are also housed in the Uplands facility.

3.3 COMPUTER FACILITIES

Personnel use Windows and Macintosh based computer systems connected via a local area network. The systems are linked to other on- and offsite hardware composed of workstations and servers, minicomputers, database and file repositories, Web servers, and supercomputer facilities.

The MSL has access to the numerous electronic resources available through Hanford Technical Library Services. Commercial databases such as BIOSIS, Chemical Abstracts, Oceanic Abstracts, Enviroline, Aquatic Sciences and Fisheries Abstracts, Pollution and Toxicology Abstracts, and many others can all be accessed quickly by computer. The Hanford Technical Library also provides links to other Department of Energy Laboratory libraries and electronic resources. Through such access to information, literature searches can be conducted efficiently.

3.4 SAFETY AND SECURITY

The safety of personnel is of paramount importance. Therefore, the buildings are equipped with surveillance cameras and structural safety features (e.g., fire doors and extinguishers, emergency lighting systems), alarm systems which serve to alert the personnel in the event of emergencies (e.g., fire/smoke alarm), and engineering controls designed to minimize exposure to potential hazards (e.g., fume hoods).

The security of the facility is an important consideration because of the type of work performed by the MSL. Access to the MSL grounds and buildings is controlled through a card-access and lock and key system. During business hours, all visitors must enter through the main lobby and sign in with the receptionist. Selected areas within the facility are secured at all times and their access limited to authorized personnel. Such areas include the walk-in cold room used for sample storage, the records storage area, the solvent shed, and the data archives. The HDI system work flow “Access and Protection Requirements at Battelle Facilities” describes the process in detail.

Computer security is a function of the PNNL network and is administered from facilities located in Richland, WA. Personnel have individual responsibility to back up files, instruments and data bases at regularly scheduled intervals which are prescribed in procedure MSL-D-004, Data Reporting, Reduction, Back Up, and Archiving.

4.0 PROCUREMENT AND CONTROL

4.1 MATERIAL PROCUREMENT AND CONTROL

Examples of items that generally have a significant influence on the quality of work, and therefore generally need defined quality requirements are the following:

- Standards and reference materials
- Reagents, chemicals and solutions
- Animals and feed
- Computer software and hardware, and
- Some miscellaneous items such as designed equipment

Procurement activities are prescribed in procedure MSL-A-012, Procurement and the HDI system work flow “Procurement” which should be consulted to determine appropriate QA requirements before initiating procurement actions.

4.1.1 Miscellaneous Procurements

Miscellaneous procurements of items that have a significant influence on the quality of work generally need defined quality requirements. When the purchaser does not know if quality requirements should be specified, the practice is to request the QAO or representative to make this determination and document it as a note, letter or email.

4.1.2 Material Receiving Inspection

When materials are ordered that require certification (i.e., standard or certified reference materials (SRMs, CRMs), standards, pre-cleaned sample containers, etc.), a request for certifications shall be made on the purchase order. Standards and reference materials must be traceable to the National Institute of Standards and Technology (NIST) or other nationally-recognized standard (e.g., American Society for Testing Materials [ASTM]). The traceability must be documented by a certificate or label that verifies this link. The traceability documentation must be received and found to be acceptable before material use. Acceptance of these items and certifications shall consist of verifying that the lot numbers on the certifications and the jar and/or boxes are the same. Approval shall be indicated by a signature and date of signature on the certificate. Pending receipt of this documentation and its acceptance, affected material must be segregated to prevent inadvertent use. Certifications received will be maintained by the QAO or in the Project files.

4.1.3 Reagent and Standard Inventory Procedures

The procurement of reagents, chemicals and solutions should include requirements for shipping stocked inventory materials with the longest period to the expiration date (i.e., the freshest material) possible, with lot numbers specified. In some cases where extremely high purity material is requested, a request for purity documentation may be necessary.

Procurement procedures should require that a manufacturer's recommended expiration date is provided with every standard material. If manufacturer's expiration dates are not provided, the laboratory must assign an appropriate expiration date in accordance with procedure MSL-A-008, Control of Standards, Reagents, Solutions, Test/Control Articles and Specimens.

The MSL follows the PNNL HDI system requirements for logging in reagents, chemicals and solutions into the associated Chemical Management System (CMS). This system provides policies and procedures regarding tracking and inventory and storage of samples as well as chemical use and disposal. The CMS is used to provide an up-to-date inventory to facilitate emergency response, monitor the location of various classes of materials and identify situations where acceptable limits for the building/facility determined by the assigned chemical hazard group and fire zone might be exceeded before a violation occurs. An assigned Sample Inventory Coordinator provides bar codes for each tracked chemical items when it is received and assigns it to a location. The item then is tracked in the CMS until disposal. The system is also used to ensure that facility limits based on the chemical hazard group and the assigned fire zone determination are not exceeded.

Personnel are required to document when chemicals are received and expiration dates as prescribed in procedure MSL-A-008, Control of Standards, Reagents, Solutions, Test/Control Articles, and Specimens.

4.1.4 Organisms and Feed

The procurement of organisms and feed for bioassays should include requirements for chain of custody of animals during shipping and documentation of any available feed analyses, feed storage recommendations, and expiration dates so that feed quality can be monitored, as prescribed in procedure MSL-A-017, MSL Requirements for Care of Fish. Animal shippers should be requested to document conditions of animals and environmental parameters (temperature) at the time of shipping for comparison with conditions encountered at the time of receipt. In some cases, it might be important to include QA requirements for a minimum/maximum thermometer or temperature strip in the cooler at the time of shipping. Requirements regarding common carriers, Saturday delivery acceptability and locations, and other details might also be specified in QA requirements documents.

4.1.5 Computer Software and Hardware

Software and hardware is procured in accordance with the PNNL HDI system procurement requirements are maintained under the PNNL Managed Hardware Program. In general, QA requirements for the procurement of software should consider the following guidelines:

- Commercial software that has been developed under the manufacturer's QA Program and fully tested before release is preferable to other types of software developed under lesser or no QA Program
- Documents necessary to demonstrate that software was developed using a Life Cycle approach such as User's Manuals shall be requested when software is ordered.
- Licenses that come with the software and original documentation should be requested, obtained and protected.
- Software that requires a signed site license agreement can only be purchased by individuals with appropriate authority.
- Hardware/Software that exceeds the most recent established PNNL monetary limit can only be purchased with appropriate management approvals.
- Software procured as a product under a subcontract must specify detailed QA requirements for software development and use, and provide plans for testing, verification and validation tests and include acceptance criteria.

4.1.6 Solvent Storage Policies

Solvents used in the laboratory are in containers of 20 liters or less. On receipt they are logged in, bar-coded, and tracked, as are all chemicals. No more than a working day's supply of flammable or combustible solvents is permitted out of flammable storage in a laboratory; at the end of the day, these materials must be returned to flammable storage. Large flammable storage cabinets, located in an area separate from the building, are used for storage of solvents that exceed the lab's storage capacity.

4.1.7 Waste Disposal

Hazardous wastes are managed in accordance with Washington State Department of Ecology's (WA-DOE's) Chapter 173-303 WAC, "Dangerous Waste Regulations." The MSL is a "less than 90-day storage" facility and a large-quantity generator and, as such, fulfills all the requirements outlined in the regulation regarding proper labeling, designating, inspections, and timely disposal of hazardous waste. Personnel that generate/handle waste are initially trained in waste management procedures and updated annually of new regulations and requirements. Procedure MSL-A-015, Waste Management and Pollution Prevention, describes the waste streams and their disposal.

4.2 SUBCONTRACTORS

The MSL does not routinely subcontract analyses that can be performed in-house, but in some situations this could occur. The MSL could also subcontract project analyses when there is a project-specific requirement. The MSL is ultimately responsible for the quality of work performed by its subcontractors. Therefore, procedures have been established to ensure that subcontractors determined to have applicable associated risks are qualified to perform their responsibilities, know the project objectives, methods, and responsibilities, and the work performed is monitored to assess conformance to the project specifications.

Whenever work is to be subcontracted to others, the MSL should advise clients of this intent and obtain their permission for this approach. For projects requiring TNI certification, documented permission from the client is required and work may be subcontracted only to TNI-certified laboratories for the specific analysis and matrix of interest or it will be pre-approved and identified in a report or in the project contract that a non-TNI laboratory was used.

In addition to the requirements prescribed in HDI work flow “Acquire Product or Service via Purchase Order-Subcontract”, it is expected that all policies, procedures, and responsibilities required by the project are flowed down to the subcontractor and verified accordingly.

PNNL provides Evaluated Supplier Options which can be used as a starting point to define subcontractors. If the subcontractor does not meet any of the evaluated supplier options, then whenever it is deemed appropriate on a risk based graded approach, an audit of subcontractor may be performed. The audit may include review of the subcontractors QA program, data audits, inspection of facilities, or inspection of project activities. The contract should include a SOW in sufficient detail so that the scope of work, methods, QA requirements, responsibilities, deliverables, and due date are clearly understood between the MSL and the subcontractor.

5.0 PROJECT PLANNING DOCUMENTS

5.1 CONTENT AND FORMAT

5.1.1 General

Project planning documents (e.g., work plans, QAPP, toxicity testing plans, field sampling plans and SOWs) are documents that describe the objectives of a project and the methods, organization, and QA and QC activities necessary to meet the goals of the project. Each project conducted by the MSL must have a planning document that adequately describes the work to be performed, has been approved by the PM, and is in place prior to the start of work.

When applicable, in the absence of client-driven requirements, the following information should be identified in project planning documents:

- A descriptive title, client name, PNNL project number, and effective date;
- The identities of the PM, task leaders, and other key project personnel, including subcontractors;
- A statement of the general goals and the specific DQOs of the project;
- A description of the experimental design and procedures;
- A description of the QA and QC procedures (including DQO's) that will be applied to the project tasks;
- The project schedule, including milestones and deliverables;
- A description of the types of data to be recorded; and
- A statement of deliverable requirements.

5.1.2 Environmental Protection Agency

When work is conducted for the U.S. EPA, it is required that all environmental data-collection activities be covered by a QAPP. Therefore, all project planning documents prepared for the EPA must adhere to specific content and format requirements, as dictated by the EPA office involved. Protocols written for studies conducted under Food and Drug Administration (FDA) or EPA Good Laboratory Practices (GLP) standards must adhere to the specifications of 21 Code of Federal Regulations (CFR) Part 58 (FDA), 40 CFR Part 160 (EPA/ Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA]), or 40 CFR Part 792 (EPA/Toxic Substances Control Act (TSCA), as applicable.

5.2 APPROVAL AND DISTRIBUTION

All planning documents shall be approved by the PM, at a minimum, before work is started on the project.

The project planning document is distributed, or made available to, all personnel involved in the project and to the QAO. It is expected that all work will be conducted according to the planning documents. Modifications to approved planning document procedures should be made only with the concurrence of the PM and client, when applicable.

5.3 DATA QUALITY OBJECTIVES

DQOs are defined as the criteria needed to design an environmental data collection program. DQOs are developed from a multi-step, reiterative process that involves, project management, technical personnel, and the individuals who will be using the data to make decisions. The DQO process may entail the following:

- Stating the problem to be resolved, including limitations of time and resources;
- Identifying the decision that will be made using the data;
- Identifying inputs to the decision, including the environmental measurements needed and the criteria for taking action;
- Specifying how the results will be summarized and used; and
- Specifying acceptable error rates (i.e., limits on uncertainty).

The objective of the DQO development process is to design a cost-effective program that will provide the necessary amount and type of sufficient-quality data.

Once the acceptable error rate has been defined, the program's QA requirements are developed. The specific types of QC samples used to measure data quality are discussed in later in this QAMP.

The QC measurements and acceptance criteria are outlined in SOPs or project planning documents. The precision and accuracy objectives specified are based on standard method performance information (when available) and historical laboratory performance but may change based on project specific criteria. When required by the client or PM, other QC checks for accuracy, precision, comparability and completeness shall be applied to each batch of samples.

During the development of DQOs, the *PARCCS* parameters of precision, accuracy, representativeness, comparability, completeness and sensitivity are commonly considered when measuring data quality. These qualitative and quantitative parameters are described below.

5.3.1 Precision

Precision measures the similarity of individual measurements of the same property, usually under prescribed similar conditions.

Measures of analytical precision may be determined by the analysis of laboratory replicates or matrix spike/matrix spike duplicate recoveries. Laboratory replicates will be prepared by homogenizing and splitting a sample in the laboratory, and carrying the sub-samples through the entire analytical process. Precision can be expressed in terms of relative percent difference (RPD) or relative standard deviation (RSD).

For replicates where duplicates are performed, RPD will be used:

$$RPD = \left(\frac{ABS(C_1 - C_2)}{Average(C_1 : C_2)} \right) * 100$$

ABS = Absolute Value

For replicates where triplicates or more are performed, RSD or CV (coefficient of variation) will be used:

$RSD = \sqrt{\left(\frac{\sum(x-\bar{x})^2}{(n-1)}\right)} * 100$	$CV = \sqrt{\left(\frac{\sum(x-\bar{x})^2}{(n-1)}\right)} * 100$

$\bar{x}$ = Sample mean AVERAGE(number1,number2,…)
n = Sample size

5.3.2 Accuracy

Accuracy is a measure of the bias of a system or measurement. It is the closeness of agreement between an observed value and an accepted value.

Accuracy of chemical analysis may be determined [for each matrix of interest (sediment, tissue and seawater)] through the analysis of laboratory control samples, matrix spikes, method blanks, SRMs (when applicable) and surrogate internal standards (organic analyses only).

- **Blank Spike (BS)/Laboratory Control Sample (LCS)** - an aliquot of clean matrix (e.g. reagent water) to which known concentrations are added and prepared, treated and analyzed in the same manner as the associated samples. Its purpose is to determine whether the method is within accepted control limits.
- **Matrix Spike (MS)/Matrix Spike Duplicate (MSD)** - an aliquot of a sample to which known concentrations are added and treated and analyzed in the same manner as the associated samples. Its purpose is to determine whether the sample matrix contributes bias to the results**.**
- **Method Blank (MB)** - an aliquot of clean matrix (e.g. reagent water) prepared, treated and analyzed in the same manner as the associated samples. Its purpose is to determine if method concentrations or interferences are present in the laboratory environment, the reagents, or the apparatus' used that could contribute bias to the results**.**
- **StandardReference Material (SRM)** - a material obtained from an independent source, is certified to a known concentration by a recognized authority (e.g., NIST) and is treated and analyzed in the same manner as the associated samples. Its purpose is to determine whether the method is within accepted control limits.
- **Surrogate Standard** - an analyte which is similar to the target analyte(s) in chemical composition and behavior in the analytical process, but which is not normally found in the samples. The surrogate is spiked in the sample prior to extraction. The recovery of surrogate is used to quantify extraction efficiency and monitor method performance.

For measurements where matrix spikes or laboratory control samples are used, percent recovery will be used to assess accuracy:

$\%R = \left(\frac{S-U}{C_{sa}}\right) * 100$	%R = percent recovery S = measured concentration in spiked aliquot U = measured concentration in un-spiked aliquot C_{sa} = actual concentration of spike added

For situations where a SRM is used, percent difference or percent recovery will be used:

$PD = \left(\frac{C_1 - C_2}{C_2} \right) * 100$	PD = percent difference C_1 = measured value C_2 = certified or consensus value	$\%R = \left(\frac{C_1}{C_2} \right) * 100$	%R = percent recovery C_1 = measured value C_2 = certified or consensus value

5.3.3 Representativeness

Representativeness expresses the degree to which data accurately and precisely represents a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition.

Representativeness will be addressed primarily by the proper handling and storage of samples and analysis within the specified holding times so that the material analyzed reflects the material collected as accurately as possible. Representativeness of data will be discussed, when appropriate, in deliverable reports.

5.3.4 Comparability

Comparability expresses the confidence with which one data set can be compared to another. Comparability will not be quantified, but will be addressed through the use of laboratory methods that are based on EPA or other recognized methods. The use of standard reporting units also will facilitate comparability with other data sets. Comparability of other data will be discussed, when appropriate, in deliverable reports.

5.3.5 Completeness

Completeness is a measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under normal conditions. Target completeness values are 100% for chemical sample analysis.

5.3.6 Sensitivity

Sensitivity is the capability of methodology or instrumentation to discriminate among measurement responses for quantitative difference of a parameter of interest.

6.0 STANDARD OPERATING PROCEDURES

Many routine analytical laboratory activities are directed and controlled by internal procedures or by published procedures. Where possible, U.S. EPA and consensus methods (e.g., National Oceanic and Atmospheric Administration (NOAA) Status and Trends) are used where the technique is applicable to the sample matrix and the overall objective of the analysis.

A list of SOPs is available on the intranet or upon request. The QAO maintains and updates the list of controlled documents.

6.1 SCOPE AND PURPOSE

The MSL encourages the preparation of SOPs for routine environmental measurement and analyses and related QA and QC activities. Research and development activities that are not routine, or are unique to a project, can be described in project planning documents such as work plans or in written protocols included in the project files. Subjects that are covered in SOPs include, but are not limited to:

- Sample collection
- Sample handling, preservation, and storage
- Chain of Custody (CoC) procedures
- Digestion and sample preparation
- Sample analysis
- Equipment use, maintenance, and calibration
- Record management
- Data reduction, processing, and validation
- QA verification activities

SOPs are documents that describe procedures that must be followed to ensure the integrity and quality of data. SOPs serve a multi-purpose function, including to

- Reduce the introduction of errors and variables by ensuring the consistent use of appropriate procedures
- Communicate to the necessary people (e.g., client, project personnel) how the work will be conducted, and provide a basis for training
- Increase the effectiveness of training by clearly and consistently communicating the approved method of performing a procedure
- Provide a historical record of the work performed
- Provide a basis for data comparability
- Provide a basis for maintaining reproducible results and producing defensible data

6.2 CONTENT AND FORMAT

Each SOP must be clearly written and include sufficient detail to clearly describe the operation to be carried out so that a qualified individual can perform the procedure. However, it should be flexible enough to accommodate expected variations while maintaining the integrity of the procedure and the quality of the data being generated. SOPs covering equipment must include descriptions of calibration, operation, and maintenance requirements. Procedural SOPs must contain sections on preparation, procedures, calculations, and quality control. Equipment and

procedural SOPs must also include a discussion of the safety concerns associated with the equipment or procedure. All SOPs must state the objective or application of the SOP topic and must stipulate the requirements for the successful completion of training. Specific requirements for content and format are prescribed in procedure MSL-A-003, Guideline's for SOP Format and Control.

6.3 RESPONSIBILITIES

The individual preparing the SOP is responsible for ensuring that the SOP completely and accurately describes the procedures, is based on sound scientific principles or recognized procedures, and conforms to the standards for procedure documentation prescribed in procedure MSL-A-003, Guidelines for SOP Format and Control.

The QAO is responsible for

- Assigning each SOP a unique number and entering it into the SOP controlled document log
- Reviewing all SOPs
- Distributing approved SOPs, including posting to the intranet
- Maintaining historical files of SOPs

6.4 REVIEWS AND APPROVALS

Draft SOPs go through a formal review and approval process in accordance with SOP MSL-A-003, Guidelines for SOP Format and Control.

6.5 DISTRIBUTION AND CONTROL

The official controlled copies of SOPs are the versions maintained in the SOP file on the intranet and are readily available to all personnel. All other copies (printed or saved in personal electronic files) are considered uncontrolled. All PNNL personnel have signed non-disclosure documents and are trained in the sensitive nature of these documents.

6.6 MODIFICATION AND REVISION

Changes to SOPs must be controlled to ensure documentation and traceability to the modification. SOP modifications will be performed in accordance with SOP MSL-A-003, Guidelines for SOP Format and Control.

7.0 LABORATORY DOCUMENTATION AND RECORDS

A critical component in the generation quality products is proper record keeping and the maintenance of the records after project completion. Documentation must be sufficiently detailed so that the data are traceable and program data can be reconstructed based on the project records. These records must be maintained in a secure location and must be identifiable and retrievable. Should the MSL be unable to retain or maintain documents for any reason (e.g., if the laboratory transfers ownership or goes out of business) all records will be transferred to the PNNL Richland, WA archive system.

7.1 DOCUMENTATION

Data generated during the course of a project must be capable of withstanding challenges to its validity, accuracy, legibility and traceability. To meet this objective, data are recorded in standardized formats and in accordance with prescribed SOPs. All personnel whose responsibilities include recording data must be aware of, and adhere to, the SOPs during the performance of their work. Briefly, data must be entered onto data sheets or in project notebooks directly, promptly, and legibly. All entries must be made in indelible ink, and must be accompanied with the date and initials or signature of the individual making the entry. In some instances (e.g. divers writing underwater or fieldworkers writing in the rain on Rite-in-the-Rain paper), pencil may be used. Changes or corrections to data must not obliterate the original entry, but must be indicated with a single line through the original entry. All changes or corrections must be accompanied by the date and initials or signature of the individual making the change and, when not obvious, an explanation of the change. Specific requirements for documentation are prescribed in procedures MSL-D-001, Recording Data on Data Sheets and Laboratory Notebooks and MSL-D-004, Data Reporting, Reduction, Backup, and Archiving.

7.2 RECORDS

The data archive system is designed to ensure that materials are stored in an orderly manner under secure conditions, and may be easily and promptly retrieved should the need arise. Data archiving requirements and prescribed in procedures MSL-D-003, Archiving of Records, Data, and Retired SOPs and MSL-D-004, Data Reporting, Reduction, Backup, and Archiving.

All material generated during a project should be archived upon completion of the project. All records necessary for the interpretation and evaluation of project data, including planning documents, raw data and other documentation, correspondence, and reports, should be retained. The PM is responsible for ensuring the project materials are collected, organized, and forwarded to the archives at the end of the project. PNNL policy is to retain electronic data files for five years, unless otherwise specified by client request. Hard copy data are stored as prescribed in procedure MSL-D-003, Archiving of Records, Data, and Retired SOPs. Archives are controlled access (locked) storage rooms at the MSL or in Richland, WA. Data are stored and retrieved by project number or central file number.

8.0 SAMPLE HANDLING, TRACKING AND DISPOSITION

Sample handling and tracking requirements are prescribed in procedures MSL-A-001, Sample Log-In Procedure and MSL-A-002, Sample Chain-Of-Custody, and MSL-E-001, Marine Resources Field Operations and Fish Research. The processing of data collected from these activities is prescribed in procedure MSL-D-004, Data Reporting, Reduction, Backup, and Archiving (Archiving may be superseded by client requirements).

8.1 RECORDS

Sample custody responsibilities must be clearly defined and understood by all personnel involved for the system to be effective. Samples are considered to be in a person's custody if:

- The samples are in a person's actual possession
- The samples are in a person's view after being in that person's possession
- The samples were in a person's possession and then were locked or sealed to prevent tampering
- The samples are in a secure area

The sample collector is responsible for the proper collection, preservation, and labeling of samples, and for documentation of sample history and custody in the field. The sample collector also is responsible for packaging the samples for shipment, maintaining sample integrity, and for arranging for transportation to the laboratory.

The sample custodian is responsible for receiving and inventorying the samples, placing them in storage, and completing the documentation associated with these procedures. The laboratory sample custodian also is responsible for informing the PM of the samples' arrival and for promptly notifying him/her of any broken, missing, or compromised samples.

8.1.1 General (Non-TNI) Samples

8.1.1.1 Chain of Custody Not required

Samples may not always require a formal log-in and/or Chain of Custody. This may occur when the samples will be returned immediately to the place it was collected, retained by the researcher, or disposed of without having previously left the custody of the researcher. Examples include:

1. While working in the field, fish are collected in beach seines, identified to species, measured, and returned to the water. Data are recorded on data forms and include the date of collection and initials of the recorder. A formal CoC is not completed for the fish sampled.
2. Eelgrass plants are collected offsite during a field project and returned to the MSL. The number of coolers containing eelgrass and being transported to the laboratory is recorded on a field data form or notebook, but a formal CoC is not completed. The exact number of plants harvested is not recorded until the plants are transplanted at the laboratory, to minimize handling of the plants. The number of plants that are transplanted is recorded in the field notebook and subsequent counts of eelgrass shoots in the tank are also recorded to document population changes over time. Each data entry includes the date and initials of the recorder.

3. Eelgrass plants are marked and later harvested from the MSL beach. A record of the location and number of plants sampled is recorded along with the date, recorder's initials and other pertinent information; however a formal CoC is not prepared. The plants are processed and dry weights are obtained to determine the plant's productivity. After the measurements are taken, the plant material is disposed of.

In these circumstances, samples are received and custody is maintained/documented according to the project planning documents.

8.1.1.2 Chain of Custody Required

When chain of custody is required, the MSL documents all sample fates for the client based on objective evidence maintained during the sample processing. Objective evidence will be defined as all information necessary to produce unequivocal, accurate records that document the applicable laboratory activities (including signatures of individuals who physically handle individual samples), accounting for all time periods associated with sample receipt, processing, analysis and storage and disposal.

In accordance with procedure MSL-A-001, Sample Chain of Custody, the PM is responsible to determine which items are required and to ensure that all relevant items are addressed because different programs have different requirements and to assist in project planning.

For test organisims, in place of a CoC a shipping form can be signed and dated and the condition of organism noted. Sample control is the formal system designed to provide sufficient information to reconstruct the history of each sample. This system involves procedural, record keeping and organizational components and is critical for any environmental program that is generating data that may be used for regulatory decisions or in support of litigation.

8.1.2 TNI Samples

Samples to be analyzed under TNI requirements require a formal log-in and Chain of Custody. Login is performed and documented in accordance with procedure MSL-A-001, Sample Log-in Procedure.

8.2 LOGIN

When samples are received from an outside source, they are logged in when received in the shipping area. If a CoC form accompanies the samples, it may used to document the date and time of sample receipt and condition; if not an internal CoC may be initiated. The sample labels are compared to the CoC and, when applicable, assigned an identification code plus sequential numbering of samples upon arrival. Sample containers are inspected for sample integrity (e.g., broken seals, broken or cracked containers, spilled samples and sample temperature). Any discrepancies identified during the process are brought to the attention of the PM who is responsible for contacting the client, when applicable.

8.2.1 Preservation

When sample preservation (e.g. temperature or pH) is indicated by the type of analysis or client specification, preservation is checked and adjusted, when applicable, in accordance with procedure MSL-A-001, Sample Log-in Procedure and/or project documents.

If the samples are not immediately required for use, they are stored under the appropriate conditions in a controlled or secure area.

8.3 SAMPLE TRACKING

Sample tracking while samples are in the laboratory is the responsibility of the individual Laboratory Supervisors and the PM. It is the responsibility of the PM to ensure that the levels of sample custody and tracking needed are specified, samples are given the appropriate priority in the laboratory, and the proper storage, analyses/tests and methods are being performed.

When living organisms are collected, the number of specimens collected is kept to the minimum the investigator determines is necessary to accomplish project goals. If vertebrate species will be collected, handled, or housed during a study, an Animal Care Committee Protocol is submitted to the Institutional Animal Care and Use Committee for review and approval prior to receiving the animals or conducting the research. It is the responsibility of the PM to ensure that sample collection, handling, storage, and/or testing are performed properly.

8.4 SAMPLE ARCHIVING AND DISPOSITION

The PM is responsible for proper disposal of residual sample material (not all samples will have residual left over for disposal). Sample disposition takes three forms: 1) dispose by appropriate means depending on sample content; 2) return to client; or 3) archive for a pre-determined amount of time. Unless arrangements have been made previously, the samples are generally disposed of by the laboratory.

8.4.1 Samples disposed of by a subcontractor laboratory

If the subcontractor laboratory or testing facility is responsible for disposing of the samples, the subcontractor is asked to notify the PM before final disposition. The PM will notify the originator that the samples are scheduled to be destroyed, or will define client requirements for an extended period of storage.

After destruction of samples, the subcontractor laboratory or testing facility is asked to return a copy of the CoC to the PM for placement in project files. The originator may be forwarded a copy of the final Chain-of Custody documentation if requested.

The PM or representative records the date of receipt on the CoC in the "Received by" section of the form space and indicates the samples were destroyed ending the chain of possession.

8.4.2 Samples disposed of by the MSL

For returned samples (should be received with CoCs) or samples that have never left MSL custody, the PM or representative will notify the originator that the samples are scheduled to be destroyed, or will define client requirements for an extended period of storage. If extended storage is not requested, the PM is responsible to ensure samples are disposed in accordance with procedure MSL-A-015, Waste Management and Pollution Prevention.

8.4.3 Samples returned to the client for disposal

Samples may be returned to the client (or the sampling site) by client request. Samples are shipped to meet Department of Transportation regulations. Generally, the samples are shipped in the same way that they were initially shipped to the MSL. Sample disposition should be documented in the central file of each project. The PM shall ensure that completed CoC are filed in the appropriate project files. The originator may be forwarded a copy of the final CoC documentation if requested.

9.0 QUALITY CONTROL

Technical personnel perform QC activities during the conduct of the project. The purpose of these functions is to measure the quality of the data and if necessary, adjust the measurement system so that the specified level of quality is attained.

9.1 GENERAL

9.1.1 Toxicity Testing and Biological Studies

For toxicity testing, each test has its own quality control criteria that are included as part of the test design established in project planning documents. Reference toxicant tests (positive controls), are performed to demonstrate that test organisms used are appropriately sensitive and that the laboratory procedures and techniques are appropriate and repeatable. A reference toxicant test is normally performed with each test, or at a minimum, once with each batch of test organisms as prescribed a procedure (e.g. MSL-T-034, Reference Toxicant Stock Solution Preparation) or project planning documents. It is the responsibility of the PM to ensure the reference toxicant database and control chart(s) are up to date with each set of test results. Each test method contains specific test acceptability criteria for controls, reference toxicant results, test conditions, etc. An individual test may be conditionally acceptable if temperature, Dissolved Oxygen (DO), or other specified conditions fall outside specifications, depending on the degree of the departure from the specified conditions and the overall impact on the test. The acceptability of the test will depend on the professional judgment of the PM or designee. Any deviation from test specifications must be noted when reporting data.

Quality control in biological studies encompasses a wide range of activities such as species identification, organism counts or density estimates, and data entry. QC activities measure the quality of the data and if necessary, adjust the measurement system so that the specified level of quality is attained. For example:

1. Fish species are often identified by two researchers and through consultation of a region-appropriate taxonomic key or guide for reference. This provides a more objective approach to species identification, especially the first time a new species is encountered or the first time a researcher performs species identification.
2. Plants and other resources are often described by the percent of open space they cover within a standardized area (e.g., 1-25%, 26-50%, 51-75%, or 76-100% cover). At the beginning of a field sampling period, researchers may standardize their estimates of percent cover by individually examining several examples of percent cover and comparing their estimates. If the estimates vary, the researchers work together until they can agree on their cover estimates before collecting actual project data individually. Periodic reassessments of standardization between researchers increases the quality of the data.

9.1.2 TNI Analyses

For analyses performed under the TNI standard, work shall be performed in accordance with approved SOPs.

9.2 LIMITS OF DETECTION

Method detection limits (MDLs) are determined for all parameters for a number of different matrices (fresh water collected from the in-house de-ionized water system, filtered seawater from Sequim Bay, Sequim Bay or other clean sediment, chicken tissue, etc.). The method used to determine MDLs is prescribed in procedure MSL-Q-007, Procedure for Determining Method Detection Limits. Limits of quantization may also be reported on request as more conservative estimates of detection limits. MDLs and their determination documentation are available on the intranet or upon request.

9.3 HOLDING TIMES AND PRESERVATION

Holding times typically begin with the day of sample collection. However, holding times can be assessed from both the date of sample collection and the date of sample receipt, depending on project planning documents. In the absence of client-specified holding times, the holding times and requirements provided in Tables 9.3.1 and 9.3.2 are used.

When samples require preservation at the MSL, a holding period before analysis may apply. Holding periods are prescribed in the applicable analytical procedures.

TABLE 9.3.1: Chemistry Sample Holding Times and Preservation

	Analysis	Preservation	Holding Time (Days)
Sediment*	Metals (including Hg)	freeze dried; 4±2°C, or -20±10°C	180[(b)]
	Methylmercury	±2°C, or -20±10°C	180[(d)]
	Organic Compounds	4±2°C, or -20±10°C	30[(b)] extraction; 40 analysis [c]
Tissue*	Metals (including Hg)	freeze dried; 4±2°C, or -20±10°C	180[(b)]
	Methylmercury	4±2°C, or -20±10°C, the freeze dry	180 [(d)]
	Organic Compounds	4±2°C, or -20±10°C	30[(b)] extraction; 40 analysis [c]
Water	Metals (except Hg)	4±2°C in transit, then <2 pH/HNO_3 and ambient	180
	Mercury	4±2°C in transit, then <2 pH/HCl and ambient	90
	Methylmercury	4±2°C in transit, then <2 pH/HCl and ambient	180
	Organic Compounds	4±2°C	7 extraction; 40 to analysis [c]

[(a)] Holding time = 6 months for freeze dried samples.
[(b)] Holding time = 6 months for frozen (-20 °C) sediments and tissues (EPA 1986 and EPA 1989).
[(c)] The 40 day holding time starts the day of extraction for organic analysis.
[(d)] No EPA holding time established; total Hg hold time used as a default.
[(*)] Metals sediment and tissue samples will be refrigerated (4±2°C) or frozen (-20±2°C) by the laboratory until freeze dried

TABLE 9.3.2: Toxicity Sample Holding Times and Preservation

Matrix	Preservation	Holding Time
Sediment	4±2°C dark/airtight	2 weeks is recommended; up to 6 weeks is acceptable; and in some cases up to 8 weeks
Effluent	4±2°C dark/airtight	36 hours from sample collection [a]
SPP/Elutriate	4±2°C dark/airtight	24 hours from preparation

[a] Every effort must be made to initiate the test with an effluent sample on the day of arrival in the laboratory. The holding time should not exceed 36 hours unless a variance is approved by the client.

9.4 CONTROL CHARTS AND PERFORMANCE BASED QUALITY

The TNI and the Navy have withdrawn requirements for control charts for inorganic analytes in favor of performance-based QC data assessment.

9.4.1 Control Charts

Control charts of reference toxicant results obtained from bioassays are used to demonstrate the sensitivity of the stock organism population. Reference toxicant tests are typically conducted concurrently with an aquatic or benthic toxicity test, using organisms from the same batch source. Details of the control charting process and criteria for assessing out of control events are described a procedure MSL-Q-010, Procedures for Control Charting Reference Toxicant Test Results or project planning documents.

When control charts are produced, they are based on normally distributed measurements and short-term variation. Precision is charted over time by calculating a mean recovery for the control sample parameters and then establishing upper and lower warning and control limits. The warning limit is defined as ±2 s and the control limits are defined as ±3 s. The control samples used for organic parameters are Blank Spikes (BS) and for inorganic parameters results from the analyses of a standard reference material are plotted. A minimum of 20 points are used to set the initial control limits for each parameter.

9.4.2 Performance-Based Quality Control

Performance-based quality control is based on a comparison between *a priori* project or method-specific data quality objectives and the results obtained for each batch of samples. In most cases, both method and project-specific DQOs are evaluated for each batch of samples analyzed. Corrective actions are specified in each analysis method and are followed to ensure that sample data obtained is of high quality and defensible. All issues regarding data quality are discussed in a narrative accompanying sample results. Documentation of the assessment of performance-based DQOs and QC sample results is provided by the use of an analyst checklist on each data package prepared by the analysts. The checklist documents issues that are addressed by completion of the appropriate corrective action during analysis and issues that could not be corrected are documented.

9.5 EQUIPMENT MAINTENANCE AND CALIBRATION

The quality of MSL products is directly related to the validity of the data produced. To produce valid data, equipment must be properly operated, maintained, and calibrated.

Preventive maintenance and primary maintenance of facilities equipment are provided through the PNNL Facilities and Operations Personnel located in Sequim, but located organizationally in Richland, WA.

The MSL maintains a wide variety of research equipment related to the collection and analysis of a variety of parameters (chemical, biological, and physical oceanographic, etc.). This research equipment is maintained to manufacture's specifications through manufacturer service contracts, service calls, factory rehab purchase requisitions, or by qualified personnel. To support the generation of data of known and acceptable quality, the following general guidelines are implemented when applicable:

1. The appropriate and necessary equipment, instruments, and supplies must be available in adequate quantities to perform the proposed work. Spare parts for critical components are maintained to minimize downtime.
2. Measuring and testing equipment is properly handled and stored to maintain accuracy.
3. All equipment involved in the collection and analysis of environmental data is operated, maintained, and calibrated according to approved procedures and specified schedules.
4. Equipment is serviced regularly by qualified individuals, either trained in-house personnel or through service contracts with the manufacturer or an authorized representative. For example, balances are cleaned and calibrated by a PNNL Evaluated Supplier, and analytical instruments have service contracts with manufacturers such as Perkin-Elmer. Most support equipment (e.g., ovens, refrigerators, freezers, hoods) servicing is done internally by PNNL's Facilities and Operations Personnel. When problems arise that cannot be corrected internally, external contractors or manufacturer's representatives are contacted.
5. Equipment that is not operational for any reason must be clearly tagged out to indicate that it is out-of-service
6. Written records of all instrument maintenance, calibration, testing, and inspection are maintained. Maintenance records contain a description of the operation or problem, the remedial action taken (if necessary), date, and the individual responsible.
7. When equipment or instrument maintenance is required, equipment is monitored to ensure correct operation. The responsible analyst monitors analytical instrument operation after maintenance by running a calibration curve and assessing results of standard reference materials (SRM), when applicable.
8. Calibrated equipment is suitably marked to indicate calibration status.
9. Written directions on equipment operation (e.g., operating manual, manufacturer's instruction, and procedures) are maintained with the equipment and are available to personnel using the equipment.
10. Balances are calibrated annually by an approved metrology laboratory and checked daily prior to use by laboratory personnel as prescribed in procedure MSL-C-009, Use and Performance Checks of Balances.
11. Applicable cold-storage facilities are monitored daily as prescribed in procedure MSL-I-026, Use of Laboratory Refrigerators and Freezers.
12. Pipettes are checked quarterly as prescribed in procedure MSL-C-010, Calibration, Verification and Use of Pipettes.

A list of equipment is maintained by the PM, when applicable. The QAO maintains and updates a list of equipment used in support of TNI work.

9.5.1 Equipment Calibrations

When applicable, calibrations or performance checks are performed on instruments and support equipment (balances, pipettes, thermometers, etc.) prior to use or at established intervals. Requirements for specific levels and frequency of calibration are described in SOPs or project planning documents. In circumstances, especially during field surveys, where calibration occurs less frequently than described in SOPs or project planning documents, the PM shall notify the client.

Calibration records are kept in the data files and are traceable to date and other applicable parameters (sample runs, standards, etc.). Corrective actions when calibration criteria are not met are described in SOPs or project planning documents.

Whenever data are recorded, the instrument model, serial number (if available), and information on whether a calibration was performed prior to sampling is recorded. If no calibration information is provided with the data, the assumption must be that the instrument was not calibrated immediately prior to use. However, calibration records that indicate the date and results of the previous calibration are acceptable (assuming it is prior to the next recommended calibration date for that instrument) may be referenced.

9.5.2 Preventive Maintenance

Instruments and support equipment are serviced regularly by qualified individuals, either trained in-house personnel or through service contracts with the manufacturer, an authorized representative or other qualified service organization. Written records of all instrument maintenance, calibration, testing, and inspection are maintained. Maintenance records should contain a description of the operation or problem, the remedial action taken (if necessary), date, the individual responsible, and where applicable, documentation of the instrument's return to acceptable use

9.6 INTERNAL QUALITY CONTROL CHECKS

The following are common types of QC analyses implemented by the MSL. It is important to note that measures made for work performed that is not under the TNI standard may be for system monitoring purposes only and are not considered as quantitative measures subject to QC requirements beyond daily calibration verification.

- **Blank Spike (BS)/Laboratory Control Sample (LCS)** - an aliquot of clean matrix (e.g. reagent water) to which known concentrations are added and prepared, treated and analyzed in the same manner as the associated samples. Its purpose is to determine whether the method is within accepted control limits. Blank spikes may be analyzed in duplicate (BSD).
- **Continuing calibration verification sample (CCV)** - A sample of known concentration that is run at the frequency described in the project planning document and/or SOP (typically after every 10 or 20 samples) to ensure that the initial calibration is still valid. The specific project planning document and/or SOP CCV % recovery range for the analysis should be followed. Analysts will attempt to run CCVs such that they bracket the analytical range of the samples run in the analytical batch.
- **Initial calibration verification sample (ICV)** – A sample of known concentration, and of a separate source from the curve is run after the calibration curve to verify instrument control. The specific project planning document and/or SOP ICV % recovery range for the analysis should be followed. For samples that are to be analyzed for the TNI, or when requested by a client, a secondary source ICV shall be run prior to running any samples.
- **Laboratory replicates** - Laboratory replicates consist of splitting a single sample or compositing and splitting two or more samples in the laboratory, and subsequently processed and analyzed as separate samples. Laboratory replicates serve as a measure of the error associated with the analytical process.
- **Matrix Spike (MS)** - an aliquot of a sample to which known concentrations are added and treated and analyzed in the same manner as the associated samples. Its purpose is to determine whether the sample matrix contributes bias to the results.

- **Method Blank (MB)** - an aliquot of clean matrix (e.g. reagent water) prepared, treated and analyzed in the same manner as the associated samples. Its purpose is to determine if method concentrations or interferences are present in the laboratory environment, the reagents, or the apparatus' used that could contribute bias to the results.
- **Standard Reference Material (SRM)** - a material obtained from an independent source, is certified to a known concentration by a recognized authority (e.g., NIST) and is treated and analyzed in the same manner as the associated samples. Its purpose is to determine whether the method is within accepted control limits.

QC samples may also be collected in the field to monitor contamination and to assess sampling error. Common field-related QC samples include

- **Equipment Blanks (EB)** - Equipment blanks are prepared in the field using the freshly decontaminated sampling equipment. De-ionized water is poured over and through the equipment, collected in an identical sampling container, and shipped to the laboratory for processing and analysis. Equipment blanks measure the contamination associated with the entire sampling and analytical process.

- **Field Replicates** - Field replicates are two or more separate samples that have been collected from the same sampling point. Field replicates also serve to measure the error associated with the entire sampling and analytical process, including variation inherent in the sampled media.

- **Reference Samples** - Reference samples are samples for which selected properties are known, generally through historical analysis. Reference samples are used as a benchmark for similar analyses.

- **Split samples** - Split samples are obtained by compositing sample material in the field and dividing the material into separate containers for processing and analysis. Split samples are used to assess the total error associated with sampling and analysis. If split samples are sent to separate laboratories for analysis, inter-laboratory variation may also be obtained.

QC checks are associated with biological toxicity testing (independent recounting of sample, reference toxicity tests, establishment of acceptable water quality measurement ranges) and data processing (proofing or double entry/comparison programs). The specific QC procedures, frequency of performance, and criteria for acceptance for all environmental data collection procedures are defined in SOPs or in the project planning documents.

The immediate monitoring of QC results by analysts allows the data collection process to be continually compared to pre-established acceptance criteria and corrected as necessary. In addition, assessment of QC results is a critical component of the data validation process and is used to interpret the accompanying sample data and to judge its acceptability and usefulness with regard to the project DQOs. QC results are reported with the project data.

10.0 APPROVALS BY EXTERNAL AUTHORITIES

10.1 ACCREDITATION/CERTIFICATIONS

A list of the most current accreditations and accredited methods is maintained by the QAO. The MSL's primary TNI accreditation is under the New Jersey Department of Environmental Protection (NJDEP).

Certification is described in procedure MSL-A-013, Laboratory Accreditation and PT Sample Analysis. Certification programs are based on the demonstration of a functional quality program, the existence of planning documents and procedures, the successful analysis of external performance samples at least twice per year for each method, parameter and matric of interest, and in some cases, periodic on-site assessments. The MSL maintains the following documentation to meet these requirements:

Quality Assurance Management Plan (QAMP)
SOPs in the following general areas

- Administration
- Conventional/General Chemistry
- Documentation, Records, and Reports
- Ecological Processes
- Inorganic Chemistry
- Organic Chemistry
- Quality Assurance
- Safety
- Toxicological/Biological Testing
- Water Quality Instrumentation

Training Files
Approved Management Signatures
Signature Log

10.2 OTHER AUTHORITIES

The MSL is inspected semi-annually by the PNNL Institutional Animal Care and Use Committee (IACUC) for compliance with Federal animal welfare regulations that require protocols for all uses of vertebrate animals to be reviewed and approved by the Committee. Approved protocols are also required for animals used in training, animals held as donors for blood and other tissues, breeding stock, and other animals held on site which are not yet assigned to a specific study protocol. Animal use requirements are prescribed in procedure MSL-A-017, Care of Animals.

11.0 PERFORMANCE EVALUATIONS

Analysts performing TNI work are degreed personnel operating analytical instruments on a daily basis. It is the PM's responsibility to ensure analysts supporting non-TNI work have experience and training required by the specific project.

The dedication of analytical personnel to the specific procedures for which they are responsible, their level of training and, daily QC assessments of proficiency through the analysis of blank samples, sample replicates, SRMs, and MSs combine to make the results produced by highly defensible, accurate, precise, and repeatable. The MSL is a specialty laboratory, providing its clients with relatively low detection limits for environmental samples. Daily proficiency is monitored at the bench level, at the level of data assessments performed on sample sets by the analyst and the Data Coordinator (data validation), and at the level of the QAO who provides data quality verification.

As part of the TNI accreditation programs, the MSL participates in performance studies at the required frequency for the accredited methods, parameters and matrices as prescribed in procedure MSL-A-013, Accreditation and Performance Testing. Performance Testing samples are purchased from a National Voluntary Laboratory Accreditation Program (NVLAP)-approved vendor. Clients are provided with the results of recent performance studies upon request.

The MSL also participates in inter-laboratory toxicology comparisons whenever offered.

12.0 DATA REDUCTION, REPORTING AND EVALUATION

12.1 DATA REDUCTION

Reduction of raw data shall be accomplished using established techniques. The calculations required for the the reduction of data may be performed manually or with the aid of automated data processing systems. In either case, the applicable SOPs for the testing and analysis of samples or the project planning documents will specify the calculations and the mode for raw data processing. If manual processing is to be used for data validation, then the applicable SOP or project planning document will provide the calculation method and the units for reporting derived values. In order to reduce the potential of errors in data transcription the manual transfer of data will be minimized. All calculations performed manually will be checked for accuracy by someone other than the individual who performed the original calculation. Data validation checks shall be documented by the signature and date of the reviewer. Separate documentation is acceptable, provided traceable records are maintained. For automated data reduction methods, the accuracy of calculations will be verified through the use of standards or test case inputs with known resultant values. For TNI projects, all data is reviewed in accordance with procedure MSL-Q-003, Quality Assurance Deliverable Audits.

12.2 REPORTS

Two types of technical reports are produced: Research and development (R&D) reports and data reports. R&D reports are produced from research of a non-standard or non-repetitive nature, data reports are produced from results of standard, repetitive types of analyses. All technical reports go through a formal review process consisting of an author review, technical peer review, editorial or QA review, and a management review. R&D reports must have an editorial review and data reports must have a QA review.

The purpose of the technical peer review is to evaluate the document for technical quality, including scientific validity and logic. This review is performed by senior technical personnel selected for familiarity with the technical discipline of the work being reported. The QA review is conducted by the QAO and encompasses accuracy, completeness, adequacy, and conformance to applicable standards and project planning documentation. Editorial review addresses grammatical correctness and consistency of style and format. The management review focuses on scientific validity, logic, conformance to client expectations, and for agreement with policies and procedures. The management reviews are performed by the Laboratory Director or delegate.

The following is a list of data that is typically reported for toxicant results:

- description of test sediment or water; collection, handling, manipulation, storage, and disposal
- description of test organisms; scientific name, age, size (when applicable), life stage, source, and their handling, culturing, and acclimation
- toxicity test method used
- date and time test started and terminated
- percent survival for each test treatment
- percent survival for each test treatment
- control treatment survival
- results of water quality measurements (may be reported as mean, range of measurements, number of times criteria limits were exceeded)

- number of organisms used per test chamber
- number of replicate test chambers per treatment
- summary of statistical endpoints (mortality, growth, LC50, no observed effect concentration [NOEC],)
- gender determinations (when appropriate)
- growth (when appropriate)
- reproduction (when appropriate)
- summaries of biological observations
- summaries of reference toxicant test evaluations
- summary of any problems encountered and corrective actions
- description of any deviations from prescribed laboratory protocols

The following is a list of data that is typically reported for field research results:

- description of study organisms; scientific name, age, size, collection method or other source, and their handling and disposition
- date and times for data collection
- weather and water conditions
- water visibility
- descriptions of sampling equipment (e.g., manufacturer and model number)
- summary of observations
- summary of any problems encountered and corrective actions

The following is a list of data that is typically reported for analytical chemistry results:

- sample receipt date and condition
- date and times for data collection
- the applicable method, matrix, instrument and SOPs
- summary of the results
- summary for DQO results
- summary of any problems encountered and corrective actions

12.3 DATA VALIDATION

Prior to their use, data shall be validated in accordance with project requirements. Validation is defined as the process through which data are accepted or rejected and consists of proofing, verifying, editing, and technical reviewing activities. Data validation requirements are prescribed in procedure MSL-D-004*,* Data Reporting, Reduction, Backup, and Archiving. Data validation is considered a technical function and should occur prior to the data being audited by the QAO.

Data validation occurs at multiple levels as data are collected and processed:

- Individuals recording data during field or laboratory operations are responsible for reviewing their work at the end of the day to ensure that the data are complete and accurate.
- Analysts and instrument users are responsible for monitoring the instrument operation to ensure that instrument has been properly calibrated.
- PMs are responsible for reviewing analytical results and supporting documentation to assess sample holding times and conditions, equipment calibration, and sample integrity. As an additional measure of acceptability, the results of QC samples are compared to the project DQOs.
- Technical personnel are responsible for reviewing the data for scientific reasonableness.

- All manual entries into databases and spreadsheets are verified, either through proofing or by double entry/comparison programs.
- All calculations performed by hand are checked for accuracy.

Data that do not meet the pre-established criteria for acceptance may be flagged (see procedure MSL-D-004, Data Reporting, Reduction, Backup, and Archiving), not reported, or reported with an explanation of the limitations, at the discretion of the PM.

12.4 DATA AUDIT PROCESS

Data produced by the MSL for work performed under the TNI standard shall be audited prior to their final release. The reported data are audited, using a process that ensures that the data are complete, accurate, traceable, and defensible. Details of the data auditing process are described in procedure MSL-Q-003, Quality Assurance Deliverable Audits.

Non TNI projects may be audited in accordance with procedure MSL-Q-003, Quality Assurance Deliverable Audits or in accordance with project planning documents.

Data shall be reviewed to ensure that the data are accurate, traceable, defensible, and complete, as compared to the project requirements. The audit procedure is a check that involves comparing selected reported values to the original data. Selection of the reported values to check can either be performed randomly or on a statistical basis. Results of the data audit are documented either on a checklist or in a summary statement. Concerns that can be corrected shall be corrected before the data are released. Deviations are required to be summarized and provided to the client.

12.5 CONFIDENTIALITY

PNNL policy does not allow the release of client data or project-related information to anyone except the client unless expressly directed by the client or an authorized representative. Client confidentiality and proprietary rights are protected whenever requested by marking documents, protecting business sensitive information, sealing records, and/or protecting access on a “need-to-know” basis.

12.6 DATA RELEASE AND EXPORT

Data used for regulatory purposes or for data collection activities that require TNI accreditation will be clearly identified. Non-TNI accredited analytes will be clearly specified and identified as not meeting the TNI standard.

Data are released as electronic files (e.g. Excel, Word, pdf) or in hard copy. Hard copy and electronic files are checked before data are released for consistency and accuracy. This is part of the data audit process. Most hardcopy data is sent to the client via Federal Express, which allows for package tracking and affords a high level of confidence that tampering, does not occur. When data are electronically provided to the client, it is the client’s responsibility to verify that the hard copy matches the electronic file upon receipt. File copies of both formats are signed and dated and kept in the project file. The MSL will assist in resolving any issues that arise during data transmission. Data files will be encrypted upon request, assuming that the encryption programs are either those currently available to PNNL personnel or provided by the client. For confidential data transmissions, the client will be asked to define an acceptable mode

of data transmission that maintains confidentiality. In the past, data has been transmitted as FTP to a secured third party site arranged by the client. Hardcopy data can be footnoted on every page as to their confidentially and evidentiary status. In addition, when required by the client, “need-to-know” cover sheets can be used. A formal procedure has not been developed for these processes because confidential and secure transmission requests to date have been infrequent and very client-specific.

13.0 VERIFICATION ACTIVITIES

To insure the products generated and the services performed meet established standards and client requirements, a systematic approach has been implemented. This approach is graded and intended to provide oversight, assessment, and corrective/verification action for a variety of projects. The goal of the process is to:

- Provide personnel and management accurate technical, business and operational performance information that promotes early identification and resolution of problems that may impact achievement of critical outcomes and objectives.
- Verifies conformance to established requirements.
- Verifies effective conduct of activities to protect the environment and the health and safety of workers and the public.
- Contributes to ongoing improvement in performance

13.1 ASSESSMENTS

Assessments are performed in accordance with the HDI work flow "Integrated Assessments" by personnel and line management to evaluate performance. Assessment methods include, but are not limited to walk through, procedure and program reviews, personnel feedback, and safety, health, and environmental evaluations.

In addition, the QAO conducts QA assessments to determine if facilities, equipment, personnel, methods, practices, records and quality control are in conformance to approved planning documents, procedures, regulations, client requirements and PNNL policy. QA assessments are scheduled based on a request from the Director, the definition of critical phase inspections by PMs or clients, and by scheduling by the QAO when a new procedure is implemented or significantly revised, when a new study type is initiated, or when data quality reviews indicate technical systems problems. External assessments of suppliers are conducted through the PNNL Environment, Safety, Health and Quality Directorate in Richland, WA and are related to qualifying preferred suppliers.

QA assessments are formal or informal verification activities that are performed in accordance with procedure MSL-Q-002, Quality Assurance Inspections of MSL System and Study Activities and the HDI work flow " Integrated Assessments". The purpose of a formal QA assessment is to determine verification with a requirement and includes formal corrective action and follow-up. If the assessment is determined to be informal, the purpose is to determine the status and to report the factual evidence and is not intended to be a verification activity with formal corrective action response, follow-up, etc. Informal assessments are generally requested by management to assess the status of a particular activity.

A schedule of all QA assessments is maintained by the QAO. This schedule will include verifications based on client needs, management requests and routine internal verifications (i.e., checking standards logs, sample preparation forms, QC checklists, equipment calibration and maintenance, etc.).

13.2 QA REPORTS TO MANAGEMENT

Biannually, the QAO will submit to the Laboratory Director a summary of the past two quarter's QA activities. Subjects to be covered in the biannual QA report are prescribed in procedure

MSL-Q-008, QA Reports to MSL Management, and shall include, but not be limited to, results of assessment activities, results of performance evaluation samples, trends of deficiencies, and other important QA-related issues.

13.3 DEVIATIONS

Each individual engaged in project activities should be alert to problems, deviations from approved SOPs, out-of-control events, or other issues that may require corrective action. The appropriate response is determined by the event. Procedure MSL-A-005, Deviations from Established Requirements provides methods for describes deviations from procedures, planning documents, and client requirements.

All deviations from approved procedures, project planning documents or this QAMP will be documented. Depending on the severity of the deviation, the QAO and the PM will determine how the deviation will be addressed and documented (i.e., through use of a Deviation Documentation Form or Quality Problem Report form as prescribed in procedure MSL-A-005, Deviations from Established Requirements). In some cases, the client may be involved in these discussions.

Deviations from project control limits will be documented. In some cases, deviations will be identified in the narrative accompanying the data set or package or in a letter to the client, and the impact of the deviation addressed. The documentation must clearly state the event and the corrective action taken in response, and must be approved by the appropriate management representative. Acceptance of data that exceeds pre-established criteria also must be documented and justified.

Below is a listing of deviation types.

- **Simple Deviation** – A simple deviation is a deviation from project control limits. The situation is documented either in log books, or on project paperwork including the case narrative. It is important to document if the sample integrity or data quality has been adversely affected.
  - **Corrective Action**- Document the situation to client. Look for opportunity to correct the situation.
- **Minor Deviation**- A minor deviation is defined as method or protocol deviation that does not appear to adversely impact the quality of the data. A minor deviation may evolve into a major deviation if an impact on data quality evolves or results.
  - **Corrective Action**- Document either with narration to client or deviation documentation. Determination of a minor deviation will be initiated by either the PM, or QAO. The corrective action will be established to assure that the highest quality of data is produced and that all contractual limits are met. It is possible for a minor deviation to result in a major deviation depending upon all circumstances.
- **Major Deviation** - A major deviation is defined as an occurrence or method or protocol deviation with an impact on project data quality or a negative effect on the outcome of a test or analysis.
  - **Corrective Action**- Formal documentation. Major deviation corrective action is tracked to completion, including signatories. The objective is to be able to institute “lessons learned” to improve systems and personnel awareness.

The following are guidelines to resolving deviations:

- All deviations from approved procedures, project planning documents or this QAMP will be documented.
- Issues that affect cost, schedule, or performance of the project will be reported to the PM. The PM will then be responsible for evaluating the overall impact to the project and implementing the necessary corrective actions.
- Deficiencies identified through QA assessment activities will be brought to the attention of the PM. Implementation of corrective action will be the responsibility of the PM.
- When sample integrity is compromised or questionable (e.g., mislabeling, broken or leaking sample containers, improperly preserved samples, expiration of sample holding times), it is the responsibility of the personnel who identify the problem to bring it immediately to the attention of the PM for resolution.
- In the event of an instrument problem, it is the responsibility of the operator to attempt to correct the problem (e.g., recalibrate the instrument). If the problem persists or cannot be identified, the issue should be brought to the attention of the Director for resolution.
- Corrective actions for results outside established DQOs are addressed in applicable SOPs.

13.4 CORRECTIVE ACTION

The need for corrective action may be identified by the technical personnel during the course of their work and through assessments or data audits. It is the responsibility of the analyst to monitor QC sample results, and ensure established criteria in method procedures or project specific criteria are met.

Each individual performing laboratory or data processing activities will be responsible for notifying the PM of any circumstance that could affect the quality or integrity of the data. It is the PM's responsibility to ensure completion of the resulting corrective action by the expected completion date, and to request independent verification (when required).

Corrective actions may include, but are not limited to, review of data and calculations, flagging and/or qualification of suspect data (see procedure MSL-D-004*,* Data Reporting, Reduction, Backup, and Archiving) or re-extraction and/or re-analysis of individual or entire batches of samples. In addition, individual analytical SOPs may contain appropriate corrective actions for various routine problems. The form of documentation is project specific, but at a minimum, the QC data that are outside the established criteria shall be flagged.

When there has been an impact on data, the PM shall ensure that there is a cross reference in the raw data that indicates there is a documented deviation and corrective action.

13.5 QUALITY IMPROVEMENT

Quality improvement is a critical aspect of the Self-Assessment Program and involves both corrective action to identified deviations and continuous improvement processes. The corrective action process involves determining, implementing, approving, and verifying the appropriate remedial action. The continuous improvement process involves determining and prioritizing improvement areas, implementing improvement action and documenting the disposition of each action.

13.6 ASSESSMENT ACTIVITIES

For all assessment activities, a system of notification and verification of corrective action is in place. An assessment report is prepared and submitted to the appropriate PM. The PM reviews the assessment results to determine overall impact and risk and then determines corrective action and prioritizes the actions. The PM assigns the corrective actions to individuals. The PM ensures that the corrective action is tracked to completion and as part of completion, documentation is included that describes the justification for completion of the corrective action. Issues that in the PM's judgment require significant corrective action should be scheduled for verification of that corrective action at a subsequent assessment.

Issues that in the PM's judgment require process improvement instead of, or in addition to, corrective action, are identified as such and any improvement actions are implemented and documented.

13.7 CLIENT COMPLAINTS

The process for tracking and addressing client complaints is the following:

- The PM is the point of contact for any client complaints.
- The client contacts the PM to discuss the concern. The contact is generally made by e-mail or telephone, although a formal written follow up letter may be sent as well.
- The PM will inform the Director of the issue(s). Concerns will be responded to in writing. A determination will be made of an appropriate response (e.g., data review and re-calculation, sample re-analysis, re-sampling and analysis, revision of deliverables), which will be discussed with the client prior to finalizing in a response letter.

A tracking system for client complaints has not been developed because client complaints are rare. If the frequency of client complaints increases (>2/year), a formal tracking system may be developed. The QAO will monitor the number of annual client complaints.

APPENDIX A: List of Acronyms

ASTM	American Society for Testing Materials
BS/BSD	Blanks Spike / Blank Spike Duplicate (aka LCS)
BIOSIS	A bibliographic database service, with abstracts and citation indexing
CCV	Continuing Calibration Verification
CDRR	Chemical Disposal Recycle Request
CFR	Code of Federal Regulations
CMS	Chemical Management System
CRM	Certified Reference Material
CSM	Cognizant Space Manager
CoC	Chain of Custody
CV	Coefficient of Variation
DO	Dissolved Oxygen
DOE	Department of Energy
DQO	Data Quality Objective
EED	Energy and Environment Directorate
EPA	Environmental Protection Agency
ES&H	Environment, Safety, and Health
ESE	Environmental and Safety Engineer
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FSR	Field Services Representative
GLP	Good Laboratory Practices
HDI	”How Do I”
HPLC	High Performance Liquid Chromatography
Hg	Mercury
IACUC	Institutional Animal Care and Use Committee
ICV	Initial Calibration Verification
ID	Identification
IOPS	Integrated Operations System
LCS	Laboratory Control Sample
MB	Method Blank
MDL	Method Detection Limit
MSL	Marine Science Laboratory
MS/MSD	Matrix Spike / Matrix Spike Duplicate
MRO	Marine Research Operations
NIST	National Institute of Standards and Technology
NJDEP	New Jersey Department of Environmental Protection
NOAA	National Oceanic and Atmospheric Administration
NOEC	No Observed Effect Concentration
NRCC	National Research Council of Canada
NVLAP	National Voluntary Laboratory Accreditation Program
PARCCS	Precision, Accuracy, Representativeness, Comparability, completeness and Sensitivity
PM	Project Manager
PNNL	Pacific Northwest National Laboratory
PT	Performance Test
PVC	Polyvinyl Chloride
QA	Quality Assurance

QAMP	Quality Assurance Management Plan
QAO	Quality Assurance Officer
QAPP	Quality Assurance Project Plan
QC	Quality Control
QPR	Quality Problem Report
R&D	Research and Development
RPD	Relative Percent Difference
RSD	Relative Standard Deviation
RSO	Radiation Safety Officer
SOP	Standard Operating Procedure
SOW	Statement of Work
SRM	Standard Reference Material
TNI	The NELAC Institute
TSCA	Toxic Substances Control Act
U.S.	United States
UV	Ultraviolet
WA-DOE	State of Washington, Department of Ecology

Appendix 1.A.D

ACZ Laboratories QAP

ACZ Laboratories, Inc.

QUALITY ASSURANCE PLAN
v.13

Effective Date: June 10, 2009

Last Review: May 2009

AUTHORIZATION SIGNATURES AND DATES:

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1 INTRODUCTION

ACZ Laboratories, Inc. is an environmental testing laboratory that provides data to clients primarily for regulatory purposes. Samples are analyzed for compliance with federal programs including the Resource Conservation Recovery Act (RCRA), Safe Drinking Water Act (SDWA), and Clean Water Act (CWA). Environmental compliance and management decisions are based on the analytical data provided, which are critical to the expenditure of large amounts of money; are important to public health safety; are important in evaluating, monitoring, and protecting the environment; and are often essential in litigation. To this effect, analytical data must always be technically sound, accurate, and legally defensible or it is useless to the end user.

An effective Quality Assurance and Quality Control program is the cornerstone of the generation of reliable analytical data. ACZ's Quality Assurance Plan (QAP) outlines the quality assurance and quality control objectives, policies, and procedures determined to be necessary to meet the requirements of the EPA, federal government entities, state agencies, other regulatory authorities, and our clients. This document provides the necessary guidelines to ensure all ACZ employees have sufficient knowledge and training to perform their job responsibilities in a manner that guarantees all data reported to all of our clients is accurate, reliable, technically sound, legally defensible, and impartial.

For data to be accurate, it must be of known and documented quality. The word "quality" has many different meanings, but for the purposes of environmental testing activities can be stated simply as "conformance to requirements." Conforming to requirements allows objective measurements to be applied, rather than subjective opinions, to determine when work is of good quality. *Quality control* refers to all activities that ensure accuracy (i.e. good quality) of the data. It requires action(s) to be taken and is typically included as part of the procedure. *Quality assurance* provides the records of the results obtained from the required action(s) and refers to the ability of the laboratory to demonstrate or prove to an outside party that the quality of the data is what the laboratory states it is. Quality assurance relies heavily on documentation, and to be effective, the documentation must: (1) assure the quality control procedures are being implemented as required; (2) assure the reported data reflect the sample as it was received, meaning sample mix-up was avoided, the sample was properly preserved prior to analysis, etc.; (3) facilitate traceability of an analytical result; and (4) be subjected to reasonable precautions to protect data from loss, damage, theft, and internal or external tampering.

Quality Policy Statement: To maintain an effective QA program, continually improve the quality of our environmental testing services, and consistently provide clients with technically sound and legally defensible data in a timely manner, the management of ACZ recognizes the importance of its commitment to:

- Ensuring good professional practice by well-trained and qualified employees with the necessary experience and skills to carry out their organizational functions and to meet or exceed ACZ's standards for the quality and reliability of its testing services.
- Ensuring the data provided to our clients is of known and documented quality, and is accurate and impartial.
- Ensuring that all quality assurance and quality control policies and procedures are communicated to and understood by all employees, and that they are implemented by all employees in their work.
- Ensuring that all aspects of the business operations are conducted in a manner that adheres to the NELAC Standards and all of ACZ's policies and procedures documented in the QAP, SOPs, emails, memos, etc.
- Upholding the spirit and intent of ACZ's Data Integrity Program and implementing the requirements of the program.

2 QUALITY SYSTEM OBJECTIVES & COMPONENTS

ACZ's QAP provides a framework that guides all technical staff and administrative personnel. The information presented is necessary to ensure all employees perform their duties in a manner that allows the company to achieve its objectives, thereby ensuring the precision, accuracy, completeness, and consistency of the analytical data reported to our clients. This framework is referred to as the Quality System. The Quality System encompasses every documented quality assurance (QA) and quality control (QC) policy and procedure and guides all business functions and laboratory operations by specifying standardized protocols to control both the short-term and long-term activities that influence the quality and defensibility of our testing services.

The Quality System is designed to be appropriate to the type, range and volume of the environmental testing undertaken. The Quality System is not a static entity and must function in a manner that allows for continuous evolution of all aspects of ACZ's business when improvements have been identified and have been determined to be necessary or beneficial. ACZ management recognizes that the staff is comprised of people who possess varied experience and knowledge and can contribute valuable insight and suggestions regarding these improvements. All employees are encouraged to be involved in this process. The following six (6) key elements form the foundation of ACZ's Quality System:

- Documents & Records
- SOPs
- Training
- Audits
- Corrective Actions
- Management Review of the Quality System

2.1 Documents & Records

The entire history of any sample must be readily understood through the associated documentation. To this extent, a formal and systematic control of documents and records is necessary for accurately reconstructing all events pertaining to any sample and for guaranteeing the quality and defensibility of the data. All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities (such as sample receipt, sample preparation, data verification and data reporting) must be documented, and all records, including those pertaining to calibration and test equipment, certificates and reports, must be maintained. Documents and records must be safely stored (protected against fire, theft, loss, deterioration, and vermin), and must be held secure and in confidence to the client for a minimum of five (5) years. Refer to §10 for details regarding the storage and control of ACZ's documents and records.

2.1.1 Documents

A document is a writing that contains information. All controlled documents are reviewed for accuracy, approved for release by authorized personnel, and properly distributed. A document control system subsequently ensures that employees use only the correct and effective version of any form, Standard Operating Procedure (SOP), or other document, which are maintained through ACZ's LabWeb intranet. LabWeb is a computerized document control system based in HTML that can be accessed from any network computer within the facility. Documents can be queried by department and then organized in several ways by clicking the appropriate header. Click on the title of the document to view it as an Adobe Acrobat (*.pdf) file. The PDF has a "read only" qualifier and does not allow changes. Users may view SOPs but the documents may not be saved to another network drive and may not be printed. Forms may be viewed and printed but may not be saved to another network drive.
All documents are categorized by department and are assigned a unique document ID that is printed in either the header or footer section. The ID nomenclature starts with either SOP (procedure) or FRM (form), followed by the 2-letter department code, the unique document number, the month and year of issue, and the revision. The effective date for any SOP or other document is included on the title page and header section of each subsequent page and indicates the implementation date.

The QA Officer has full responsibility of the Document Control System. Documents can be changed, overwritten, or saved as a different document only by employees with Domain Administer computer rights (primarily IT and QA staff). A new or revised document is reviewed, and following approval, the document control number is

updated and the SOP or form is uploaded to Labweb. When a new version of an SOP is added to Labweb, the previous version is removed from the active list, date-stamped and electronically archived in a designated location on the network. This automatic process guarantees that ACZ can retrieve the version that was in effect at any given time. Controlled forms are not currently archived.

2.1.2 Records

A record is any information or data on a particular subject that is collected and preserved. Records are produced on a daily basis and contain original, factual information from an activity or study. For ACZ's purpose, this information may be recorded by the following means: LIMS database, logbooks, raw instrument data, worksheets, and notes (or exact copies thereof) that are necessary for the reconstruction and evaluation of the report of the activity or study. The record management system provides control of records for data reduction, validation, reporting and storage, and also provides control of all laboratory notebooks and logbooks. The system must allow for historical reconstruction of all laboratory activities that produced analytical data, must document the identity of personnel involved in sample receipt, preparation, calibration or testing, and must facilitate the retrieval of all working files and archived records for inspection and verification purposes. At a minimum, the following criteria for records must be met:

1) Instrument logbooks must be kept up-to-date on a daily basis. In general, document all relevant activities when the event occurs.

2) Dilution factors and observations must be recorded at the time they are made, and notes regarding the sample(s) or analysis must be identifiable to the specific task.

3) A detailed description of any departure from a documented procedure, and the reason for the departure, must be provided at the time it is performed.

4) All generated data must be recorded either by an automated data collection system or must be recorded directly, promptly and legibly in permanent ink (blue or black is preferred).

5) Erroneous entries (hard copy or electronic) cannot be destroyed by methods such as erasures, overwritten files or markings. Refer to §16 for ACZ's error correction protocol.

6) Any change(s) to hard copy records must be clearly initialed and dated by the responsible staff. Changes to electronic records must also be traceable to the individual who made the change, and the reason for the change must be provided.

7) Records generated by computers must have hard copy or write-protected backup copies.

2.2 Standard Operating Procedures

A documented procedure is required for all phases of ACZ's business operations, from sample log-in through sample disposal. A Standard Operating Procedure (SOP) is a written document that details the manner in which an operation, analysis, or action is performed and thoroughly prescribes the techniques and procedures, which are the accepted process for performing certain routine or repetitive tasks. Analytical SOPs must be written with adequate detail to allow someone similarly qualified, other than the analyst(s) who routinely performs the procedure, to reproduce the procedure used to generate the test result. To the extent possible, administrative SOPs [non-technical] must include specific requirements pertaining to the process; however, the procedure itself may be a more general description so as to lend a degree of necessary flexibility to account for client requests and other circumstances, which may be outside of ACZ's control.

Proposed revisions to any test SOP must be noted on the SOP Revision Form (FRMQA030). Proper use of FRMQA030 ensures the SOP continues to include all requirements of the procedure. All procedural revisions must be reviewed and approved by QA prior to implementation. Changes to provide additional clarification, correct typographical errors, etc. do not need to be approved but need to be noted on the revision form to ensure the changes are included during the next revision. Analytical SOPs must be reviewed annually using the SOP Review Form (FRMQA035), and Administrative SOPs must be reviewed regularly and revised if necessary to ensure the information is accurate and reflects current practice.

Documenting changes in the controlled copy of any SOP is not permitted. Refer to §10.5.1 for additional information on SOPs.

SOPs are proprietary documents and ACZ does not distribute them freely. Any copy sent electronically or otherwise to an outside party is considered uncontrolled, and the recipient understands that additional changes can be made without prior notification. The use of uncontrolled copies of SOPs is not permitted on site unless approved by QA, and such documents will be initialed and dated by QA personnel when issued.

Before a new procedure, application, or instrument can be implemented, an SOP must be developed. Following QA review, an effective "working draft" will be issued to allow the user(s) to "fine-tune" the document. If a client requests a procedure for which there is not a published method or an existing SOP, ACZ will utilize the process described in the SOP *Client Service Policies and Procedures* (SOPAD043). Analytical SOPs are written in accordance with the NELAC Standards and must include or reference the following items, where applicable:

1) identification of the test method
2) summary, scope & application of the test method, including matrices & components to be analyzed
3) references, including documents provided by instrument / equipment manufacturer
4) sample collection, preservation, & storage
5) equipment & supplies
6) reagents & standards, including storage conditions & shelf-life for each
7) safety
8) interferences
9) complete procedure, including details and acceptance criteria for initial & continuing calibration
10) data review & assessment, including protocols for handling out-of-control or unacceptable data
11) quality control, including acceptance criteria & corrective action for handling failed quality control
12) calculation equations (dilution factors, RPD, % recovery, etc.) & calibration formulas
13) method detection limit & reporting limit
14) method performance, including Demonstration of Capability and Method Detection Limit procedures
15) pollution prevention & waste management
16) definitions
17) tables, diagrams, flowcharts

2.3 Training

It is the responsibility of ACZ's management to ensure the competence of all employees who perform environmental tests and other specific duties, operate equipment or instrumentation, give opinions and interpretations, evaluate results, and sign test reports. Additionally, ACZ management is responsible for formulating the goals and policies with respect to the necessary education, training, and skills of all personnel and for providing training that is relevant to the company's present and anticipated tasks.

Employees must possess the appropriate combination of education, experience, and skills to adequately demonstrate a specific knowledge of their particular functions and to carryout those functions in a manner that meets or exceeds ACZ's standards and expectations. Additionally, each staff member must demonstrate an understanding of laboratory operations, test methods, related quality assurance and quality control procedures, and management of records and documents to the extent necessary to successfully perform their job duties.

All full-time and part-time personnel must complete a formal training process for Safety, Ethics, Quality Assurance / Quality Control, and Sexual Harassment on the first day of hire and are subsequently responsible for complying with all requirements that pertain to their organizational functions. For all technical staff, training for analytical procedures must be completed prior to independent generation of client data, including Proficiency Testing samples. In general, any staff member who is undergoing training must be provided with appropriate supervision. It is the responsibility of each supervisor or manager to ensure personnel within his or her department is supervised, competent, and is working in accordance with ACZ's Quality System.

2.3.1 Safety Training

Safety training is scheduled with ACZ's Chemical Hygiene Officer and includes viewing a video of general laboratory safety, a complete review of ACZ's Chemical Hygiene Plan, and a building tour to identify the location of Material Safety Data Sheets, emergency showers, eye wash stations, and emergency exits. Following completion of the training, the employee takes an exam, which allows the CHO to evaluate his/her understanding of the material covered.

2.3.2 Data Integrity Training

ACZ is committed to fostering and enforcing an ethically sound work environment that encourages the conscientious production of accurate, technically sound and legally defensible data. Initial and follow-up data integrity training is required for all full-time and part-time employees (permanent or temporary) as described in ACZ's SOP *Data Integrity Principles & Policies* (SOPAD039). Initial training provides a general introduction to ACZ's Ethics program, ACZ's Code of Conduct, Code of Ethics, and zero-tolerance policy. Each new employee is also introduced to the company's Ombudsman. Follow-up training is provided within 30 – 60 days and includes a more in-depth review of unacceptable practices. The employee is required to read SOPAD039 prior to attending the session. On an annual basis, a review of SOPAD039 and exercises in making ethical decisions, as well as other relevant information, are presented to all employees.

2.3.3 QA Training

2.3.3.1 All full-time and part-time employees attend an initial orientation session, which is based on the most current version of ACZ's Quality Assurance Plan [QAP] and focuses on the relationship between quality control, quality assurance, environmental testing, and environmental monitoring.

2.3.3.2 Follow-up training is completed within 30 – 60 days and includes a more detailed review and discussion of QA policies and procedures. By this time, employees are expected to be familiar with their responsibilities and have a general understanding of ACZ's operations. The employee must read ACZ's QAP and any pertinent supporting SOPs prior to attending the training, and should prepare questions in advance, as material in each document will be reviewed and an opportunity to seek clarification will be provided. The supervisor must schedule sufficient time for the employee to read all pertinent documents prior to follow-up training.

2.3.3.3 A performance review will be conducted for a new employee after 90 days from the hire date. The review is conducted by the supervisor and is based on general work performance, supervisor observations, and feedback from the QA department.

2.3.4 Sexual Harassment Training

Sexual Harassment training is required for each new employee and includes viewing a video that demonstrates the identification, reporting, and remediation of harassment issues in the work place.

2.3.5 Technical personnel must be thoroughly trained in the analytical techniques and operating principles for all pertinent method procedures. Under no circumstances may any analyst independently generate or review client data for a test procedure before completing the required training and receiving the explicit approval of the QA department. §5 provides details of ACZ's technical training program.

2.3.6 An employee performing only data AREV or SREV functions must be appropriately trained regarding QC requirements, corrective action(s), and data qualification criteria stated in the effective version of the test SOP. The trainee must first read the SOP, and then review all pertinent information with the department supervisor. Items covered during training must be documented using the appropriate form, and both the supervisor and the trainee must sign the form. Thereafter, the effective version of the test SOP must always be used for data review.

2.3.7 Continuing training must be documented and at a minimum, the documentation must certify that the employee has read, understands, and agrees to follow the effective version of a revised SOP or other in-house document. The department manager is required to meet with their staff to review the change(s) and to ensure each employee fully understands the change(s). Training is documented using either FRMQA023 or FRMQA030, whichever is most appropriate.

2.3.8 Training is required for all employees whose activities are affected by any procedural change(s) to an SOP and is considered to be complete once the department supervisor has reviewed the change(s) with all pertinent staff members and each employee has subsequently initialed and dated the changed item(s) on the SOP Revision form (FRMQA030). SOP revisions must be covered during initial method training and data review (AREV/SREV) training. FRMQA004 & FRMQA012 may also be used to document training on SOP revisions providing the training dates on these documents post-date the revisions.

2.3.9 ACZ recognizes the benefit of continuing education and encourages employee participation in advanced training courses, seminars, and professional organizations and meetings.

2.4 Audits

The purpose of any audit is to verify performance and compliance to documented Quality Assurance and Quality Control policies and procedures, and to identify discrepancies when they exist. In the latter case, any problems must be addressed and resolved in an appropriate manner in order to assure the Quality System is continuously improved on all levels.

2.4.1 External Audits

External audits are conducted to ascertain compliance with rules, regulations, and additional criteria for certification, and will have a higher degree of formality than internal audits. Where mandatory records are required, compliance with such will be critically evaluated. The search for any corrective actions and the correction of problems identified in a previous audit will also be an important activity. The ease with which important records and information can be retrieved is a criterion for judgment of the management practices of a laboratory and may dictate the depth of the audit. Individual state agencies, its NELAC Primary Accrediting Authority, and current and potential clients typically audit ACZ.

The on-site assessment is generally a two to four day process during which the regulating agency conducts an entrance interview and tours the facility before performing an in-depth review of documents, workgroups, reports, electronic data files, etc. A critical aspect of the on-site assessment is review and verification of bench-level documentation and analyst interviews to determine actual laboratory practices. It is ACZ's policy to always have QA personnel present during an interview. If necessary, the President or Production Manager may attend the interview. An exit interview is conducted upon completion of all on-site assessment activates, during which observations and findings are reviewed. The agency will submit a final report to ACZ, generally within 30 days, detailing all pertinent findings and recommendations.

Upon receipt and review of the agency's report, the QA department will meet with each department manager to develop a corrective action plan, which must be submitted to the agency by the date indicated in their report. Each finding or group of similar findings is addressed as a major corrective action as described in §2.5.2. Employees may not make changes to any laboratory or other practice based on comments or opinions expressed by the regulating agency during an interview or any other stage of the on-site assessment. ACZ will revise polices and procedures as necessary upon completion of the major corrective action process. The audit report and all subsequent corrective actions are thoroughly documented, and all documentation is retained for at least five (5) years.

2.4.2 Internal Audits

ACZ is responsible for the quality of its data and must take reasonable efforts to assure itself and all interested parties of the confidence that can be placed in it. To this extent, internal audits of its activities must be conducted to verify continued compliance with the Quality System. It is the responsibility of the QA Officer to plan, direct, and organize internal audits; however, a trained and qualified individual, independent from the area or system being audited, may be designated by the QA Officer to conduct an internal audit. The area of activity audited, the audit findings, and subsequent corrective actions must be documented, and all documentation must be retained for at least five (5) years. At a minimum, all TNI certified methods are audited triennially with at least one method from each department audited annually.

Whenever any internal audit finding casts doubt on the effectiveness of the operations or on the correctness or validity of the test results, timely corrective action must be taken, and the client(s) must be notified in writing, as soon as the extent of the problem can be determined, if investigations show that the laboratory results have been affected.

At a minimum, internal audits are conducted for the following departments. Method audits performed for all analytical departments listed below encompass both qualitative evaluation of the operational details of the QA program and quantitative evaluation of the accuracy of data generated by the laboratory staff. These evaluations do not include the real-time review of laboratory raw data or final reports for routine quality control sample verification.

- Log-In
- Reporting
- Wet Chemistry Manual
- Wet Chemistry Instrument (Prep and Analytical)
- Metals (Instrument & Prep)
- Soils
- Radiochemistry (Prep and Analytical)
- Organics (Prep and Analytical)

More frequent internal audits may be scheduled depending on the following criteria:

- Number and type of corrective actions filed for a method or activity
- Client complaints
- Continued failure to achieve acceptable results for a Proficiency Testing sample
- Findings from an external audit
- Request from management

All findings from internal audits are directed through ACZ's corrective action system. Each finding is assigned a corrective action number (similar findings may be combined). A general description of the process is as follows:

1) Findings and observations are summarized in a report.

2) The report is distributed to the department supervisor, Production Manager, and President.

3) The supervisor reviews the report with their staff, develops, and composes a plan of corrective action (POC) and estimated completion date for each finding. The POC should be proportional to the finding and the estimated completion date commensurate with the demands of the tasks required for the corrective action.

4) The supervisor submits the plan of corrective action to the QA Officer or designee for review and approval.

5) The QA Officer or designee reviews the plan of corrective action for each internal audit finding. Once the plan of corrective action is accepted, a major corrective action number is assigned to each planned corrective action or group of similar corrective actions.

6) The supervisor negotiates the corrective action and submits a Corrective Action Report (FRMQA001) for each major corrective action number to the QA department for final review.

7) Once all corrective actions associated with the internal audit have been completed and approved, the internal audit process is complete.

Additionally, an in-depth review will be conducted if there is any evidence of inappropriate actions or vulnerabilities related to data integrity. This review shall be handled in a confidential manner until a follow up evaluation, full investigation, or other appropriate actions have been completed and the issue(s) clarified. Refer to ACZ's SOP *Data Integrity Policies & Procedures* (SOPAD039). All documentation related to the investigation must be maintained for at least five (5) years.

2.4.3 Electronic Data Audits

Periodically ACZ performs or hires a third party auditing firm to perform a full level audit of analytical data, either on-site or off-site. The auditing firm or internal auditor provides ACZ management with a report citing the deficiencies and recommendations. After review of these findings by management, the QA Officer, and the production supervisor, corrective actions are initiated to ensure that any deficiencies are rectified.

2.4.4 Proficiency Testing [PT] Program

ACZ is required to participate in a formal Proficiency Testing Program at the frequency stipulated by regulating agencies. These "performance audits" are facilitated through the introduction of blind samples, purchased from approved vendors. ACZ analyzes PT samples for most accredited parameters twice in a calendar year, with each study being approximately six (6) months apart. These tests are analyte, matrix, and technology specific, but are not method specific, and provide useful information regarding the accuracy of the analytical data being produced. ACZ participates in the Water Supply (WS) study for SDWA, the Water Pollution (WP) study for CWA, the Soil and Underground Storage Tank studies for RCRA, and Radiochemistry PT study for Drinking Water.

Following log-in, the PT sample is prepared by the analyst according to the vendor's instructions and is then analyzed in the same manner as client samples as described by the test SOP. **NOTE:** Analysts must record the date of preparation (and time of preparation if the holding time is $\leq$ 72 hours) on the subsample container and on the associated workgroup bench sheet(s). Analysis must be performed as soon as possible after diluting the concentrate, as indicated in the vendor's instruction pamphlet. Metals analyses must be completed within 48 hours of diluting the concentrate, as indicated in ACZ CAR519, unless the diluted concentrate will be digested prior to analysis.

Data is compiled by the QA department and reported to the vendor no later than the study close date. The vendor evaluates the data as "acceptable," "not acceptable," or "check for error" by comparing the reported values to statistically derived acceptance criteria and issues a report within 21 days from the study close date. Upon receipt of the report, the QA department initiates a major corrective action for the PT study if any "not acceptable" results were reported. Each production supervisor must investigate all "not acceptable" results for their department, indicate possible causes and determine the appropriate corrective action(s) by the designated due date. If necessary, the QA department will order follow-up samples to confirm the system deficiency has been corrected. Refer to ACZ's SOP *Proficiency Testing Program* (SOPAD011) for additional information.

Strict rules apply regarding the exchange of information for any PT sample:

- ACZ shall not send any PT sample, or a portion of a PT sample for accrediting purposes to another laboratory for any analysis.
- ACZ shall not knowingly accept any PT sample or a portion of a PT sample for accrediting purposes from any other laboratory.

- Employees of ACZ shall not discuss PT data results with any other person outside of the laboratory, in particular any person associated with another laboratory.
- Employees of ACZ shall not attempt to obtain the results or assigned values of any PT sample from our PT Provider prior to the close of the study.
- PT samples shall not be used for batch duplicates or spikes.

2.5 Corrective Action

When any problem, deviation or failure is identified within the Quality System or when any change is made to a previously documented company-wide protocol, a corrective action must be initiated. Corrective actions are a fundamental element of ACZ's QA Program, as a successful Quality System requires the identification of deficiencies and depends on the development, implementation, and documentation of effective contingency plans and resolutions to effectively address the deficiencies.

Problems can ordinarily be classified two ways: 1) undesirable but not critical or 2) critical and requiring immediate action. To this extent, ACZ utilizes two types of corrective actions: Minor and Major. A minor corrective action pertains to any temporary deviation from a policy or procedure and may be initiated by any employee in order to resolve an immediate problem that is isolated or may impact only one workgroup or several related workgroups. Minor corrective actions do not require QA follow-up. Major corrective actions address system-wide errors or failures and require the root cause(s) of the error or failure to be determined and the resolution to be documented and implemented.

2.5.1 Minor Corrective Action

The minor corrective action report (FRMQA001) allows for complete documentation of any temporary deviation from the SOP or other protocol. The employee who initiates the corrective action will complete Section 1 of the report. Documentation must be accurate and must provide a complete detailed explanation of the situation for future reference. The department supervisor should always be informed of the need for a minor corrective action and may provide additional information in the appropriate section. The project manager may also provide additional information in the appropriate section if necessary. QA does not need to close a minor corrective action; however, the employee may review the report with QA personnel and request their signature in the appropriate section.

Complete documentation may be provided either on the workgroup bench sheet or on the data review checklist in lieu of using FRMQA001 if the deviation applies to a limited number of workgroups. Use FRMQA001 if the deviation applies to many workgroups and attach a copy of the completed form to each workgroup before the workgroup is scanned. If the report is generated after the workgroups have been scanned, then the workgroup must be retrieved and rescanned with the report included as part of the data package. In this case, a note is made on the front page of the workgroup package indicating the reason the workgroup was rescanned (i.e. "CAR attached, WG rescanned"). If appropriate, a minor corrective action will be addressed in the case narrative of the client report.

2.5.2 Major Corrective Action

It is the responsibility of the QA Officer to notify laboratory management in writing of departures from the Quality System, and it is the responsibility of the laboratory management to ensure that any corrective action that arises is discharged within the time frame indicated on the corrective action report, or additional communication must be provided to the QA Officer (see item 3 below).

A major corrective action is initiated whenever a system failure has been identified or whenever an audit finding or other circumstance casts doubt on the correctness or validity of the analysis result(s). The client must be notified in writing if their work is affected. The QA department will work with the Project Manager to determine if a revised report must be issued to the client. See ACZ's SOP *Client Service Policies and Procedure* (SOPAD043) for details. A major corrective action may also be initiated when the need for preventive action has been identified (refer to §2.5.4).
Only QA department personnel may open and close a major corrective action. When opened, the corrective action will be assigned a unique tracking number (referred to as the CAR number) to ensure that ACZ maintains a complete and

accessible record of all Quality System deviations or failures, root cause determinations and subsequent resolutions, and preventive actions. All associated documentation must be retained for at least five (5) years as described in §10.

Other examples of circumstances requiring a major corrective action include, but are not limited to:

- Contamination trends as indicated by blanks routinely above acceptable levels
- Spikes, surrogates and lab control samples continually outside acceptance limits
- Change to the MDL and/or PQL (RL) for a procedure
- Client inquiries about data anomalies
- "Not Acceptable" Proficiency Testing results
- Results of internal or external audits
- Discrepancies observed at any stage of data review or reporting
- Hold times or deadlines routinely missed
- Evidence of insufficient or inadequate training

Following initiation, the procedure for a major corrective action proceeds to an investigation by the assigned individual to determine the root cause of the problem and to identify possible resolutions to rectify the problem. The action(s) most likely to eliminate the problem and prevent recurrence of the problem must be selected, documented and implemented, and pertinent staff members must be trained, if necessary. Changes resulting from the corrective action will be monitored, if necessary, to ensure the resolution(s) are shown to be effective. A general outline of the procedure is as follows:

1) Initiation: Any employee may initiate a corrective action by notifying QA. The department manager should always be notified first of any problem and then inform QA. If determined to be necessary, QA personnel will open a corrective action and assign a unique tracking number.

2) Assignment: QA assigns the corrective action to the person(s) responsible for performing the "root cause" determination.

3) Investigation and Action: Must be completed within two (2) weeks from the date the corrective action was initiated. The need for an extension must be communicated to the QA department.

    a. The assigned individual(s) perform a "root cause" determination to identify the suspected cause(s) of the problem.

    b. A resolution to correct the problem and prevent its reoccurrence must be determined, and the estimated date by which the resolution will be completed and implemented must be indicated in the appropriate section of the form. Resolution may be done solely by the person(s) who investigated the root cause or it may require input from one or more additional departments.

4) Project Manager Review: If necessary, the PM will determine whether affected data will be accepted or rejected, contact the client, and reissue a revised report if necessary. Project Manager review may not be required for every major corrective action.

5) Conduct additional training if necessary. Training must be documented using the appropriate form and must include a description provided by the person who conducts the training. All trainees are required to sign and date the form to acknowledge he/she has received training, understands the change(s) and agrees to adhere to any change(s) in a policy or procedure.

6) Revise SOP(s). Proposed revisions must be documented on the SOP Revision form (FRMQA030) and approved by QA before trained personnel initial / date and implement the changes. Use FRMQA023 if the changes are incorporated into the SOP and a new effective version is issued.

7) Submit all supporting documentation to QA to be attached to the hard copy of the report.

8) QA reviews the corrective action. If satisfactory, the corrective action is closed and the implementation date is documented in the space provided.

9) If necessary, QA conducts follow-up. Follow-up is scheduled after sufficient time has elapsed to observe the efficacy of the corrective action and may need to be done multiple times. If the corrective action is determined to be ineffective, then a new major corrective action will be initiated and the process repeated.

2.5.3 Technical Corrective Actions

Technical corrective actions apply to departures or deviations from the quality control parameters stated in individual test SOPs. Each test SOP must include all required quality control that applies to the procedure (as stipulated by the method and other regulatory agencies) as well as the performance frequency, acceptance criteria and corrective action for handling failed quality control measurements. Each SOP must describe the procedures to be followed for reviewing and assessing data, including corrective action for handling out-of-control or unacceptable data. The required protocol for technical corrective actions is summarized below. ACZ's protocols are included within the [ ].

1) identify the individual responsible for assessing each nonconformance and initiating or recommending corrective action [analyst who performs AREV]

2) define how the analyst must treat data if associated quality control measurements are unacceptable [§12 of SOP]

3) specify how non-conformance and subsequent corrective actions are to be documented [data review checklist]

4) specify how management reviews the corrective actions [reviewed during SREV]

To the extent possible, samples shall be reported only if all quality control measures are acceptable. If a quality control measure is found to be out of control then the corrective action described in the SOP must be performed. Alternatively, report data with the appropriate qualifier if reprocessing and reanalysis is not possible. The qualifier must be assigned to any sample(s) associated with the failed quality control measure. A current list of all extended qualifiers is available in the LIMS database and may be accessed by all employees.

2.5.4 Preventive Action

Preventive action is a pro-active process to identify opportunities for improvement rather than reacting to the identification of problems or complaints. Needed improvements and potential source(s) of any nonconformance, either technical or concerning the Quality System, must be identified and addressed. Examples of preventive action include but are not limited to: maintaining a cross-trained staff; maintaining a supply of spare consumable parts; monitoring the performance of support equipment; performing routine maintenance on instruments; maintaining an adequate supply of standards/reagents; ordering supplies before running out; completing log-in review in a timely manner; ensuring ACZ can perform work before samples are accepted; correcting quotes before samples are logged in; and analyzing samples by the appropriate method.

2.6 Management Review of the Quality System

At least once per calendar year, ACZ's management conducts a review of its Quality System and all activities related to its environmental testing services to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. At a minimum, the review must take the following into account:

- Status, review, and discussion of major corrective actions
- Results of recent PT studies and corrective actions initiated / completed
- Review of recent external audits
- Review of internal audits
- Presentation of ideas to improve efficiency and productivity
- Presentation of ideas to improve service and data quality
- Status of state certifications
- Feedback from clients
- Feedback from employees
- Ethics Program
- Ombudsman
- Changes in the volume and type of work undertaken
- Other pertinent issues

2.6.1 Department Reports

Each department manager completes a Department Report (FRMQA041) prior to the Management Review meeting. Each item on the report is to be evaluated as it pertains to the individual department. FRMQA041 is provided in APPENDIX D – Forms for Management Review of the Quality System
.

2.6.2 Management Review Report

The completed department reports are submitted to ACZ's President by the specified due date, and the information from each report is reviewed and compiled to complete the Management Review Report (FRMQA042). A copy of the completed report is issued to each manager in advance of the Management Review meeting. At a date / time specified by the President, all managers meet as a group to discuss the report. Other formats may be utilized at the President's discretion. All reviews will be appropriately documented and all documentation retained for at least five (5) years as described in §10 (Control & Storage of Records & Documents). FRMQA042 is provided in APPENDIX D – Forms for Management Review of the Quality System
.

3 ETHICAL AND LEGAL RESPONSIBILITY

All ACZ employees have an ethical and legal responsibility to produce data that is accurate, reliable, and legally defensible. ACZ's proactive program for the prevention and detection of improper, unethical or illegal actions includes the implementation in 2002 of an Ombudsman who acts as a neutral party and serves as a confidential liaison between ACZ employees and upper management regarding questions, problems, complaints, suggestions, or ethical dilemmas.

All employees are educated with regards to ACZ's Code of Conduct and Code of Ethics as well as ACZ's zero-tolerance policy, which is strictly enforced. Additionally, employees are informed about the processes in place to ensure employees are free from any undue internal or external commercial, financial or other pressures that may adversely effect the quality of an employee's work, endanger the trust in the independence of ACZ's judgment, or compromise the integrity of ACZ's environmental testing activities. A more detailed description of all aspects of the ethics program is provided in ACZ's SOP *Data Integrity Principles & Policies* (SOPAD039).

ACZ will not tolerate any unethical or improper activities or behavior. Violation of company policies may lead to repercussions ranging from a severe reprimand to termination, and possible criminal prosecution if warranted by the situation. ACZ has access to many resources that may be utilized at any time to help clarify any situation determined to be a "gray area." Employees are strongly encouraged to seek further guidance from a supervisor, ACZ's Ombudsman, President, or QA staff whenever doubt is raised. Activities that will not be tolerated include, but are not limited to:

- **Misrepresentation of a procedure or documentation** – Intentionally performing a job duty in a manner that does not comply with a documented procedure, including but not limited to a test SOP or method used for sample analysis; providing inaccurate and misleading documentation associated with a data package or failing to provide the necessary documentation as part of a data package.

- **Falsifying Records** – Providing false information on personal credentials, resumes or educational transcripts, logbooks, raw data and client reports, or creating data without performing the procedure (also known as dry labbing).

- **Improper peak integration** – Intentionally performing improper integration of data chromatograms so quality control samples meet acceptance criteria. This is also known as peak shaving or peak enhancing.

- **Improper clock setting** – Readjusting the computer clock so that it appears samples were analyzed within hold times.

- **Improper representation of Quality Control samples** – Failing to treat batch quality control samples in the same manner as client samples (including Proficiency Testing samples) or misrepresenting any type of quality control sample associated with the preparation batch and/or analytical batch.

- **Improper calibration** – Intentionally performing improper manipulation of calibration data or forging tune data so that it meets acceptance criteria.

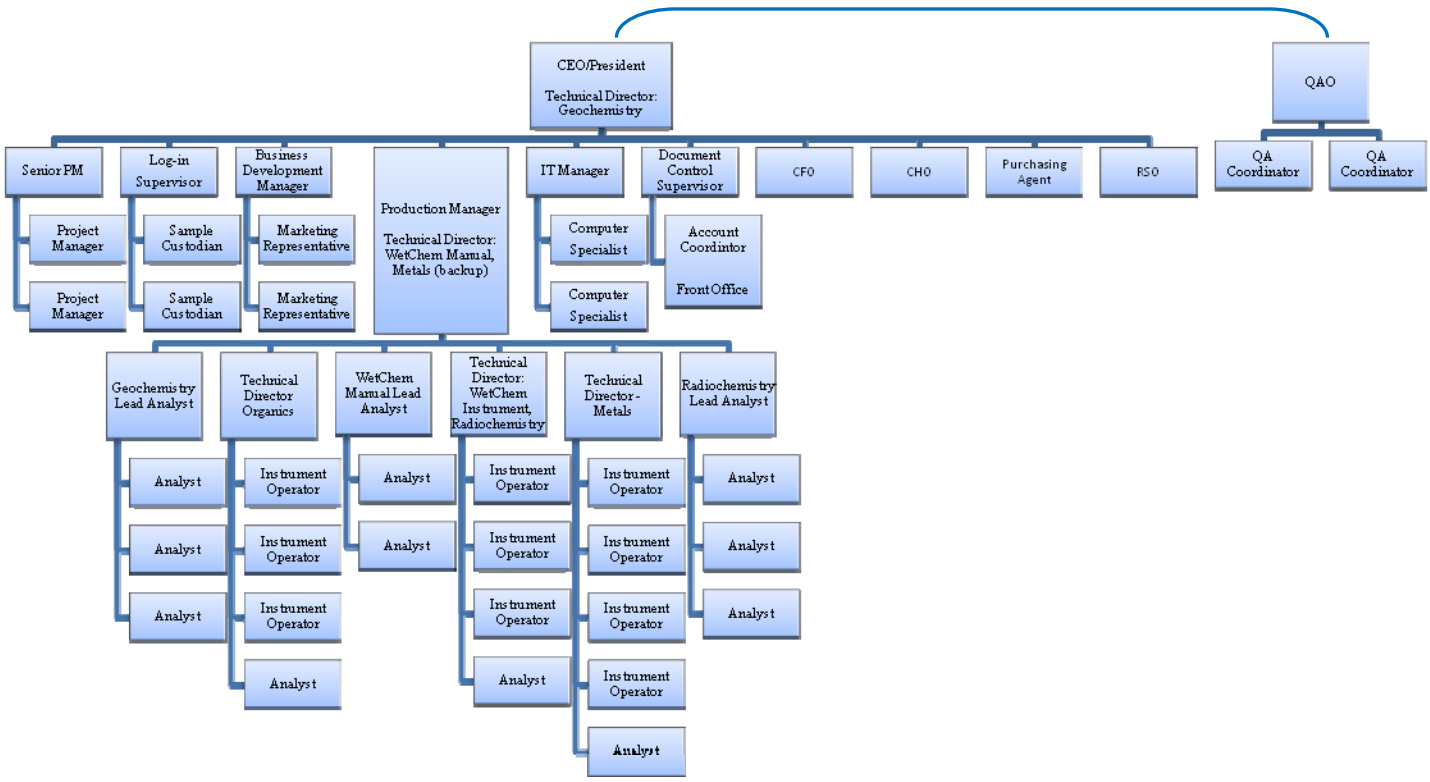
- **File Substitution** – Replacing invalid data with valid data from a different time so the analysis appears to be successful.

4 PERSONNEL AND RESPONSIBILITIES

Due to the nature of regulatory oversight and the increasing demands of the environmental lab industry, QA issues permeate all aspects of our business, the largest and most critical of which are operations (production). On a daily basis, QA and Production must efficiently function together to consistently provide our clients with technically sound and legally defensible data and to ensure the Quality System remains an integral part of all areas within ACZ. The President must rely on regular input and feedback from ACZ's QA Officer and Production Manager, and to this effect, upper management is defined as ACZ's President, QA Officer and Production Manager. It is the responsibility of upper management to document company policies, objectives, systems, programs, procedures, and instructions to the extent necessary to assure the quality and defensibility of all data.

ACZ is organized such that the President also works directly with and relies on input and feedback from the Senior Project Manager, Business Development Manager, Production Supervisors, Document Control Supervisor, IT Manager, Chief Financial Officer, and Chemical Hygiene Officer. These individuals are responsible for managing both the day-to-day operations and long-term goals within their respective areas. It is the responsibility of all managers to ensure that all documented ACZ policies and procedures, including those in the QAP and associated SOPs, are communicated to, understood by, made available to, and implemented by ACZ personnel.

Figure 4-1. Employee Organizational Chart



4.1 President/CEO

The President is ultimately responsible for all analytical and operational activities of the laboratory and must ensure that 1) the laboratory carries out all environmental activities in such a way as to meet the requirements of the TNI Standards and 2) the laboratory satisfies the needs of the client and the regulatory authorities. General duties involve budgeting for all departments, making decisions on capital equipment and automation; developing company policies and benefits; addressing personnel issues such as hiring, firing, and promotions; and working with clients on various matters. Day-to-day responsibilities include providing direction to all laboratory departments including laboratory operations, accounting, marketing, QA, and client services. Additional responsibilities are as follows:

- Work directly with ACZ's Ombudsman to provide and maintain a mechanism for confidential reporting of ethical/data integrity issues as well as issues that may directly affect current ACZ policies.
- Define the minimal level of qualification, experience, and skills necessary for all laboratory positions.
- Provide the QA Officer with defined responsibility and authority for ensuring the successful development, implementation, and management of ACZ's Quality System.
- Provide the Production Manager with defined responsibility and authority for ensuring the technical operations and provision of resources needed to maintain the required quality of laboratory operations.
- Provide adequate supervision of environmental staff by persons familiar with methods and procedures, purpose of each test, and assessment of the test results.
- Ensure all technical staff has demonstrated capability in the activities for which they are responsible and ensure that the training of each member of the technical staff is kept up-to-date.
- Ensure the QA Officer has access to the highest level of management at which decisions are made on laboratory policy or resources.
- Provide managerial staff the authority and resources needed to discharge their duties.
- Provide technical personnel the resources needed to discharge their duties.
- Specify and document the responsibility, authority, and interrelationship of all personnel who manage, perform or verify work affecting the quality of calibrations and tests.
- Implement appropriate and current guidelines for all lab methods and procedures to ensure data quality and efficiency of analyses. Ensure all method protocols utilized by ACZ meet the QC requirements as established by EPA or other governing agency.
- Document all policies and procedures related to the analytical and operational activities of the laboratory.
- Provide support to technical staff to ensure timely completion of all laboratory work, and develop contingency plans to ensure workflow progresses as planned.
- Meet quarterly (or more often) with the QA Officer and Production Manager.

4.2 QA Officer

The QA Officer reports directly to the President; however, the QA department is considered a separate entity from operations in order to assure data is evaluated objectively and assessments are performed without outside (i.e. managerial) influence. The QA Officer has direct access to the President, and is therefore able to discuss and/or resolve all concerns, policies, etc. related to quality assurance or quality control. The primary responsibility of the QA Officer is to develop, implement, and manage all aspects of ACZ's Quality System, and he/she may take any action necessary to ensure all ACZ employees adhere to all policies, procedures, and objectives documented in ACZ's QAP, SOPs, memorandums, emails, etc. If warranted, the QA Officer has the authority to halt the performance of a single method or the production of a department, and if necessary, the operations of the entire laboratory, and will grant permission to resume when satisfied that the issue(s) have been resolved. Additional responsibilities include but are not limited to those stated in FRMAD060 and the following:

- Review and revise ACZ's QAP and provide training for all employees following approval of a new version.
- Provide QA orientation to new employees.
- Meet quarterly (or more often) with the President and Production Manager.
- Work with department managers to develop and improve training protocols.
- Conduct department training sessions as needed to address specific problems and questions.
- Arrange for or conduct internal audits; notify management of deficiencies; and track corrective actions.
- Organize all external audits; notify management of deficiencies; and assign and track corrective actions.
- Review and approve SOPs (may designate responsibilities to QA Coordinator).
- Meet at least quarterly with Production Supervisors to provide information, respond to questions, etc.
- Manage Proficiency Testing (PT) program (may designate responsibilities to QA Coordinator).
- Coordinate and maintain all regulatory and client certification programs.
- Review and validate a determined percentage of all data packages from Log-in to Reporting.
- Work with marketing/client service representatives on QA aspects of proposals.
- Work with Project Managers and the Production Manager to resolve client feedback regarding data quality.
- Review and maintain records and documentation for audits, certifications and all other QA issues.
- Schedule electronic data audits with third-party.

  Qualifications:

  - General knowledge of the analytical test methods
  - Documented training and/or experience in QA procedures
  - Knowledge of the Quality System as defined under NELAC

4.3 QA Coordinator

The QA Coordinator reports directly to the QA Officer and assists the QA Officer with the development, implementation, and management of the Quality System. Primary job responsibilities are as follows:

- Review and maintain records/documentation for employee training including DOCs, MDLs, etc.
- Provide initial QA orientation to new employees.
- Provide follow-up QA training to new employees.
- Schedule analyses and compile and report data for Proficiency Testing (PT) program, including DMRQA.
- Initiate and track corrective actions related to PT samples and manage all documentation associated with analyses.
- Review and approve SOPs.
- Conduct internal audits, notify management of deficiencies; and track corrective actions.
- Conduct department training sessions as needed to address specific problems and questions.
- Update control chart-generated QC limits in the LIMS database as needed.
- Monitor control & calibration of support equipment

Qualifications:

- General knowledge of the analytical test methods
- Documented training and/or experience in QA procedures
- Knowledge of the Quality System as defined under NELAC

4.4 Production Manager

The Production Manager reports directly to the President. General duties involve working with analytical department supervisors on a daily basis to prioritize client projects and QA deadlines and to track sample analyses in order to maintain acceptable turn-around-times for project completion. The Production Manager also addresses personnel, instrumentation, and reagent/supply issues that may affect the completion of the scheduled work and works directly with the QA department to ensure all Quality System requirements pertaining to production are successfully completed in a timely manner. Additional responsibilities are described in FRMAD060.

- Conduct weekly meeting with Production Supervisors to discuss current and upcoming workload, scheduling, priority projects, QC requirements, instrument / equipment issues, personnel, etc.
- Schedule QA work (MDL studies, DOCs, PT sample analysis, SOP revisions, etc.) with department supervisors in order to ensure QA requirements are kept up-to-date.
- Meet at least quarterly with the President and QA Officer.
- Communicate with Project Managers regarding project/instrument status. Notify PMs if problems exist that may affect the project completion date.
- Work with marketing/client service representatives on production aspects of proposals.
- Work with Project Managers and the QA Officer to resolve client feedback regarding data quality.
- Perform checks of sample status using LIMS database to help the laboratory staff meet all established hold times and to determine that analyses can proceed as scheduled to meet required turn around times.
- Provide hands-on support to analysts when necessary to ensure timely completion of all laboratory work, and develop contingency plans to ensure workflow progresses as planned.
- Work with QA Officer to develop and improve training protocols, conduct department work sessions to address specific problems and questions.

  Qualifications:

  - General knowledge of the analytical test methods
  - Minimum four (4) years of laboratory experience
  - Minimum two (2) years of supervisory experience
  - General knowledge of lab-wide systems (including but not limited to log-in and reporting)

4.5 Production Supervisor

Each Production Supervisor is a full-time employee who reports to the Production Manager and exercises day-to-day oversight of laboratory operations for their specific area(s) of expertise. Each supervisor must be familiar with the test methods and related theory and instrumentation, as well as the assessment of results. In addition to monitoring the standards of performance, validity of all analyses, and quality of all data generated in their respective department(s), each supervisor is also responsible for ensuring that a new analyst has successfully completed all training requirements and is adequately prepared to commence work on client samples. Additional responsibilities are described in FRMAD060. If any supervisor is absent for more than 15 consecutive calendar days then another full-time staff member meeting the required qualifications will be assigned to perform the supervisor's duties.

Required Qualifications for a Production Supervisor:

1) Chemical analyses (Organics & Metals): BS or BA in chemical, environmental, biological sciences, physical sciences or engineering, with a minimum of 24 college semester credit hours in chemistry and at least two (2) years of experience in the environmental analysis of representative inorganic and organic analytes for the which the laboratory seeks or maintains accreditation. A masters or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

2) Inorganic Chemical analyses (other than Metals): At least an earned associate's degree in the chemical, physical, or environmental sciences, or two (2) years of equivalent and successful college education, with a minimum of 16 college semester credit hours in chemistry and at least two (2) years of experience performing such analyses.

3) Radiological analyses: BS or BA in chemistry, physics, or engineering, with at least 24 college semester credit hours in chemistry and at least two (2) years of experience in the radiological analyses of environmental samples. A masters or doctoral degree may be substituted for one (1) year of experience.

4.6 Business Development Manager

ACZ's Business Development Manager reports directly to the President and supervises all Client Service Representatives, each of who conducts marketing and sales efforts on behalf of ACZ with potential, new and existing clientele, and develops and maintains long-term relationships with customers by working with Project Managers when necessary. Additional responsibilities of the Business Development Manager are described in FRMAD060. ACZ's Client Service staff is authorized to review all contractual agreements with clients, review all proposals and develop price quotations for routine and non-routine analytical projects.

4.7 Project Manager (PM)

The Senior Project Manager reports directly to the President and is responsible for overseeing the PM department. Additional responsibilities of the Senior PM are described in FRMAD060. Each Project Manager serves as the primary laboratory contact for each ACZ client, handles all client service requests, and investigates and resolves any problem brought to ACZ's attention by the customer. In order to provide consistency, each PM is assigned a list of clients, and it is the primary responsibility of each PM to ensure all of their client project needs are managed on a day-to-day basis and met in a timely manner and that all data submitted to the client is of high quality. All PMs work directly with the Production Manager and Production Supervisors regarding client data issues (due dates, hold times, retests, data quality, etc.), with Document Control regarding client reports and with the QA department regarding data quality questions or concerns.

4.8 Instrument Operator

Instrument operators report directly to the respective Production Supervisor. The position involves the analysis of various matrices for trace level contaminants using specialized and technical instrumentation, and each operator must be capable of performing all job duties in an accurate and proficient manner. Education will be verified by providing a copy of a college transcript or diploma, which is maintained in the employee's personnel file. Experience is verified by ACZ's CFO prior to completing the hiring process (verbal or documented verification provided by each reference listed on a resume or application is acceptable). The operator must demonstrate understanding of related theory, mathematics, analytical instrumentation and data interpretation. This work is predominantly intellectual and involves the continuous use of professional and sound judgment. The employee must meet or exceed all requirements for generation of litigation-quality data and must also continue to demonstrate increased proficiency regarding the interpretation of the data as well as the operation and troubleshooting of the assigned instrument(s). These improvements should be attainable through ongoing efforts in-house as well as through specialized instruction at off-site locations. Prerequisites regarding education and experience, as well as job responsibilities and performance expectations are described in FRMAD059. Exceptions pertaining to experience or education will be made on a case-by-case basis.

Qualifications:

- BA or BS in Chemistry or related science or a minimum of 3 years of relevant experience in lieu of degree
- Prior laboratory experience is preferred but is not required.
- Successful completion of training by supervisor or proficient instrument operator

4.9 Laboratory Analyst [Technician]

The laboratory technician reports directly to the respective Production Supervisor. The position involves analysis of various matrices using appropriate analytical techniques and support equipment as well as preparation of samples for instrument analyses. Each technician must be capable of performing all job duties in an accurate and proficient manner. Education will be verified by providing a copy of a college transcript or diploma, which is maintained in the employee's personnel file. Experience is verified by ACZ's CFO prior to completing the hiring process (verbal or documented verification provided by each reference listed on a resume or application is acceptable). The technician must demonstrate understanding of related principles and mathematics, must possess common sense and mechanical skills, and must seek professional judgment from the supervisor as necessary. The employee must meet or exceed all requirements for generation of litigation-quality data as well as sample preparation tasks and routine analyses, and must also continue to demonstrate continuous improvements. These improvements should be attainable through ongoing training efforts in-house as well as through training opportunities at off-site locations. Prerequisites regarding education and experience, as well as job responsibilities and performance expectations are described in FRMAD058. Exceptions pertaining to experience or education will be made on a case-by-case basis.

Qualifications:

- BA or BS in Chemistry or related science is preferred but is not required
- Prior laboratory experience is preferred but is not required
- Successful completion of training period by supervisor or proficient technician

4.10 Information Technology (IT) Manager

The Information Systems Manager reports directly to the President and is responsible for the oversight of the IT department regarding the installation and maintenance of ACZ's computer network and all hardware and software and related equipment deployed on the premise. Additional responsibilities are described in FRMAD060. The department is also responsible for developing, maintaining, and improving custom written applications for laboratory automation and efficiency as well as for ACZ's Oracle database, Intranet (Labweb), Internet and electronic diskette deliverables (EDDs).

4.11 Log-In Supervisor

The Log-In Supervisor reports directly to the President and is responsible for the oversight and management of all department personnel and operations. Primary responsibilities include fulfillment and shipment of bottle orders to the client's destination in a timely manner, receipt of all incoming samples, evaluation of all incoming samples against ACZ's Sample Acceptance Policy, entering samples into the LIMS database, and performing timely review of all logged samples. Additional responsibilities are described in FRMAD060.

4.12 Document Control Supervisor

The Document Control Supervisor reports directly to the President and is responsible for the oversight of the Document Control department. Primary responsibilities include the generation of client reports and EDDs and the maintenance, organization and control of all hard copy data and records, including workgroup data, client reports, CCOCs, QA records and documents. Additional responsibilities are described in FRMAD060.

4.13 Chemical Hygiene Officer (CHO)

The Chemical Hygiene Officer is primarily responsibilities for oversight of ACZ's documented Chemical Hygiene Plan, conducting initial and refresher safety training for all employees, monitoring exposures, and maintaining records for Material Safety Data Sheets, injury reports, chemical exposure reports, etc. Additional responsibilities include as working with management to develop and implement policies to improve the program. The person designated as CHO must have completed at least one basic laboratory safety course and has one year's experience performing laboratory work, preferably with responsibility for at least one area of laboratory safety.

4.14 Radiation Safety Officer (RSO)

ACZ Laboratories, Inc. must always have a RSO while the Radioactive Materials License is active. The President appoints a Radiation Safety Officer to act as his/her representative in implementing the Radiation Safety Program. The RSO's responsibilities include developing radiation safety guidelines in accordance with Nuclear Regulatory Commission (NRC) rules and regulations, and for assuring compliance with those guidelines by ACZ personnel. The RSO will work with ACZ's administration to implement policies and seek ways to improve the safety program. The person designated as RSO must have completed a Radiation Safety Course or have at least 3 years of experience prior to being officially designated as the RSO. The RSO reports directly to the President of ACZ.

4.15 Chief Financial Officer (CFO)

ACZ's Chief Financial Officer is primarily responsible for all financial matters including payroll, accounts receivable, accounts payable and financial statements; monthly and annual balance and profit and loss statements; and assisting with annual budget preparation. In addition, the CFO maintains and monitors the security system and electronic time clock, invoices client projects from the database, updates customer account information, acts as the administrator for 401k/Profit Sharing Plan, maintains and executes the Employee Benefits Manual and assists in hiring process by posting job openings, scheduling qualified candidates for interviews, checking references, and ensuring a new employee provides proof of education.

4.16 Purchasing Agent

Primary responsibilities include generating material requisitions and tracking all subsequent purchase orders; inspecting all incoming goods; generating PCNs for all incoming standards, reagents, and chemicals; tracking and maintaining an adequate supply of laboratory consumables.

5 TECHNICAL TRAINING

Prior to the independent generation or review of data for client samples (including PT samples), all analysts must undergo a formal, documented training process. Technical personnel must be thoroughly trained in the analytical techniques and operating principles and procedures for the methods utilized by ACZ. This process includes but is not limited to: reading the associated published method, reading all related SOPs, improving laboratory skills, learning troubleshooting, maintenance, calibration and operating procedures for pertinent equipment and instruments, and creating workgroups and reviewing data through the LIMS database.

It is the responsibility of the department supervisor to determine that a new analyst is properly trained, has successfully completed all initial training requirements and is prepared to commence work on client samples. Under no circumstances may any analyst independently generate client data before receiving the explicit approval of the QA department.

5.1 The effective version of the test SOP provides the framework for training for all sample preparation and analysis. The SOP is typically based on published approved methodologies (EPA or other) and incorporates any necessary activities and protocols not included in the published method(s) as well as requirements stipulated by other regulatory agencies.

5.2 Training for data AREV or SREV only must be documented as specified in §2.3.6.

5.3 Each employee must be trained either by the department supervisor or by an analyst within the department who is proficient in the area of testing and has been designated by the supervisor. Whenever possible, anyone performing training must meet the following requirements:

1) Documentation of training on the effective version of the test SOP.
2) Documented approval for the analysis.
3) A current IDOC or CDOC.

Exceptions may be granted on a case-by-case basis as approved by the QA Officer.

5.4 Initial training is documented using the Initial Method Training form (FRMQA004). Once training has been completed, the trainee and the instructor fill out the form together to ensure all pertinent information has been addressed and to ensure the trainee comprehends the material and is provided an opportunity to ask questions or request additional training. The trainee's signature is an attestation that he/she has read, understands, and agrees to always follow the effective version of the SOP.

5.5 To demonstrate an aptitude for the procedure, the analyst must perform a successful Initial Demonstration of Capability (IDOC) prior to independent preparation and/or analysis of client samples. Performance is documented using FRMAD023. The data is reviewed initially by the department supervisor and the analyst (AREV), and both individuals must initial and date the review checklist.

5.6 SREV for any preparation workgroup is performed by the department supervisor or a qualified analyst, and SREV for any analytical workgroup is performed by QA.

5.7 Prior to performing an IDOC, a new analyst should be provided sufficient opportunity to practice the procedure. This confirms the analyst understands the procedure and feels comfortable performing the procedure independently. Data associated with any practice is not submitted to QA.

5.8 It is not necessary for the first IDOC attempt to pass; however, the supervisor needs to review the analyst's techniques if multiple attempts do not pass.

5.9 A thorough review of the raw data is performed as part of initial method training and should include particular attention to details not presented in LIMS or on the final report, such as generating final sample concentration from the instrument response provided in the raw data (if applicable), verifying correct standard and reagent traceability.

5.10 Where specified by the method or a regulating entity, and as stated in the test SOP, successful demonstration of performance such as Linear Calibration Range determination (LCR) or Method Detection Limit (MDL) study must be completed prior to independent analysis of client samples.

5.11 All initial training documentation must be submitted to the QA department as a complete package. At a minimum, the package must include:

1) Initial Method Training form (FRMQA004), signed by the trainee and instructor (or department supervisor).

2) IDOC documentation:

- ✓ Completed and signed certification statement (FRMAD023)
- ✓ Workgroup bench sheet, raw data, and all supporting documentation

3) If applicable, MDL study for each instrument. Complete FRMAD031 and attach all related raw data and supporting documentation.

4) If applicable, calibration range study for each instrument. Complete FRMQA029 and attach all related raw data and supporting documentation.

5) For all determinative methods utilizing a calibration curve or average response factor, the Method Calibration Form (FRMQA050).

5.12 Following review of all pertinent training documentation, QA will issue procedure-specific clearance for the trainee to independently generate and review data for client samples. This permission is tracked and may be viewed on a designated location on the public network drive.

1) Approval for preparation procedures is granted after the instrument data has been reviewed and approved.

2) An unapproved analyst who is "shadowing" the trainer (observing, learning the organization of the lab, reagent room, etc.) may not assist with the procedure, and the workgroup documentation must bear only the initials of the trainer, who is fully responsible for the data.

3) If the analyst has successfully completed training for a procedure and generates client data or reviews client data prior to QA approval, then any workgroup(s) or data review checklist must also bear the initials of a proficient analyst, with current approval for the method, who oversees the analyst's work for the procedure and assumes full responsibility for the data. The primary analyst must always be aware that he/she is responsible for the workgroup. The use of another employee's initials without their explicit approval is expressly prohibited.

5.13 The supervisor is responsible for ensuring the training of each analyst is kept up-to-date. Each analyst must read, understand, and agree to follow the effective version of the SOP and continued proficiency must be demonstrated and documented annually for each analyst.

5.14 Each production supervisor routinely conducts department meetings to discuss procedures, work schedules, resources, questions and concerns, problems, QA, etc.

6 SAMPLE COLLECTION & HOLDING TIMES

Sample collection procedures are well documented by the EPA and other agencies, and ACZ's clients are instructed to provide representative samples whenever possible. ACZ supplies its clients with the containers and other materials necessary to maintain sample integrity (to the extent possible) from the time of collection through analysis. Although ACZ does not perform sample collection activities, each project manager or client service representative will assist a client with specific sampling requirements as needed, or when necessary, will direct a client to other resources. The following sections include general information on sample containers, preservatives and holding times, which are essential components in maintaining the chemical and physical properties possessed by the sample at the time of collection.

6.1 Sampling Containers and Preservatives

The EPA outlines the requirements for sample container types, sample volume and preservation. ACZ inventory includes various sizes of plastic and glass containers that range from pre-sterilized to certified-clean by the supplier. Amber bottles are used when specified by the method. Glass containers are obtained from vendors that specialize in the sales of environmental sample containers, and all non-certified bottles are purchased from reputable lab/industry vendors. Refer to FRMAD045 and FRMAD046 for bottles types and preservation techniques for specific analyses. Refer also to APPENDIX A Required Container Type, Preservation Techniques, and Holding Times for additional information regarding EPA requirements container types and preservation.

All sample containers shipped to our clients are new, contain the appropriate preservative(s), and are color-coded to identify preservation and storage. Out-going containers are packed in clean coolers with a copy of ACZ's Sample Acceptance Policy, general directions for sample collection, bottle labels, ice packs, sampling information, blank chain of custody, return shipping labels, and custody seals. Trip blanks and rinsette water are included when requested by the client or when mandated by a specific analytical method. After samples have been collected they are cooled to a temperature > 0 °C and < 6 °C. Samples that require thermal preservation must be maintained within this temperature range until all analyses have been completed.

6.2 Holding Times

The EPA has conducted lengthy studies of sample degradation versus time to establish a maximum holding time for each method, and the results of these studies are compiled into holding-time tables to provide guidelines for litigation purposes. Data for a sample prepared / analyzed outside of the established holding time are the most difficult to defend in court. Holding times will vary slightly from regulation to regulation, thus further emphasizing the need for a client to consult with their Project Manager prior to sample collection. The holding time begins from the time or date of collection in the field. APPENDIX A Required Container Type, Preservation Techniques, and Holding Times outlines holding times (a hold time stated in 40CFR supersedes the published method). **NOTE**: The sampling date for PT samples is the preparation date, which must be documented on the workgroup and the container of prepared sample.

If ACZ Laboratories, Inc. receives samples past holding times or near the expiration of the holding time, sample analysis will proceed unless the client has indicated on the CCOC that an attempt to contact the client must first be made. Analyses performed outside of holding time will be appropriately qualified on the final report. Holding times $\leq$ 72 hours are calculated based on the hour of the sample date/time. Holding times > 72 hours are calculated based on the day of the sample date/time.

In general, and unless otherwise noted in the test SOP, sample preparation and analysis must be completed within the stated holding time. For analyses that extend beyond the intended scope of the method for an analyte or matrix, the hold time stated in the SOP must be met, or samples must be appropriately qualified.

7 SAMPLE CUSTODY & SAMPLE HANDLING

Sample custody begins with the receipt of sample containers from the client and continues beyond preparation and analysis to the proper disposal of primary and secondary sub-samples. Complete and accurate documentation must be provided at all stages of custody. There are many key elements to sample custody including laboratory security, chain of custody records, sample storage, internal custody logs, sample tracking within the laboratory, control of subcontracted work, and sample disposal.

7.1 Laboratory Security

A secure facility is essential to maintaining sample and data integrity and to providing safety to employees and visitors. ACZ has an electronic security system, which controls and limits access to only authorized personnel. The following steps have been taken to ensure this security:

- All entryways are armed and a proximity reader at the east entrance and west shipping entrance allows access to an employee only after he/she passes their card.
- Employees may enter/exit only through the west door at Log-In and the east door next to the lunchroom.
- During normal business hours, public access into the building can be made at the front entrance and the west shipping entrance. Both doors are equipped with a buzzer.
- The outside doors at the west shipping entrance remain unlocked; however, the doors between the vestibule area and sample receiving area are controlled by the electronic security system.
- Building access is limited to specific hours of the employee's shifts.
- All employees are required to use their access cards to enter and exit the building.
- If any employee does not have their access card, they must sign in at the front desk and notify ACZ's CFO. A temporary card will then be activated and issued to the employee for the day. This ensures a record is maintained of which personnel were in the building at any time.
- Visitors must enter and exit through the main entrance and must sign the register at the front desk upon arrival and before departure. A visitor badge is issued at sign in and collected at sign out. There are two types of badges, red & green. A red badge will not function as an access card and symbolizes the visitor requires an escort. A green badge symbolizes the visitor does not require an escort and will function as an access card. The decision to issue a green or red badge is determined, first, by the visitor's trust level and, second, by the visitors access needs. Visitor badges must be collected when the visitor leaves for the day.
- Emergency Exit doors are to be used only for emergency purposes. If a door is opened, a siren alarm will sound.
- It is against company security policy to loan or transfer access cards to anyone, including other ACZ employees. Employees may not allow a non-shift employee to enter the building.
- Vendors and delivery services enter the building via the west shipping entrance.

7.2 Sample Receipt and Log-in

Upon delivery of samples to ACZ, Log-In personnel evaluate the condition of the cooler and custody seals. The custody seals are then broken to retrieve the Chain of Custody (COC), which must be signed by the sample custodian to document the transfer of possession of the samples to ACZ. Once a cooler is opened, the pH of each sample is checked, if necessary, to verify the

method preservation requirements have been met. The pH check is documented along with cooler temperature, radioactivity screen and other pertinent sample information.

Any problems, such as expired hold times, lack of preservative or improper cooler temperature, are noted and the Project Manager must contact the client as soon as possible so that a contingency plan can be initiated if necessary. Samples are logged-in as outlined in the SOP *Sample Receipt & Log-In Procedure / Maintenance of Sample Integrity* (SOPAD016) and are delivered to the assigned storage areas. Following log-in, every project is reviewed by the assigned PM, and upon completion of the review, the client receives an electronic summary, referred to as the "Login Review Report" that details the project information. This summary allows the client an opportunity to make changes to the project before samples are analyzed. Refer to ACZ's SOP *Client Service Policies and Procedures* (SOPAD043) for additional information.

7.3 Internal Custody Logs

Some clients may specify additional custody tracking of the samples once they have been logged in. Internal custody may require that samples are stored in a manner that ensures limited access. The internal custody log (FRMQA015) shall accompany the samples from log-in through completed analysis. The person responsible for the work signs and dates each entry and/or page in the logbook. When all data from a sample set is compiled, copies of all logbook entries shall be included in the final report package. For projects requiring internal custody, ACZ will adhere to the procedure described in the SOP *Client Service Policies and Procedures* (SOPAD043).

7.4 Sample Tracking

Sample flow through the laboratory is facilitated by the use of an Oracle-based LIMS database (Laboratory Information Management System). Every product (requested analysis) logged into the LIMS for a sample has a specific, pre-determined department path. All products have default paths of at least Login Review and Reporting. Between these two departments, a product may go through, for example, Soil Prep and Metal Analysis or Soil Prep, Organic Prep and GC Analysis. At each department step in a product's path, the status can be updated and viewed at any time. Analytical product statuses are defined below. Additional information regarding sample tracking is available in the SOP *Client Service Policies and Procedures* (SOPAD043).

NEED	Prep or Analysis has not been started
WIP	Prep or Analysis has been started (Work In Progress)
PREP	Sample preparation is complete and sample is ready for analysis
UPLD	Analytical data has been uploaded into LIMS
AREV	Analyst has reviewed and accepted analytical data
SREV	Supervisor has reviewed and accepted analytical data
DONE	Analysis or task has been completed
REDO	Sample requires reanalysis
REDX	Sample requires re-digestion/extraction
CANT	Sample preparation or analysis cannot be performed

8 PROCUREMENT, INVENTORY & TRACEABILITY OF SUPPLIES

8.1 Procurement / Inventory

All consumable supplies are purchased from reputable vendors that have been evaluated for service, quality, and price. To the extent possible, materials traceable to national or international standards of measurement are purchased for use in technical operations. Supplies are purchased using ACZ's purchase order (PO) and inventory system database. The Purchasing Agent is not permitted to make a substitution for any material(s) specifically requested unless the department supervisor approves the substitution. Upon receipt, reagents, chemicals, standards, and other laboratory consumables are stored in the Chemical & Supply Room, which has limited access, or are delivered to the laboratory. Refer to ACZ's SOP *Purchase, Receipt, and Storage of Consumable Materials for Technical Operations* (SOPAD037) for additional information.

8.2 Glassware

ACZ uses only laboratory grade glassware. Prior to use, glassware is cleaned using Alconox® or Chemsolve® (or other appropriate detergent) and then rinsed with Type I water. Glassware for trace metals is subsequently rinsed with 50% Nitric Acid and rinse again with Type I water. Glassware for nutrients is subsequently rinsed with 10 or 20% Hydrochloric Acid and then with Type I water. All glassware for organic analyses is washed with Alconox® then rinsed with de-ionized water and kiln-baked. Glassware for radiochemistry analyses is washed first with Contrad70® and then with 50% Nitric Acid and is rinsed with Type I water. Clean glassware must be stored in an enclosed cabinet or other suitable container and/or covered with Parafilm or foil.

8.3 Other Supplies

Routine consumables (centrifuge tubes, autosampler tubes, pipette tips, etc.) are purchased through an automatic system managed by Fisher (RIMS). All other supplies are purchased on an as-needed basis through ACZ's Purchase Order and inventory system database. Refer to SOPAD037 for additional information.

8.4 Traceability of Standards and Reagents

To provide complete traceability, each data package must reference every standard and reagent used for sample preparation or analysis, including but not limited to acids, bases, preservatives, color reagents, pH indicators, buffers, instrument reagents. Each PCN and/or SCN must be documented either on the workgroup bench sheet, data review checklist, or a current standard/reagent form. The open date for all original containers is not tracked in LIMS; however, good laboratory practice dictates that the open date always be noted on the sample container.

8.4.1 Primary Control Number (PCN)

Upon receipt, all stock chemicals, standards, and reagents are assigned a unique PCN in LIMS for tracking and traceability purposes. A label with the PCN and the expiration date is affixed to both the container and the Certificate of Analysis (if applicable). Document Control enters the data for each PCN using the certified value(s) supplied by the vendor, as indicated on the Certificate of Analysis. Because the certified value is entered, the final concentrations for prepared standards may vary slightly from the theoretical value indicated in the test SOP. Non-certified values are not entered and are not used for quality control purposes. Document Control maintains certificates of Analysis, and a copy of the PCN report is generated and maintained. If the certified reference values for any PCN are changed, then complete documentation must be provided as a major corrective action (FRMQA001).

NOTE: Only Document Control and QA personnel are authorized to enter or edit PCN data.

8.4.2 Secondary Control Number (SCN)

To ensure complete traceability, a unique SCN must be created when any intermediate or working standard is prepared from one or more stock solutions, stock chemicals, or intermediate solutions. A standardized format is used for creating the SCN: a two-letter code indicates the lab section and is followed by the prep date and then by a daily sequential number. For example, the SCN **II051128-2** denotes the second standard prepared on November 28, 2005 in the Inorganic Instrument lab. An acceptable alternative is to let LIMS assign a unique number when prompted.

A SCN for any working standard subjected to a LIMS calculation must be created electronically in LIMS. The initial volume and concentration of each constituent and the final volume of the prepared solution are entered in the SCN Wizard program to calculate the final concentration(s) of each analyte using the formula $C_1V_1 = C_2V_2$. The preparation date, expiration date, and preparer's initials are included as part of this electronic record. A hard copy of the SCN report may be affixed to the standard/reagent logbook, depending on individual department practice; however, it is not required.

Prepared reagents do not require a SCN to be created electronically in LIMS; however, preparation must be recorded in the department's designated logbook. At a minimum, the logbook entry must clearly identify what reagent was prepared, its subcomponents, the preparer's initials, the preparation date, and the expiration date. This information is sufficient for color reagents, buffer solutions, instrument reagents, etc. because details of the preparation are stated in the test SOP.

8.5 Preparation and Expiration of Standards and Reagents

8.5.1 Preparation of Standards and Reagents

Refer to individual test SOPs for detailed information regarding standard and reagent preparation.
In general, either Class A pipettes or mechanical pipettes are used to measure and dispense aliquots of any solution used to prepare a standard or reagent. Accurate delivery of mechanical pipettes must first be verified as described in ACZ's SOP *Control, Calibration, and Maintenance of Measuring and Test Equipment* (SOPAD013).

The term QS referenced in many test SOPs is the acronym for *Quantity Sufficient* and refers to the addition of appropriate diluent to the solution to achieve the final volume. All containers of prepared reagents and standards stored for more than one day must be properly labeled with the SCN (or other unique identifier), preparation date, and expiration date. Preparation of reagents and standards must be documented as described in §8.4.2.

8.5.2 Expiration of Purchased Standards and Chemicals (PCNs)

In general, purchased liquid standards or reagents are assigned a default expiration date of one year from receipt. When provided, the manufacturer's expiration date will be assigned in lieu of the default expiration date. Solid materials are assigned a default expiration date of five (5) years from receipt.

An expired stock material may continue to be used only if its reliability can be verified. For the purpose of ensuring transparency, the rationale for extending the expiration date must be documented on FRMQA051 and submitted to the QA department for approval. If the extension is granted, FRMQA051 is filed with the certificate of analysis. Unusable materials must be replaced and the standard or reagent remade as soon as possible. Remove the container from the lab or the supply room and dispose of properly. Contact ACZ's CHO for assistance.

8.5.3 Expiration of Prepared Standards

Storage conditions and shelf life for prepared standards are provided in the individual test SOPs. The following guidelines may be used to determine the shelf life for a prepared standard:

1) A standard that has been prepared in-house may continue to be used after its assigned expiration date for as long as its reliability can been verified. Whenever possible, reliability should be verified by comparison to another, unexpired standard containing the same constituents. For applicable procedures, instrument response may be considered when determining whether or not a solution is still reliable.

- In cases where reliability has been verified, the expiration date of the SCN must be updated in LIMS or the standard/reagent logbook. The rationale for extending the expiration must be documented on FRMQA051 and submitted to the QA department for approval.

- In the event the solution was used prior to updating the SCN then documentation must be provided as part of the workgroup to indicate the solution was used past the shelf life stated in the SOP (a minor corrective action or FRMQA051 may be used if more than one workgroup is affected). The expired standard must be remade as soon as its reliability becomes questionable – it is the responsibility of the analyst to use their best judgment.

2) The shelf life of any prepared standard with any analyte concentration < 10 mg/L is 90 days from the preparation date. This is a general guideline – if any constituent does not remain in solution for 90 days, then the standard must be prepared more often. If the manufacturer's expiration date for any stock standard is sooner, then the expiration date of the SCN is the manufacturer's expiration date for a single analyte solution or the earliest manufacturer's expiration date for a multiple analyte solution.

3) The shelf life of any prepared standard with analyte concentration $\geq$ 10 mg/L is one year from the preparation date. This is a general guideline – if any constituent does not remain in solution for one year, then the standard must be prepared more often. If the manufacturer's expiration date for any stock standard is sooner, then the expiration date of the SCN is the manufacturer's expiration date for a single analyte solution or the earliest manufacturer's expiration date for a multiple analyte solution.

4) In general there are no manufacturer expiration dates for Radiological isotopes. If provided, these will be used; otherwise, the default expiration date of one year from receipt will be assigned when the material is received and can be subsequently updated at yearly intervals as needed for as long as the material remains useable. Because the shelf life of a radiological isotope is dependent on the half-life, the isotope will be deemed expired when it falls within 3 times the detection limit of the method.

5) In general, prepared Radiochemistry standards expire one year from the preparation date. The solution may be re-evaluated using control charts, efficiency checks, or other criteria and the expiration date extended by year intervals if the solution is still deemed usable. Refer to the specific test SOP for details.

8.5.4 Expiration of Reagents

In general, a reagent is a solution, other than a surrogate or internal standard, which is used for any step of sample preparation or analysis but does not contain the target analyte(s). Storage conditions and shelf life are stated in the individual test SOPs. The expiration date can be extended for a prepared reagent provided its reliability can be verified. LCS/LFB performance (QC criteria met) may be used to verify reagent stability if the control standard is a valid indication of the reagent's continued functionality/stability. Reagents used to treat samples for interference may not be verified this way. Reagents used to dissociate complexed target analytes may not be verified this way unless the LCS is an appropriate complex. FRMQA051 must be submitted to QA for approval whenever an expiration extension is requested.

9 MAINTENANCE & CALIBRATION OF INSTRUMENTATION & EQUIPMENT

9.1 Maintenance of Instruments and Support Equipment

The best protocol for producing quality work is to prevent errors and non-conformances rather than to react to and correct problems after they occur. An essential part of this protocol is ensuring that all laboratory instrumentation and equipment used for the generation of data has been optimized and is functioning properly before commencing work on client samples. Performing routine maintenance and optimizing instrument-operating conditions prior to sample analysis minimizes instrument downtime, thereby improving productivity and ensuring quality of the data. It is the responsibility of the designated analyst(s) to perform and properly document daily and routine maintenance, instrument optimization, troubleshooting, any instrument servicing or repair, and any repair or replacement of parts.

All manufacturer-prescribed inspection and maintenance must be performed according to the schedule indicated in the operator's manual (or similar) provided by the manufacturer and must be documented either in the instrument logbook or a separate maintenance logbook or on the instrument maintenance checklist (available in LabWeb). ACZ management recognizes that performing all maintenance procedures at the frequency indicated by the manufacturer may not be economically feasible or a significant increase in workload may require the maintenance be performed at a later time if instrument performance is deemed to be acceptable; therefore, at a minimum, the instrument part(s) must be inspected regularly according to the schedule. The analyst must use their professional judgment to determine if maintenance or replacement is necessary at that time. Refer to ACZ's SOP *Control, Calibration and Maintenance of Measuring and Test Equipment* (SOPAD013) for details for each specific instrument or instrument type.

Additionally, all support equipment (any device that may not be the actual test instrument, but is necessary to support laboratory operations) must be monitored regularly to confirm proper functioning. The temperature of all drying ovens, refrigerators, freezers, and incubators must be checked each working day (except Sundays or holidays) and each check recorded on the associated Temperature Logsheet. Refer to SOPAD013 for more detail.

Equipment that has been subjected to overloading or mishandling, gives suspect results or has been shown to be defective or outside specified limits must be taken out of service and FRMAD029 attached to indicate the instrument or equipment is waiting for repair and cannot be used. During this downtime the department supervisor, Production Manager, and Project Manager may collectively determine it is necessary to sub-contract samples until correct performance of the repaired instrument or equipment has been demonstrated by a successful calibration or other suitable test. Document all contact with the manufacturer, as well as all repairs and other services, in the instrument or maintenance logbook to be used as a reference for solving future instrument problems. Additionally, when instrumentation or equipment goes outside of the direct control of the laboratory, the functioning and calibration status must be checked and shown to be satisfactory before it is returned to service. Refer to SOPAD013 for additional information.

To minimize downtime, each laboratory should maintain an adequate inventory of reagents, stock standards, glassware, etc. and should keep a sufficient supply of extra "critical" parts in-house rather than possibly delay sample analysis while waiting for parts to arrive. Keep in mind that parts from a vendor may be back-ordered and will not be available for immediate shipment. Additionally, an MDL study, MDL verification, calibration range determination, etc. must be performed for all methods on each instrument used to analyze client samples. This ensures any "backup" instrument can be utilized for analysis of client samples as soon as needed, rather than delaying production to first successfully complete any QC requirement(s).

9.2 Instrument Calibration

The accuracy of all instrument-generated data is ultimately dependent upon the proper initial calibration of the instrumentation used for any particular analysis. In order to perform quantitative measurements, the initial calibration must be established and verified, at the frequency required by the method or by the manufacturer (whichever is more stringent), before samples are analyzed. In general, calibration or standardization involves defining the relationship between instrument response and the amount or concentration of analyte introduced into the instrument. The graphical depiction of this relationship is referred to as the calibration curve.

Calibration frequency must be performed in accordance with the manufacturer's guidelines, test method or other regulatory requirements, or client contract stipulations, whichever is most stringent. Every calibration or standardization must meet the acceptance criteria stated in the SOP and must be subsequently verified by analyzing an initial calibration verification standard (ICV) or other control standard (if specified in the SOP) that contains all target analytes and has been prepared or obtained from a different source than the one used to prepare the calibration standards.[1] Whenever possible, calibration standards and the second-source verification standard should be prepared on different days. If they are prepared concurrently, then another qualified analyst should prepare the second-source verification standard. This eliminates the possibility of the same analyst preparing both solutions incorrectly, an error difficult to detect.

A continuing calibration verification standard (CCV) containing all analytes of interest must be analyzed at the frequency stated in the test SOP to ensure the stability of the initial calibration curve has not varied over time due to any change in the analytical instrument and its detection system, such as instability of standards, instrument cleanliness, column performance, matrix effects, flow changes, and changes within the laboratory environment.

For applicable methods, all initial and continuing calibration steps must be clearly detailed in the test SOP. Additionally, each test SOP must specify the frequency and acceptance limits for the calibration and subsequent verification (ICV and CCV). In general, acceptance criteria are method-specific; however, the SOP may also include requirements of other regulatory agencies. Prior to resuming sample analysis, immediate corrective action must be taken if the calibration, ICV, or CCV is outside of the acceptance criteria. Technical corrective actions are described in the individual test SOPs. Refer also to §11.2 for additional information.

General calibration guidelines are listed below. Additional information is provided in the individual test SOP's and ACZ's SOP *Control of Measuring & Test Equipment* (SOPAD013).

- Understand the method requirements for calibration (minimum number of standards, etc.)
- Use the correct calibration model (linear, second-order, etc.)
- Include all target analytes in the calibration standards and second-source standard
- Analyze a calibration standard with a concentration less than or equal to the reporting limit.[2]
- Do not remove points from the middle of the calibration (only high or low standard may be dropped).
- Calibration is a single-event process. A retest of a calibration standard must be performed immediately.
- Documentation and resolution of calibration abnormalities is absolutely critical

[1] If a second source standard is not available then a different lot(s) of the same standard(s) may be used. If a different lot is not available then an analyst who did not prepare the calibration standards may prepare the calibration verification standard. The latter is an exception, and an attempt must first be made to purchase a different lot from the same vendor whenever a second-source standard is not commercially available.

[2] In general, the concentration of the low calibration standard is equal to the reporting limit, because lesser values are qualified as estimated; however, actual lab practice may differ and must be stated in the test SOP.

10 CONTROL & STORAGE OF RECORDS & DOCUMENTS

A formal and systematic control of records and documents is necessary for accurately reconstructing the entire history of any sample as well as to guarantee the quality and defensibility of the data. All information pertaining to instrumentation and equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, data verification and data reporting must be documented, must identify all personnel involved, and must be readily understood. All records, including those pertaining to calibration and test equipment, certificates and reports, must be maintained, and the management system must facilitate the retrieval of all working files and archived records for inspection and validation purposes. Documents and records must be safely stored (protected against fire, theft, loss, environmental deterioration, and vermin) and must be held secure and in confidence to the client for a minimum of five (5) years. The hard copy of all records and documents must be maintained in a designated storage area with limited access. To the extent possible, hard copies for the most recent two (2) years are stored on-site, and if necessary, may be moved to off-site storage after two years. Off-site storage conditions must meet the same criteria that apply to on-site storage.

10.1 Workgroups

10.1.1 Changes made to any workgroup record (hardcopy or text file) must be documented.

1) If a workgroup is "dissolved" to change the status then all data must first be deleted, and the workgroup is then either re-reviewed or re-uploaded. In either case, the analyst is prompted in LIMS to provide an explanation of why he/she is performing the task.

2) Changes to text files must be documented on the hard copy of the workgroup.

10.1.2 Workgroup data that is re-uploaded *for any reason* must first be deleted. Use one of the following options in LIMS\Sx Analysis.

1) Choose "Delete workgroup data and set to WIP."

2) In either the AREV or SREV function choose "Errors" and then "Reupload."

If any of the data changes then a new Run Approval report must be printed and attached to the hard copy of the workgroup, and the workgroup must be rescanned.

10.1.3 Document Control or other administrative personnel use a multi-page scanner with its own PDF scanning software to scan all hardcopy portions of workgroups.

1) Before the workgroup is scanned, the top page is reviewed to make sure it has both the AREV and SREV initials and dates, and that errors have been properly corrected.

2) The person scanning the workgroup must initial and date in the lower right hand corner of the front page by the person. This provides a record of the scan date.

3) The workgroup is scanned to the designated network directory and is then moved through an automated process to the appropriate read-only LabWeb directory, which is accessible to all employees. When a workgroup is rescanned, the previous file is maintained. A copy will be automatically created so as not to overwrite any files and will have a letter appended; starting with "A" the first time the workgroup is rescanned. The most current file will not have a letter appended.

10.1.4 The hard copy is filed by workgroup number in a storage box. The front of the full storage box is labeled with the year and the workgroups contained in the box. The first box of each new calendar year is "1." Full boxes are consecutively numbered, transferred to a designated location and stored in numerical order. The storage room is locked at all times. Access is limited and is tracked through an access logbook.

10.1.5 Workgroups moved to storage may be accessed; however, a checkout card must hold the place of the workgroup in the file and must indicate who removed the workgroup, the workgroup number, and the date the workgroup was removed. When the workgroup is returned, then the checkout card is removed.

10.2 Electronic File Retention & Storage

All electronic records, stored either on instrument computers or on the network, are systematically backed up to disk and tape. These records include Oracle data, instrument raw data, workgroups, client reports, instrument upload files, SOPs and other controlled documents, telephone records/voice mails, and department data. Tape backups are performed each week. Network and archive backups are copied to disk nultiple times during the week. The tape from the first Friday of the month is pulled from service and placed in a secure, data-rated, 4-hour fireproof, safe that is located in the CFO's office. On a regular basis, the monthly tapes are moved to ACZ's safety deposit box at a local bank.

10.3 Instrument Data Files

Instrument raw data files are backed up by ACZ's Instrument Data Backup Application (IDBA). IDBA is a program that accesses local directories from instrument computers. Each night the program retrieves and backs up individual data files from the specified directory on each instrument computer. Refer to ACZ's SOP *Backup and Archive of Instrument Data Files* (SOPAD044) for details.

10.4 Client Reports

10.4.1 Client reports are generated and signed electronically and are automatically stored as a PDF at a designated location on the network that has limited access. If a copy of any report exists on the network, and a new report is generated, then the existing copy will be renamed so that it is not overwritten. This way ACZ maintains a copy of all reports generated for a client.

10.4.2 Hardcopy documentation associated with a client project (CCOC, invoice, Login Review Form, etc) is filed by project number and stored in the document storage location.

10.4.3 Electronic Diskette Deliverables (EDD) are stored on the network at a designated location.

10.4.4 Changes to data may be necessary due to reporting requirements. These changes are made after the routine workgroup approval step and may include changes to reporting qualifiers, QC Summary qualifiers, report notes, etc. A record of the change must be made in the project "Change Log." Access the Change Log from the LIMS2000 menu/Reporting/Report Approval form. Refer to ACZ's SOP *Client Service Policies and Procedures* (SOPAD043) for additional information.

10.4.5 The Change Log must be used when a reported parameter is moved from one workgroup to another. The preferred way to do this is for a PM to either document the necessary changes in the Change Log and then notify the reporting department of the required changes or notify the reporting department immediately that a change is necessary. In the case of the latter, the reporting department makes the changes and then logs this action in the Change Log. Refer also to ACZ's SOP *Client Service Policies and Procedures* (SOPAD043).

10.4.6 Once a project has been invoiced, the directory on P:\Client is moved to the designated network location as a read-only PDF. If a project is un-invoiced, the project folder is copied to P:\Client where changes can take place.

10.4.7 In general, changes are not allowed to projects (including compilation) if the project has been invoiced. If a change needs to be made, the project must first be un-invoiced. At the time of un-invoicing, the user must provide a reason in LIMS to explain why the project was un-invoiced. This information is then stored in the Oracle database.

10.5 Documents

10.5.1 Standard Operating Procedures

10.5.1.1 Refer to §2.2 for additional information pertaining to SOPs.

10.5.1.2 The original master copy of each SOP is maintained through a combined effort of QA and Document Control. Master copies are organized in three-ring binders, which are kept in the Document Control office. An SOP Control Form (FRMQA003) is kept with each master copy and indicates each controlled copy of the SOP that was issued as well as the date and to which lab(s) the copies were distributed.

10.5.1.3 When a new version of any SOP becomes effective, the master copy of the previous version is retained and filed in the Document Control office. All controlled copies of the previous version are collected and disposed of. The collect date is documented on the SOP Control Form, which is maintained with the associated master copy SOP.

10.5.1.4 A controlled copy of the SOP is kept in each location the procedure is performed.

1) Each lab or department is issued one controlled copy of all relevant SOPs. The controlled copy must not be removed from the assigned area for an extended period of time and may not be photocopied. An additional controlled copy of any SOP or individual replacement pages of any SOP will be distributed upon request.

2) An SOP Revision Form (FRMQA030) is required for any change to an SOP occurring between versions. Any revision to a procedure must be noted on the form and must be approved by QA before changes may be implemented. Once the revision has been approved by QA, the change must be initialed and dated by the pertinent department supervisor and all employees performing the procedure. This serves as documentation that all relevant employees have been trained to follow the revision. In general, anyone with a current DOC must initial & date the revision. Once all necessary signatures have been garnered, a copy is made to store with each distributed controlled copy, and the original revision form is placed in the "to be scanned" inbox. The revisions are scanned, the PDF emailed to the QAO, and the original revision form is stored with the SOP master copy. The PDF is copied into an appendix at the end of the SOP so that all revisions are reflected in LabWeb. All revisions are incorporated into the SOP before a new version is released. Revisions are retained and filed with the SOP version which was effective during their implementation.

3) To ensure outdated information is not inadvertently used as a reference, an uncontrolled copy of any SOP is not allowed unless issued by QA. Additionally, an electronic copy of any SOP becomes obsolete and must be deleted from a network drive or email once the effective version has been uploaded to LabWeb.

10.5.2 When documents are found to contain conflicting policies or procedures, the more recent document will be followed.

10.5.3 All controlled forms must be printed from LabWeb and may not be stored on a separate network drive. If photocopies are used then any unused copies of the expired version must be disposed of as soon as a new version is uploaded to LabWeb. This ensures that the effective version of any controlled form is in use at all times.

10.5.4 Any controlled SOP(s) issued to an employee must be collected upon resignation or termination.

10.5.5 Employees utilize an uncontrolled copy of the Data Integrity SOP or QAP for initial or continuing training purposes. All copies are collected following completion of the training session.

10.5.6 Only Document Control and QA personnel are authorized to enter or edit data for a PCN.

10.5.7 The hard copy of each PCN report generated in LIMS is stored in a three-ring binder that is maintained by the Document Control department.

10.5.8 The original certificate of analysis for any stock material, if provided, is attached to the hard copy PCN report.

10.5.9 Accreditation certificates are scanned as a PDF to a designated network location. The original copy is maintained by Document Control. Certificates are also posted to ACZ's website.

10.5.10 Original calibration certificates and related documentation for support equipment (including but not limited to pipettes, thermometers, and glass micro liter syringes) are maintained by Document Control.

10.5.11 LIMS and other problems pertaining to IT are documented and managed by the electronic system called Help Desk. If an employee encounters a problem that requires attention, then that employee will submit a request through Help Desk. The request requires a priority to be assigned to the appropriate employee(s) for resolution. This system allows ACZ to track all changes made to computer systems. Reports are routinely generated to evaluate the status and eventual resolution of computer issues.

10.6 Records

10.6.1 Records include, but are not limited to: all logbooks; phone logs; raw data, derived data, and calibration data; training documentation (training forms, MDL studies, DOCs, etc.); proficiency testing results; calibration and certification records; internal audit reports; external audit reports; corrective action reports; management reports; and regulatory correspondence.

10.6.2 Records related to sample log-in are maintained as described in SOPAD016.

10.6.3 Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media, dictated observations, and recorded data from automated instruments.

10.6.4 Original copies of records, except those pertaining to analytical data, are maintained by the QA department or Document Control, and access is limited.

10.6.5 Relevant qualifications, training skills, and experience of technical personnel are maintained in the employee's training file.

10.6.6 Records such as transcripts, applications for employment, performance evaluations, etc. are maintained in the personnel files, which are stored in the secured office of the CFO.

10.6.7 The DOC certification statement (FRMAD023), initial method training form (FRMQA004), General Lab Practice Training Form (FRMQA047), and Method Calibration Training Form (FRMQA050) are filed with the workgroup if the DOC was logged-in; otherwise, the DOC package is filed in the method files. An analyst training spreadsheet referencing training dates and documentation locations is maintained on a public drive.

10.6.8 Each employee's legal name, legal signature, and initials are documented on the New Employee Checklist (FRMAD043). The form is maintained in the employee's personnel file, which is stored in the Controller's office. A master signature/initial log is maintained for anyone employed at ACZ prior to the implementation of FRMAD043.

10.6.9 Each Organic Instrument ICAL data package is scanned to the designated network directory as a read-only PDF and the hard copy stored in labeled boxes. ICAL information that needs to be attached to any subsequent workgroup(s) must be printed from the PDF.

10.6.10 Logbooks must be maintained and controlled as described in SOPAD013.

10.6.11 Project Managers are responsible for maintaining all emails pertaining to a client and/or project. Refer to ACZ's SOP *Client Service Policies and Procedures* (SOPAD043).

10.6.12 Procedural change(s) made to a SOP must be noted on the SOP Revision Form (FRMQA030) and approved by QA prior to implementation. The revision form includes an effective date field.

10.6.13 Any correction to a hard copy record must be made by crossing through the error with a single line, and the correction must be clearly initialed and dated by the responsible staff. Erroneous entries cannot be destroyed by erasures, other markings or use of Whiteout®.

10.6.14 Changes to electronic records must be traceable to the individual who made the correction, and the reason for the change must be provided. Erroneous entries cannot be destroyed by methods such as overwritten files.

10.6.15 Record Storage and Retention

10.6.15.1 The minimum retention period of five (5) years may be increased dependent upon client request, regulatory requirement, or civil action order.

10.6.15.2 Records stored by a computer must have hard copy or write-protected backup copies.

10.6.15.3 Records stored only on electronic media must be supported by the hardware and software necessary for their retrieval and utilization in the proper format.

10.6.15.4 Records stored on electronic media must be stored in a way to provide protection from electronic or magnetic sources.

10.6.15.5 Scanned workgroups and client reports are backed up to an off-site electronic data vault, which is secure, fireproof, and equipped with data redundancy. Electronic data backups occur daily (including Saturday and Sunday) after 12:00 am. Each month a tape of all ACZ data is stored in a bank safety deposit box.

NOTE: Data files that precede June 1, 2005 are stored to tape and/or DVD, which are kept in a bank safety deposit box.

10.6.15.6 If there is a change in ownership and/or a change in location, all records and documents will be made available to all accrediting authorities for five (5) years. Under no circumstances shall any records or documents be destroyed – all records and analyses performed that pertain to NELAC accreditation are subject to inspection by the NELAC accrediting authorities during this five (5) year period. A new owner of ACZ will assume possession of all records and documents.

10.6.15.7 If ACZ goes out of business, all records and documents will be stored and maintained according to protocol in a location to be determined at the time of closure. All records will be maintained for at least five (5) years and will be made available to all accrediting authorities.

10.6.16 Access to Archived Records

10.6.16.1 Access to archived information must be documented with an access log. A log is kept in each storage location, and any person entering a storage location must provide the required information in the log.

10.6.16.2 Hard copy records are stored in a locked environment with limited access. When a record is removed from its location, a "checkout card" must be filled out to indicate who removed the record, the date the record was taken, and a description of the record. The card marks the place in the storage box, and when the record is returned the card is pulled from the box.

10.6.16.3 Any changes to be made to archived data will require assistance from IT to do so.

10.6.16.4 Electronic data that has been archived to a more permanent media (disc & tape) is stored in a bank safety deposit box. Access is limited and must be documented in the logbook maintained by Document Control.

10.6.17 Record Disposal

10.6.17.1 Records are disposed of in a manner to ensure client confidentiality.

10.6.17.2 Stored records will be reviewed to determine which ones can be destroyed. Any record older than five (5) years from the current date will be destroyed, unless client request, regulatory requirement, or civil action order dictates otherwise.

10.7 Computer Data and Records

10.7.1 Network File Server

Computer files pertaining to all aspects of ACZ's business are stored on a file/print server. To gain access, an employee logs on to the "LAB" domain. Each employee has a unique network user name so that security rules may be enforced. No "guest" logon is permitted. Every employee belongs to a specific "group" and directory security is enforced through privileges granted to these groups. Typically, an employee is granted access to files that pertain to their job functions; otherwise, read-only access or no access is granted.

Data generated and reported by ACZ is extremely confidential and the company may be liable for the consequences of the release of this data to any unauthorized person. The implementation of password security is not arbitrary and ensures data is protected and cannot be disclosed to outside parties. Weak, unchanging passwords make this scenario more likely.

In general, the network will prompt employees to change their password every 30 days. The password must be at least five (5) characters. Numeric characters are optional. Passwords may not be shared with other employees. The use of another employee's password (with the exception of common passwords for shared computers) is grounds for disciplinary action.

10.7.2 LIMS Server

1) Information stored on the LIMS server consists of all sample and client information needed for day-to-day production activities. The information is stored using an Oracle database application. Access is controlled through membership in "groups." Employees may update and change database records according to their job responsibilities. Otherwise, information is restricted to read-only access or no access.

2) No modifications to data can be made through applications not authorized by ACZ's IT department unless a CAR or Help Desk ticket is submitted or documentation is provided on the hardcopy of the workgroup. Unauthorized applications include any form of direct database manipulation.

3) Tracked changes will be audited on a regular basis by the QA department or designee to ensure sufficient information is being supplied as to why changes occur. The explanations must be professional and specific.

10.7.3 Docs Server

Access to the docs server is read-only and is permitted through Internet Information Services (IIS) authentication and is logged in IIS log files. The server is updated on a regular basis by automated scripts.

11 ELEMENTS OF QUALITY CONTROL

A critical focus of ACZ's quality control policies and protocols involves monitoring sample preparation and measurement processes to determine matrix effects and to evaluate laboratory performance. Quality control samples are typically analyzed with every batch of environmental samples. Each test SOP provides detailed information regarding quality control sample types, acceptance criteria, and corrective actions, if applicable to the procedure, and reflects the requirements of the method and/or other regulatory authorities.

Performance control samples demonstrate precision or accuracy and expose out-of-control events. Matrix-specific control samples indicate possible effects of the matrix on method performance and may also identify data as in-control or out-of-control. Data that is out-of-control dictates corrective action ranging from re-extraction / re-analysis to reporting data with qualifiers. In general, the corrective action specified in the SOP must be performed if any quality control sample does not meet the acceptance criteria. Data associated with failed quality control cannot be qualified after the initial analysis without acceptable justification.

To the extent possible, client samples are reported only if all quality control measures are acceptable. If any measure is outside of the acceptance criteria, and the data will be accepted and reported to the client, then the appropriate data qualifier(s) must be assigned to all associated samples. The list of current extended qualifiers is maintained in the LIMS database.

11.1 Method Performance

11.1.1 Negative Control – Prep Blank (Method Blank)

The prep blank is used to assess possible contamination introduced during sample processing steps. A prep blank is prepared using Type I water or other similar matrix similar that is free of the target analyte(s) and contains all reagents in the same volumes used to prepare the client samples. The prep blank must be prepared, processed and analyzed in the same manner as the associated client samples. Unless specified in the test SOP, sample concentration may not be corrected for the prep blank value.

While the goal is to have no detectable contaminants, each prep blank must be carefully evaluated as to the nature of the interference and the effect on the analysis of each sample in the batch. Contamination in the prep blank results from four principle sources: the environment the analysis is performed in; the reagents used; the supplies and apparatus used; and the analyst performing the analysis. Contamination sources vary and the test SOP must be referenced to determine the appropriate corrective action(s).

When contamination is suspected, the source(s) must be investigated and measures taken to correct, minimize or eliminate the problem, and associated client samples must be reprocessed and reanalyzed. Alternatively, report data with the appropriate qualifier if reprocessing and reanalysis is not possible or if one of the following criteria applies:

i) The concentration of a target analyte in the blank is at or above the acceptance limit and the measured concentration of the analyte in an associated sample is greater than 10 times the measured concentration of analyte in the blank.

ii) The concentration of a target analyte in any associated sample is less than the MDL.

iii) Corrective actions could not be performed or are ineffective. Thoroughly document any corrective action taken and the outcome.

11.1.2 Positive Control

11.1.2.1 Laboratory Fortified Blank (LFB)

An LFB is required for methods that do not include a Laboratory Control Sample but include a fortified matrix (spike). The LFB is an aliquot of reagent water to which a known quantity of each target analyte is added. It is treated exactly like a client sample, and its purpose is to determine whether the methodology is in control, and whether the laboratory is capable of making accurate and precise measurements. When the acceptance criteria for the LFB are exceeded (i.e. high bias) then any associated client sample with a measured concentration less than the MDL may be accepted and reported with the appropriate qualification.

11.1.2.2 Laboratory Control Sample [LCSW (Water) or LCSS (Soil)]

The performance of both sample preparation and analysis of each sample batch may be monitored by an LCS. The LCS is a matrix-specific standard (whenever possible) of known analyte concentration(s) that may be prepared by the laboratory or purchased pre-made. The LCS must be carried through the entire preparation and analytical schemes with the client samples. Analysis and evaluation of the LCS allows for confirmation of the applicability of the preparation procedure to the analytes. Evaluate data using the following guidelines:

1) When only an LCSW is analyzed, the results must be within the acceptance limits or the entire batch of samples must be re-prepped and retested.

2) An LCSW duplicate (LCSWD) may be prepared and analyzed with the batch, typically in lieu of a matrix duplicate or spike duplicate. Data is acceptable if the LCSW and/or LCSWD is within the acceptance limits and the RPD passes. Associated samples must be re-prepped and reanalyzed if either of the following occurs:

   - LCSW/D RPD fails the acceptance criteria specified in the SOP.
   - % R of both the LCSW and LCSWD is outside the acceptance limits.

3) For a solid or semi-solid matrix, an LCSS and LCSSD are prepared and analyzed.[3] The data is acceptable if the LCSS and/or LCSSD is within the acceptance limits and the RPD passes. Associated samples must be re-prepped and reanalyzed if any of the following occurs:

   - LCSS/D RPD fails the acceptance criteria specified in the SOP.
   - % R of both the LCSS and LCSSD is outside the acceptance limits.

4) When the acceptance criteria for the LCS are exceeded [i.e. high bias] then any associated client sample with a measured concentration less than the MDL may be accepted and reported with the appropriate qualifier.

5) Refer to §11.1.3.3 for additional information regarding data assessment for solid-matrix workgroups prepared with both LCSS/LCSSD and MS/MSD.

11.1.2.3 Radiological Tracers

Radiological tracers are used for Thorium and Uranium analyses. The tracer reacts in the same manner as the target isotope and is used to asses analyte recovery. The tracer is added to client samples, controls, and blanks in accordance with the requirements stipulated in the test SOP. Because the tracer recovery has a direct impact on the LLD, the recovery must be high enough to yield LLDs that are within the scope of the project or meet ACZ's acceptance criteria. Refer to the test SOP for evaluation criteria and corrective action(s) for out-of-control tracer recovery.

[3] Corrective action for Recommendation #5 cited in the 2002 ADHS audit report.

11.1.3 Sample Specific Controls

The effect of different sample matrices on the performance of any method can be profound; therefore, matrix spikes, duplicates, and surrogate compounds are analyzed to evaluate matrix effects on data quality. Each SOP includes specific information regarding the usage and evaluation of matrix-specific QC samples and also states the required corrective action to take if any matrix QC fails.

ACZ provides analytical services to numerous and varied clients; therefore, the possibility of routinely favoring one client is highly unlikely. Over the course of time, no single matrix type will always be spiked or duplicated, and no one client will be selected for a high percentage of spiked or duplicated samples. If either of these occurs, it is due entirely to chance. Samples are selected for a workgroup by due date or priority – not by client – and are presented in the workgroup in increasing numerical order according to project number. A client's samples will be grouped together within the batch – in this way, a single client cannot be selected for a spike or duplicate, unless all of the client samples in the batch are from the same project. ACZ recommends that the analyst, to the extent possible, select samples to spike or duplicate that are representative of the workgroup. Analysts are not to associate QC with a client sample known to be or believed to be any type of blank or Proficiency Testing sample. Several exceptions exist for selecting samples for spiking or duplicating:

1 A sample is not spiked or duplicated if the volume is inadequate, and the client sample and QC sample(s) would require dilution; however, if no other option is available then the client sample and Duplicates should be prepared and analyzed on the same dilution whenever possible. Matrix spikes will not be accepted on different dilutions (minor d.f. variations in soils samples are acceptable) unless no other alternative exists. The data must be qualified in this event.

2 Use the same weights (or as similar as possible) to prepare duplicates of solid matrix samples.

3 A client may request that one or more of their samples be spiked or duplicated. A “RUN QC” comment is added when the sample is logged in to notify the analyst that QC must be performed for a specific sample or project. If a client requests that their sample(s) be spiked or duplicated then ACZ is obliged to accommodate the client.

4 If TDS data indicates a sample would require dilution, then the sample should not be selected for spiking. Performing dilutions increases the likelihood of introducing error due to pipetting, and it is possible that spike recoveries may be incorrectly influenced by this error. A high TDS value will not influence whether or not a sample is duplicated.

5 A reactive sample is unpredictable and is a poor choice for spiking or duplicating.

6 A PT sample is not a real-world sample and is a poor choice for spiking or duplicating, because the data does not provide any useful information about possible matrix effects. Spike or duplicate a PT sample only when there are no client samples in the workgroup.

11.1.3.1 Surrogates

Surrogates are organic compounds that are similar to the target analyte(s) in chemical composition and behavior in the analytical process, but are not normally found in environmental samples. Surrogates are included in the scope of Organic methods and are used to evaluate accuracy, method performance and extraction efficiency and shall be added to environmental samples, controls, and blanks, in accordance with the method requirements.

Whenever a surrogate recovery is outside the acceptance limits, the corrective action(s) stated in the test SOP must be performed. If corrective actions could not be performed or are ineffective, then the appropriate qualifier is applied to the sample results and reported to the client.

11.1.3.2 Matrix Spike Samples

A matrix spike sample (however named) is used to determine the level of bias (accuracy) associated with a particular matrix. For the purposes of this document, "MS" designates a matrix spike, and "MSD" designates a matrix spike duplicate. Spikes are prepared by adding a known and appropriate quantity of each target analyte to a replicate aliquot of client sample.

The required analytical frequency is specified by the method or other regulating entity and is indicated in the test SOP. Each result is evaluated against the acceptance criteria, and matrix effects are determined and reported to the client. The following evaluation criteria apply to spikes that are subjected to processing steps and post-digestion spikes (analytical spikes).

- Percent Recovery (%R) is considered for all spikes.
- %R is evaluated only if the theoretical concentration in the spiked aliquot is greater than or equal to the reporting limit; otherwise, each associated client sample must be reported with the appropriate qualifier, regardless of %R.
- If %R for the MS and/or the MSD is outside of the acceptance limits, the RPD passes, and all other pertinent prep and instrument QC passes, then each associated client sample may be accepted and reported with the appropriate qualification.

11.1.3.3 Matrix Duplicates and Matrix Spike Duplicates

The matrix-specific precision associated with an analysis is determined through the use of a matrix duplicate (DUP) or spike duplicate (MSD), which are performed at a frequency specified by the method or other regulating entity (refer to the specific test SOP). The results are evaluated, and the matrix effect on precision are determined and reported to the client.

- Relative Percent Difference (RPD) is considered for all duplicates except non-drinking water samples for radiochemical analyses (§12.4.4).
- RPD for a spike duplicate is evaluated only if the observed concentration is greater than or equal to the reporting limit; otherwise each associated client sample must be reported with the appropriate qualifier.
- RPD for a matrix duplicate is evaluated only if the observed concentration is greater than 10 times the MDL; otherwise each associated client sample must be reported with the appropriate qualifier, regardless of RPD.
- In the absence of other contributing factors, a DUP failure for a solid or semi-solid matrix is attributed to non-homogeneity of the sample, and each associated client sample may be reported with the appropriate qualifier.
- For an aqueous matrix, if the DUP fails then all associated samples and the DUP must be retested. If permitted by the instrument software the sample and DUP can be reanalyzed at the end of the analysis in lieu of retesting all associated samples.
- For an aqueous matrix, if the MS/MSD RPD fails then the associated samples must be reanalyzed. If permitted by the instrument software the sample and MS/MSD can be reanalyzed at the end of the analysis in lieu of retesting all associated samples.

- If applicable, evaluate the LCS/LCSD if the RPD fails for a matrix duplicate or spike duplicate. Each associated client sample may be reported with the appropriate qualifier if the LCS/LCSD meets the criteria stated in §11.1.2.2.

- For a solid or semi-solid matrix, if both the LCSS and LCSSD recoveries pass but the RPD fails, then acceptable precision may be demonstrated by a passing RPD for the MS/MSD, and each associated client sample may be reported with the appropriate qualifier.

11.2 Instrument Specific Controls

All data must be associated with a passing instrument calibration and initial calibration verification. To the extent possible, all data must be associated with passing continuing calibration verification. If the initial calibration verification results (ICV/ICB) are outside of the acceptance criteria, then the source(s) of the failure must be identified, necessary corrective action(s) performed, and the instrument recalibrated if necessary before proceeding with sample analysis.

If the continuing calibration verification results (CCV/CCB) do not meet the acceptance criteria then the source(s) of the failure must be identified and corrective action(s) performed, including recalibration if necessary, before continuing with sample analysis. If reanalysis of any sample(s) associated with failing calibration verification is not possible then the associated data must be reported with the appropriate qualification.

For instruments that permit the analysis of subsequent workgroups using the most recent calibration, two (2) consecutive attempts of the opening CCV/CCB are allowed. If both attempts fail to produce acceptable results then the source(s) of the failure must be identified and corrective action(s) performed, including recalibration if necessary, before commencing sample analysis. If a CCV retest fails and the instrument is not recalibrated, 2 consecutive passing CCV's are required before continuing with analysis.

Unless stated otherwise by the test SOP, passing calibration verification must always bracket all batch quality control samples, and results for additional instrument check standards, if applicable, must be within the acceptance criteria stated in the SOP. However, when the acceptance criteria for a CCV or CCB are exceeded (i.e. high bias) any associated client sample with a measured concentration less than the MDL may be accepted and reported with the appropriate qualification.

11.3 Other Control Indicators

11.3.1 Internal Standards

Internal Standards (IS) are measured amounts of certain compounds added after preparation or extraction of a sample to be analyzed by GC/MS or ICPMS. The IS is an analyte not likely to be found in the environment and is used in a calibration method to correct sample results affected by column injection losses, purging losses or viscosity effects. The IS is added to client samples, controls and blanks in accordance with the method requirements. When the results are outside of the acceptance limits for applicable quality control samples, corrective actions shall be performed. Once system control has been reestablished, all samples analyzed while the system was malfunctioning shall be reanalyzed. If corrective actions could not be performed or are ineffective then the data for each client sample must be appropriately qualified on the final report.

11.3.2 Trip Blank

The trip blank is a sample container filled in the laboratory with Type I water that is shipped to the collection site in the sample cooler, returned to the laboratory, logged-in, and analyzed in the same manner as the client samples. With the exception of Hg-1631, trip blanks are not opened in the field. If a target analyte is detected in the trip blank then the appropriate data qualifier is applied to pertinent results from those samples returned to ACZ in the same cooler as the trip blank. Trip blanks are typically prepared for Hg-1631, Cyanide, and VOA samples.

11.3.3 Instrument Blank

The instrument blank is an aliquot of Type I water processed only through the instrument steps of sample analysis and is used to determine presence of instrument contamination. For Organic instrument methods, neither surrogate nor IS standards are added.

11.3.4 Equipment Blank

An equipment blank is provided by the client and is used to assess the effectiveness of equipment decontamination procedures. Type I water is poured into (or over) or pumped through the sampling device, collected in a sample container and transported to the lab to be analyzed for all parameters requested for the environmental samples collected at the site. If any target analyte is detected then all associated sample results must be qualified on the final report.

11.3.5 Ambient Blank

The ambient blank consists of Type I water poured into a VOA vial at the sampling site (in the same vicinity as the associated samples). It is handled like an environmental sample and transported to the laboratory for analysis. Ambient blanks are prepared when samples are to be analyzed for VOA analytes and are used to assess the potential introduction of contaminants from ambient sources (e.g., active runways, engine test cells, gasoline motors in operation, etc.) to the samples during sample collection. The frequency of collection for ambient blanks is specified in the client's field-sampling plan and are not required for all projects.

12 EVALUATING QUALITY CONTROL SAMPLES

In general, acceptance criteria for quality control samples are method-specific; however, compliance with the requirements of clients and regulatory or other accrediting agencies must also be demonstrated. Immediate corrective action must be taken if any quality control is outside of the acceptance criteria. Appropriate corrective actions are described in the test SOP. To the extent possible, client samples are reported only if all quality control measurements are acceptable. If a quality control measure is outside of acceptance criteria, and the data must be reported, then all samples associated with the failed QC must be reported to the client with the appropriate data qualifier(s). Clients will occasionally request limits different from those in a published method. If a client has data quality objectives that require modification of our guidelines then we may deviate from those guidelines only if more stringent controls are requested. ACZ's policy is to adhere to the strictest limits as a means of meeting all agency and client requirements.

For methods that do not specify acceptance criteria for any type of quality control measurement, limits may be generated by plotting historical data in a control chart once a minimum of 20 data points is available. A control chart application may be accessed through LIMS and allows the user to create limits, either from a specified number of data points or for a specific time period, that are set at $\pm$ 3 times the standard deviation from the mean percent recovery. Current control limits are also plotted to provide a direct comparison of the two sets of data. New limits developed from a control chart must be documented on FRMQA039 and must be reviewed by the QA department prior to implementation. (In lieu of submitting FRMQA039, an excel spreadsheet or other document containing all the information fields present in FRMQA039 may be submitted to the QA department.) If the new limits are approved, then QA personnel will update LIMS. Refer to ACZ's SOP *Control Charting Application and Procedure* (SOPAD041) for further details. Default acceptance criteria established by the Arizona Department of Health Services (ADHS) may be used in lieu of generating a control chart to establish limits; however the SOP must specify which limits are in use. [4] **NOTE:** For all data evaluation, final results ending with 1 – 4 are rounded down and results ending with 5 – 9 are rounded up.

12.1 Accuracy

Accuracy is defined as "the degree of correspondance between a measured value and the true or expected value of the quantity of concern."[*] Control samples (LCS or LFB) and spiked samples are analyzed with every batch of samples or as stipulated by the specific test SOP to assess accuracy and matrix effects.

- Percent Recovery (%R) for a control sample is calculated as follows:

$$\%R = \frac{M}{S_p} \times 100$$

Where: M = Measured concentration of the control sample
S_p = True value of the control sample

- Percent Recovery (%R) for a spike is calculated as follows:

$$\%R = \frac{M - S}{S_p} \times 100$$

Where: M = Measured concentration of the spiked sample
S = Measured concentration of the sample aliquot
S_p = True value of the spike concentration

[4] Arizona Adiministrative Code (A.A.C.), Title 9, Ch. 14, Article 6, Exhibit II (December, 2006)

[*] "Quality Assurance of Chemical Measurements," Taylor, J., 1987

12.2 Precision

Precision is defined as "the degree of mutual agreement characteristic of independent measurements as the result of repeated application of the process under specified conditions." Matrix duplicates and spike duplicates are analyzed with every batch of samples or as stipulated by the test SOP to determine the precision associated with the analysis. If any method does not specify acceptance criteria for the RPD, then default criteria of RPD $\leq$ 20 is used (a value that rounds to 20 is acceptable). [5] The Relative Percent Difference (RPD) as an absolute value is calculated as follows:

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

Where: S = Sample Value
D = Duplicate Value

12.3 Other Calculations

- Solids Dilution Factor (assume 100% solid for "as received" samples):

  $$\text{Dilution Factor} = \frac{V}{(W)(\%\ \text{solid})}$$

  Where: V = Final digestate volume, in mL
  W = Sample weight used, in g
  %solid = %solid or air dry solid, as a decimal

- Sample Concentration for Solids:

  - wet weight [biota tissue, fruit or vegetable matter, etc.]: $mg/Kg = \frac{DF * C * V}{W}$

  - dry weight [plant matter, grasses, soil, sludge, etc.]: $mg/Kg = SF * C * DF$

    Where: DF = instrument dilution factor
    C = raw data value, in mg/L
    V = Final volume of digestate, in L
    W = sample weight used, in Kg
    SF = soil dilution factor

- Percent Difference for Serial Dilution (SDL):

  $$|\%D| = \frac{[I - (s * 5)]}{I} \times 100$$

  Where: I = initial sample result
  s = serial dilution result (raw data value)

  For SDL calculations in LIMS, "s" is multiplied by 5 and the resulting "reg value" is compared to the "found value" to calculate %D.

[5] ADHS Information Update #87 (July 7, 2005)

12.4 Radiochemistry Calculations: (**NOTE**: Formulas for error, LLD, & activity in the indidual test SOP's supercede the general equations detailed below.)

12.4.1 Activity

The results of radioactivity are typically reported in terms of activity per unit volume or mass. Units are normally expressed in picocuries (pCi), which equal 2.22 disintegrations per minute (dpm). Specific formulas to determine activity are in the SOP for each method. The general formula is as follows:

$$C = \frac{R_{net}}{(e)(y)(i)(v)(u)}$$

Where: C = activity per unit volume (pCi/L)
R_{net} = net counts per minute
e = counting efficiency, cpm/dpm
y = chemical yield
i = ingrowth correction factor
v = volume or mass being counted (L)
u = units correction factor, 2.22 for cpm to pCi

12.4.2 Counting Error

Radiochemical data are considered incomplete without reporting associated random and systematic errors. For this reason all radiochemical results should be accompanied by a counting error at the 95% confidence level (1.96*standard deviation). The general counting error formula is as follows:

$$E = \frac{1.96\left(R_o / t_1 + B / t_2\right)^{1/2}}{(e)(y)(i)(v)(u)}$$

Where: E = counting error
R_o = gross sample, cpm
t_1 = sample count duration, min
B = background, cpm
t_2 = background count duration, min
e, y, i, v, and u are as previously defined.

12.4.3 Lower Limit of Detection (LLD)

LLD (also referred to as Minimum Detectable Activity or MDA) is considered the smallest quantity of sample radioactivity that will yield a net count for which there is a pre-determined level of confidence that radioactivity is present. At the 95% confidence level, the following equation calculates the LLD for any single nuclide. The calculation uses the standard deviation for the background counting rate, assuming the sample and background counting rates should be very similar at the LLD. The formula for determining LLD is as follows:

$$LLD_{95} = \frac{4.66S_b}{(e)(y)(i)(v)}$$

Where : LLD_{95} = Lower limit of detection at the 95% confidence interval
S_b = Standard deviation of the instrument background counting rate, cpm

e, y, i, v, and *u* are as previously defined

12.4.4 Precision

The normalized absolute difference, or Replicate Error Ratio (RER), between the sample and the laboratory duplicate, given by the following equation shall be used to determine that results do not differ significantly when compared to their respective 2* sigma uncertainty.

$$RER = \frac{\left|Sx - Dup\right|}{\sqrt{(Sx_{error})^2 + (Dup_{error})^2}} \leq 2$$

Where: Sx = sample concentration in pCi/L
Sx_{error} = sample counting error (in pCi/L) at the 95% confidence level.
Dup = duplicate concentration in pCi/L
Dup_{error} = duplicate counting error (in pCi/L) at the 95% confidence level.

NOTE: For Radchem Drinking Water samples, both RPD and RER are used to evaluate precision. For non-Drinking Water samples, only RER is used; however, data for both RER and RPD are uploaded to LIMS for all analyses. Use the following guidelines to correctly assess precision. Further details are provided in ACZ's Wiki and must be consulted to ensure data for each workgroup is correctly evaluated. Go to LabWeb \ Wiki \ Analytical Departments \ Radio Chemistry.

Drinking Water:

RPD $\leq$ 20, RER < 2.0 – Precision is judged to be in control
RPD $\leq$ 20, RER > 2.0 – Precision is judged to be in control; case narrative required for RER
RPD > 20, [sx] < 5x [LLD], RER < 2.0 – Precision is judged to be in control; qualify data.
RPD > 20, [sx] > 5x [LLD], RER> 2.0 – Precision of the prep batch is questionable.
RPD > 20, [sx] > 5x [LLD], RER < 2.0 – Precision of the prep batch is questionable.

Non-Drinking Water:

RER < 2.0, RPD $\leq$ 20 – Precision is judged to be in control.
RER < 2.0, RPD > 20 – Precision is judged to be in control; RPD must be qualified.
RER > 2.0, RPD $\leq$ 20 – Precision of the sample prep batch is questionable.
RER > 2.0, RPD > 20 – Precision of the sample prep batch is questionable.

13 VALIDATION & REVIEW OF ANALYTICAL DATA

ACZ has the responsibility to always provide the best data possible to ensure our clients can make sound and cost-effective decisions regarding public health and the environment. In order to generate and report reliable data, the analytical systems used need to be properly functioning, and the review process must be conducted in a manner that is logical and reasonable and would be defensible if subjected to legal scrutiny. Decisions regarding data quality must be meaningful and must be backed by good science and sound professional judgments.

The entire validation and review process encompasses more than solely evaluating the final results for client and quality control samples. To this extent, the necessary steps must also be performed *prior* to sample preparation or analysis to ensure the quality of the data. Following sample analysis, data is uploaded to the LIMS database and then submitted to a variety of process chains such as calculations, rounding, application of qualifiers, etc. A multi-level data review process is utilized to verify the uploaded analytical data meets all documented ACZ requirements as well as any client-specific quality objectives. For additional details of the data reduction, review, and validation process, refer to ACZ's SOP *Data Review Process* (SOPAD032). At a minimum, the validation process must include the following steps, as applicable:

- Monitor the expiration dates for all stock, intermediate, and working standards, reagents, and chemicals.
- Prior to analysis, determine that holding times have not been exceeded. Unless otherwise specified by the test SOP, sample preparation and analysis must be completed within the holding time.
- Prior to analyzing samples, verify the correct set-up and operation of the instrument or equipment. Perform calibration, maintenance, and optimization as necessary to ensure proper functioning.
- In general, for QC frequency of 1 per10 or less client samples, the first set of QC is associated with samples 1 – 10. If there are fewer than 20 samples in the workgroup, then the remaining client samples are associated with the second set of QC.
- Before completing workgroup creation, verify the correct PCNs and/or SCNs have been entered. Percent recovery for control samples and spikes is calculated using the information in LIMS for each.
- Verify the proper sub-sample (green dot, yellow dot, etc.) is being used for preparation or analysis.
    - Notify the supervisor or Production Manager as soon as possible if a sample cannot be located.
    - Document on the bench sheet if a sub-sample other than the type indicated in the SOP is used.
- Compare the Log-In number on the sample container to the Log-In number on the bench sheet and make a visible mark next to each sample on the workgroup to indicate the check has been performed.
- Clearly label tubes, beakers, autosampler cups, etc. to identify the sample (and dilution factor, if applicable).
- Manage sample volume to ensure all analyses from a bottle type can be completed.
- Document all dilution factors on the bench sheet at the time the dilution is performed.
- Record complete and accurate observations, as necessary, when an analysis, sample preparation, or sample matrix is unusual or problematic.
- Ensure transcription errors do not occur. Verify all data manually entered into LIMS is correct before completing the upload process.
- The calibration workgroup must be associated with all subsequent workgroups. Record the calibration workgroup number (or calibration file name) on the data review checklist.

- Provide complete traceability for all standards and reagents used for sample preparation and analysis.

- Quality control samples must be treated in the same manner as client sample, including preparation.

- If it is necessary to perform a calculation manually, use the values in the raw data [do not truncate] and then round the final result to no more than three (3) significant figures. If the final result passes the acceptance criteria then pass the QC in LIMS and note on the data review checklist that it passes.

- LIMS performs several additional QC calculations on the approved data including cation/anion balance (CAB) checks, calculated TDS versus actual TDS ratios, and Total versus Dissolved ratios. The Project Manager may update the status of the pertinent sample(s) to REDO if one of these calculations indicates a discrepancy with the associated data.

- If two attempts fail to produce acceptable data then notify the supervisor or Production Manager before taking further action. It may be necessary to first determine if a larger problem is interfering with the analysis. Investigate the problem before qualifying the associated data.

- If there is an indication that the analytical system is out of control then the issue(s) must be investigated. Notify the supervisor immediately. Conduct troubleshooting in an organized manner.

- All data must be reviewed initially in LIMS [AREV] by the analyst who performed the analysis or by another qualified individual who has previously been granted approval. The department supervisor or another qualified individual performs the secondary review [SREV]. The following are data review guidelines:

  1 A data review checklist must be completed during the review process. Verify all items listed and note any errors, problems or non-compliances and the corrective action(s) taken.

  2 If applicable, review the raw data to verify the analytical system was in control and to ensure no anomalies exist. Check for notes on the bench sheet regarding the preparation or analysis.

  3 For client samples and quality control samples, ensure all results are within the measurement range and are bracketed by a passing calibration and passing calibration verification [ICV/ICB or CCV/CCB]. Sample values outside of the measurement range must be appropriately qualified if reanalysis is not possible.

  4 The corrective action specified in the SOP must be performed if any quality control sample does not meet the acceptance criteria. Data associated with failed quality control cannot be qualified after the initial analysis without acceptable justification.

  5 Data is more acceptable if the preparation and analysis were performed within the holding time. If reprep or reanalysis will be conducted outside of the holding time, check first with the supervisor.

  6 Confirm all dilutions are appropriate. A reasonable explanation must be provided on the bench sheet if a sample was diluted and the value is less than the reporting limit (refer also to §15).

  7 If the initial analysis indicates possible positive or negative matrix interference then the sample(s) should be retested on dilution to confirm. The sample needs to be retested only one time – if a background effect is still evident, then note the event on the data review checklist and qualify the associated data.

  8 If a spike fails, determine if the sample concentration is disproportionate to the spike added. If the analyte concentration in the sample is > 4x the spike added then note the failure on the checklist and appropriately qualify the associated samples.

  9 If a spike recovery indicates the sample was not spiked, then re-prep / retest all associated samples.

10 Each associated client sample must be appropriately qualified if the matrix spike, matrix duplicate or spike duplicate data cannot be used for validation purposes.

11 Confirm failed QC by verifying the correct PCN or SCN was entered. Make corrections if necessary before proceeding with data review.

12 Verify all assigned qualifiers are appropriate. Does use of a particular qualifier make sense? Could data be defended using the qualifier(s) assigned to the scenario or problem?

13 If a case narrative is necessary, the reason for accepting and reporting the data must be sound and logical. Provide sufficient and accurate verbiage to ensure the data is legally defensible.

14 If a sample was retested in the same workgroup, verify the correct data will be reported. All other data for the sample must be failed – LIMS cannot report multiple data for the same sample.

15 Confirm all samples have the correct status (PASS, FAIL, REDO, REDX) before completing the review process. For multi-parameter workgroups, all analytes must have the correct status.

16 Refer also to §11 for data evaluation criteria.

14 DETECTION LEVELS

Current practice identifies several detection levels, each of which has a defined purpose: Instrument Detection Limit (IDL), Method Detection Limit (MDL), Reporting Limit (RL), and Practical Quantitation Limit (PQL). The MDL and PQL are stated in each test SOP and are adjusted accordingly in LIMS when data is uploaded to reflect the use of smaller sample volume (dilution) or larger sample volume (concentration).

14.1 Instrument Detection Limit (IDL)

The IDL is the concentration of substance that produces a signal greater than three standard deviations of the mean noise level or the concentration that can be determined by injecting a standard to produce a signal that is five times the signal-to-noise ratio. The IDL should always be below the MDL and is not used for compliance reporting, but is useful for estimating the amount of analyte needed to produce a signal in order to calculate an estimated method detection level and for comparing the attributes of different instruments.

14.2 Method Detection Limit (MDL)

The EPA defines the MDL as the "minimum concentration of substance that can be measured by a specific testing protocol and reported with 99% confidence that the analyte concentration is greater than zero…" This confidence interval means that any substance detected at a concentration equal to the MDL is 99% likely to be present, but it also means there is a 1% chance that the substance will be considered falsely present (false positive). The MDL procedure is designed so that the probabilities of both false positive and false negative errors are acceptably small; however, the procedure has limitations. Data users must understand the limitations when evaluating low level data and must proceed with caution when interpreting data reported between the MDL and PQL in order to minimize the risk of making poor environmental decisions.

MDLs are dependent on variables (temperature, instrument conditions, analysts, matrix, etc.) and are typically determined by processing, preferably over the course of several days, at least seven individual replicates of a fortified blank sample through the method's preparation and analytical schemes. MDLs determined for the same method / matrix / technology must be compared to ensure they are in agreement.

ACZ maintains a current MDL for each method. Unless specified by a method or to meet the needs of a special project or client request, a MDL is considered current if no changes have been made to (1) extraction or analytical procedure, (2) type of column used, if applicable, (3) instrument location, (4) instrument sensitivity (i.e. no major repairs or extensive servicing), and (5) other modifications of this type. A qualitative verification of the MDL must be performed annually for each applicable method, analyte, instrument, and matrix and before a new instrument or method is utilized for client samples. Refer to ACZ's SOP *Demonstration of Capability & Method Detection Limit Studies* (SOPAD001) for additional information.

14.3 Practical Quantitation Limit (PQL)

At the MDL, data is not quantifiable, and the uncertainty is $\pm$ 100% (or $\pm$ MDL). The PQL represents the lowest quantitative level that can be achieved with good certainty during routine operations. Because data reported at or above the PQL is reproducible, the client or other end user will be assured that the result is valid and independent of variable analytical conditions. This reproducibility allows for comparison of analytical results over a relatively long period of time, which is important to the monitoring of environmental data. ACZ defines the PQL as a value typically 2 – 10 times the MDL. Reported values less than the PQL are qualified as estimated. The region between the MDL and PQL is a continuum of uncertainty, lacking distinct cutoff points, and the error below the PQL is increased to the extent that the statistical validity of the result is questionable.

15 SAMPLE DILUTIONS

Sample dilution may be necessary for one or more of the following reasons: (1) sample concentration exceeds the established measurement range of the procedure / method (2) sample volume or material is limited (3) matrix interference is indicated or suspected (4) sample matrix is reactive (5) aqueous sample contains high sediment (6) color, odor or other physical characteristics are present (7) For ICP and ICPMS, TDS is greater than 2000 mg/L. In all cases, the analyst must use good professional judgment when determining the most appropriate dilution. Whenever possible, analyze a client sample and its associated matrix spike(s) and/or matrix duplicate on the same dilution. If circumstances prohibit retesting, including reanalysis that would occur past the holding time, then the data must be reported with the appropriate qualifier(s).

For samples that contain high concentration of analyte(s), the analyst will use their knowledge of the measurement range of the procedure to determine an optimal dilution that yields quantifiable data with minimal error propagation. In general, prepare the dilution so the final concentration is near the mid-point of the measurement range. A sample must be retested on a smaller dilution if analyte concentration is less than the reporting limit – exceptions must be explained on the bench sheet. For multi-parameter analyses, it may not be possible to report all analytes within the desired range, and the analyst must use their best judgment when determining a reasonable dilution factor.

The following requirements pertain to all dilutions:

- Document all dilution factors on the bench sheet when the dilution is performed
- Assign the appropriate "D" qualifier if data for the diluted sample is less than the reporting limit
- Retest sample on smaller dilution if the result is less than the reporting limit (or document justification for accepting the data on the bench sheet or data review checklist)
- Document the reason for any dilution on the bench sheet [not required for sample values that exceed the measurement range of the procedure]
- Provide accurate documentation for the benefit of preparation of a case narrative, data validation, review by a regulatory agency or other third party, and reconstruction of the sample's history

16 ERROR CORRECTION PROTOCOL

When an error occurs in any type of record it must be crossed out with a **single line**, not erased, deleted, obliterated, or made illegible, and the correct value entered alongside. All changes to hard copy records must be initialed and dated by the person making the correction. [6]Under no circumstances may White-Out® or any other substance be used to conceal data. Concealing or improperly altering data is fraudulent and may be cause for termination from ACZ. Equivalent measures must be taken to avoid loss or change of original data in the case of records stored electronically. Refer to §10 for details of corrections made to electronic records. The following is an example of proper error correction:

fleece BWC 10-20-06
Mary had a little lamb, it's ~~feet~~ as white as snow. And everywhere that ~~Lary~~ went, the lamb was sure to go.
Mary BWC 10-20-06

[6] There is one exception to this rule. Client identification may be obliterated from a record if it's presence compromises client confidentiality (e.g. client ID is mistakenly entered in a logbook). In this event, the rationale for obliteration must be clearly stated and initialed and dated by the person making the correction.

17 COMPUTER / AUTOMATED PROCESSES

ACZ employs its proprietary (Laboratory Information Management System) to acquire, record, process, store and archive our data. It is the primary application for all employees and encompasses the combination of hardware and software throughout the entire facility to provide the interface for tasks such as creating workgroups, reviewing data, and generating client reports. ACZ implements the defined standards of Good Automated Laboratory Practices (GALP) to establish a uniform set of procedures to assure that all LIMS data used by our clients are reliable, credible, and legally defensible.

17.1 Software

The software used to achieve GALP goals is a combination of industry standard commercial software and internally developed applications. Commercial software is purchased through professional and well-developed companies such as Oracle, Microsoft and Lab Vantage Systems that complete sufficient testing and quality control to assure their product(s) functions properly. Internal applications undergo testing before being implemented and distributed throughout the laboratory.

Instrument data is automatically backed up anytime a file is saved through a client-server process running on most instrument PCs. This ability allows ACZ to see any version of a file created or modified during data processing. Electronic records are protected, backed up and archived to prevent unauthorized access or amendment. Refer to §10 of this document and ACZ's SOP *Backup and Archive of Instrument Data Files* (SOPAD044) for details.

17.2 Hardware

ACZ deploys many application servers using industry standard architecture. All servers run standard enterprise operating systems such as Microsoft Windows Server and SuSE Linux for file and print services, intranet, web hosting, several databases and the phone system. All data residing on network servers are routinely backed up to maintain a historical record of all data generated.

To the extent possible, instrument PCs comply with at least the recommendations of the instrument manufacturer and are connected to ACZ's network allowing transparent backup and access to computers by system administrators.

17.3 Security

GALP security is controlled through a set of passwords. A log-in name and password are required to access ACZ's network. User passwords must be at least five characters and must be changed when the user is prompted. Each user has a given set of network rights and is restricted to software necessary to complete their job functions as well as his/her own documents. Refer also to §10.7.1 for additional information.

A firewall protects the network from internet traffic. The only traffic permitted access to the internal network is protocols approved by ACZ such as IMAP, SMTP and HTTP. Incoming and outgoing E-mail is scanned for viruses, then scanned for inappropriate content and quarantined if necessary. Web traffic that is potentially harmful or inappropriate is blocked by a scanning application running on a proxy server.

18 CLIENT SERVICES

18.1 Subcontracting

ACZ utilizes subcontract labs to perform analyses for various reasons. A subcontracted lab must, at a minimum, adhere to the same quality assurance standards implemented by ACZ and must be NELAC certified for the subcontracted analysis. When applicable, ACZ advises its clients in writing of its intentions to subcontract any portion of the testing to another party. Non-NELAC work performed by a subcontracted lab must be clearly identified in the subcontract lab's report. ACZ scans this report as an attachment to be included as part of ACZ's final report. A comment is added to ACZ's final report indicating which subcontracted laboratory performed the analyses. Refer to ACZ's SOP *Client Service Policies and Procedures* (SOPAD043) for additional information.

18.2 Data Reporting

Once all analyses and the entire review process have been completed, a client report is generated and submitted for final validation by the Project Manager. If necessary, a case narrative is written describing the details of the project and any non-conformances or other relevant issues. The PM electronically signs the report, and the Document Control department sends the report to the client in an electronic format. At a minimum, the following information appears on an ACZ analytical report:

Client Name	Sample Matrix
Client Address	Parameter/Analyte
Client Contact	Method Reference
Lab Sample ID	Result
Client Sample ID	Units
Client Project ID	LIMS Qualifier (U, B, J, H)
ACZ Report ID	MDL or LLD
Date/Time Sampled	PQL or RL
Date/Time Received	Analyst's Initials
Date/Time Analyzed	Extended Qualifiers (as separate page)

A complete electronic data package contains the analytical reports, the external chain of custody records, sample shipping documentation, and any other relevant project information. Department Reference Sheets explaining acronyms, qualifiers, and method references are also included. All of these documents are an integral part of the final data package and must always be viewed as a whole. To prevent the separation of reports, each page identifies the project number, the sequential page number, and the total number of pages in the data package. Refer to ACZ's SOP *Client Service Policies and Procedures* (SOPAD043) for more detail.

If requested by a client, custom and standard Electronic database deliverables (EDDs) are generated by the Document Control department. These deliverables, containing data in client specified format, are sent by e-mail with the client report. EDDs and analytical reports access data from the same Oracle tables, thus eliminating the possibility of inconsistent results. Refer to ACZ's SOP *Client Service Policies and Procedures* (SOPAD043) for more detail.

18.2.1 ACZ Reporting Levels

ACZ provides different levels of data packages based on client request. ACZ defines the different levels as follows:

Level 2: Standard analytical reports

Level 3: Standard analytical reports, standard QC Summary and Electronic Data Deliverable (EDD)

Level 4A: Standard analytical reports, Extended QC Summary (standard QC plus calibration verification checks, interference checks and serial dilutions) EDD, raw data and run logs. This package can be provided either on a disk or in a full paginated data package with the raw data

Level 4B: Includes everything in Level 4A with the addition of CLP like forms incorporated into the paginated data package

NOTE: Surcharges apply for non-standard reports.

18.3 Data Confidentiality

ACZ has an obligation to each client to maintain custody of samples, data, and reports and to keep all data or other information confidential. To uphold this responsibility, ACZ retains custody of the information at all times – data or other client information obtained by ACZ is not allowed to leave the premises. This includes but is not limited to Chains of Custody, raw data, workgroups, run logs, logbooks, reports, QC summaries, data packages and other media containing data. Client data cannot be released to anyone except the client (as directed on the Chain of Custody) or the client's designated representative, and project data, including any client information, is not to be discussed with anyone other than ACZ employees and/or the client without first receiving written permission from the client. Additionally, client-specific information is not to be documented on raw data, workgroups, logbooks, or other records that may be provided to any client as part of an extended data package. All information must be referenced using only the ACZ log-In number. Refer to ACZ's SOP *Data Integrity Principles and Policies* (SOPAD039) for additional details of policies pertaining to confidentiality.

With the rapid advances of computer and information technology, it is possible for an employee to work at home and access the same electronic data and documents they could access while at ACZ. Accessing data from outside of ACZ could potentially compromise security, confidentiality and custody issues. ACZ's policy on external computer access is as follows:

External access to the ACZ network is limited to employees that may need to access information remotely. Employees requiring such access use ACZ's Virtual Private Network (VPN). The VPN client is setup on the employee's computer so that it adheres to ACZ security standards. These standards include (1) a unique user name (2) a password with at least 12 characters, and (3) 128 bit encryption of data to and from the client from the ACZ servers. After the VPN server has authenticated the employee, the employee must logon to the ACZ domain through normal domain security in order to access any ACZ network resources. Most employees initiate a "Remote Desktop" connection to their office PCs, thus ensuring that ACZ data is never accessible from the client PC hard drive.

18.4 Client Feedback

Handling client feedback is a joint effort between QA, Project Managers, Production Supervisors, and Client Service representatives. If a client has a concern or complaint, either a Project Manager or Client Service Representative takes the call and initiates the feedback procedure by documenting the complaint or problem and requesting the assistance of the Production Supervisor and/or QA Officer. If the issue cannot be easily resolved then it must be documented using FRMAD024, which is routed from the initiator to other appropriate parties, including the QA Officer if necessary. All client feedback is submitted to upper management as part of the Management Review of the Quality System. Refer to ACZ's SOP *Client Service Policies and Procedures* (SOPAD043) for additional information.

19 RADIOCHEMISTRY

19.1 DATA TRANSFORMATION

Unlike other laboratory divisions, ACZ's radiochemistry department utilizes excel spreadsheets to transform instrument response into final results. Spreadsheet equations are locked and password protected in order to reduce the likelihood of inadvertent modifications. Additionally, spreadsheet equations are validated by the radiochemistry supervisor or a sufficiently experienced analyst on an annual basis. Initial validation must be performed by hand calculating results. Annual validation may be performed by populating the current template with data that has been hand calculated in a previous validation and comparing the calculated results from the current template to the hand calculated results from the previous validation.

19.2 INSTRUMENTATION

Radioanalytical instrumentation is located adjacent to the radiochemistry prep lab. In order to maintain appropriate temperature control in the instrument lab, separation must be maintained. The door between the two lab areas must be kept closed when not in use. Except as noted, instrument checks and other determinations must be performed and documented annually, or more often if necessary.

NOTE: To eliminate potential contamination, planchets must be stored in a covered container or in a drawer.

19.2.1 Gas-Flow Proportional Counter

19.2.1.1 Instrument Reliability Test (Voltage Plateau Determination) – The proper voltage plateau for alpha and beta is where the counting rate is consistent (should not exceed > 5% over a 150 volt change in anode voltage).

19.2.1.2 Cross Talk (Carryover) Check - Cross talk is defined as the percentage of alpha counts represented on the beta plateau. Once the amount of cross talk is determined, the cross talk settings are adjusted on the instrument to eliminate cross talk.

19.2.1.3 Detector Efficiency Curve (Self Absorption) - Efficiency curves are graphs plotting counts versus sample density and determine the efficiency of the alpha and beta counter based on sample density. This factor is part of the overall determination of sample activity.

19.2.1.4 Background Determination - Characteristic of most detectors is a background or instrument count rate attributed to cosmic radiation, radioactive contaminants in instrument parts, counting room construction material and/or the proximity of radioactive sources. Placing an empty planchet in the counting chamber and counting it for as long as the longest sample-counting duration can determine the background rate (or a background check can be completed overnight). An overnight background determination must be completed weekly. The daily background rate must be analyzed daily for each detector.

19.2.1.5 Instrument-Response Check Source - This continuing calibration check verifies the instrument response and stability and is performed daily for each detector. If the source count is within two standard deviations (sigma) of the previously determined average count rate, instrument reliability and stability is established. If the check source is outside the ±2 sigma-warning limit, then the variability should be further investigated. If the check source is outside the ±3 sigma out of control limits, then no further samples

should be analyzed until the problem is resolved. If insufficient data exists for control charts, ±10% of the initial value is considered acceptable.

19.2.2 Liquid Scintillation Counter

19.2.2.1 *Optimal Window* - When determining radionuclides by liquid scintillation, it is necessary to select the optimal window by counting a standard for five minutes and generating a sample spectrum. For better clarity, a log scale for the channel number axis should be used. On the graph, the region of interest is determined by the energy of the peak one is trying to quantitate. The optimal window is formed by extending this region by 10% on each side of the alpha peaks.

19.2.2.2 *Efficiency Quench Curve* – The liquid scintillation instrument, a Beckman LS 6000TA, automatically corrects for quenching by the H - Method. Refer to SOPRC010 for details.

19.2.2.3 *Background Check* - Three background blanks are run with every batch. The first two are run immediately after calibration. The third, the CCB, is employed as a measurement of instrument drift and is run immediately before the final LCS. For both checks, the counting duration must be equivalent to the longest sample counting duration.

19.2.2.4 *Instrument-Response Check Source* - This continuing calibration check verifies instrument response and stability and must be performed daily. If the source count is within two standard deviations (sigma) of the previously determined average count rate, instrument reliability and stability is established. If the source rate is outside the ±2 sigma-warning limit then the variability should be further investigated. If the source check is outside the ±3 sigma out of control limits, then no further samples should be analyzed until the problem is resolved. Resolution might include a new efficiency curve, background checks, and/or instrument maintenance. If insufficient data exists for control charts, ±10% of the initial source value is considered acceptable. The source for this check is a Tritium standard.

19.2.3 Alpha Spectrometer

19.2.3.1 *Energy vs. Channel Calibration* - Each alpha spectrometer has a set number of channels associated to it. To associate these channels to a specific alpha particle, the channels must be calibrated. One known calibrated solid source is placed into the detector and analyzed for five minutes to determine its associated channel to its calibrated energy peak. Since the energy is linear across the channels, all of the channels now have an associated energy. This determination is performed on an annual basis, or whenever maintenance is performed that could potentially affect the calibration.

19.2.3.2 *Background Checks* - Characteristic of most detectors is a background or instrument count rate attributed to cosmic radiation, radioactive contaminants in instrument parts, counting room construction material and/or the proximity of radioactive sources. Placing an empty sample tray in the counting chamber and counting it for as long as the longest sample-counting duration can determine the background rate (or a background check can be completed overnight). An overnight background determination must be completed at least quarterly.

19.2.3.3 *Instrument-Response Check Source* - This continuing calibration check verifies the instrument response and stability and is performed daily. If the source count is within two standard deviations (sigma) of the previously determined average count rate, instrument reliability and stability is established. If the source rate is outside the ±2 sigma-warning limit, then the variability should be further investigated. If the source

check is outside the ±3 sigma out of control limits, then no further samples should be analyzed until the problem is resolved. Resolution might include a background check, and/or instrument maintenance. If insufficient data exists for control charts then ±10% of the true value is considered acceptable.

19.2.4 Gamma Spectrometer

19.2.4.1 *Background Checks* –Characteristic of most detectors is a background or instrument count rate attributed to cosmic radiation, radioactive contaminants in instrument parts, counting room construction material and/or the proximity of radioactive sources. A cave background must be measured monthly and the background gross activity recorded. The cave background is determined by counting the empty cave for a period of time at least as long as the longest sample-counting duration. Additionally, background is measured prior to each batch analysis by placing a blank water sample within a Marinelli beaker in the counting chamber and counting it for as long as the longest sample-counting duration. When drinking water samples are present in the batch, and additional background check is measured at the end of the batch to monitor instrument drift.

19.2.4.2 *Instrument-Response Check Source* - This continuing calibration check verifies instrument response and stability. This check is performed for every workgroup. If the source count is within two standard deviations (sigma) of the previously determined average count rate, instrument reliability and stability is established. If the source rate is outside the ±2 sigma-warning limit, then the variability should be further investigated. If the source check is outside the ±3 sigma control limits, then no further samples should be analyzed until the problem is resolved. Resolution might include a background check, and/or instrument maintenance. If insufficient data exists for control charts then ±10% of the true value is considered acceptable.

APPENDIX A Required Container Type, Preservation Techniques, and Holding Times

Parameter	Container	Preservation [a, b]	Maximum Holding Time [c]
Alkalinity	HDPE or Glass	≤ 6 °C	14 days
Acidity	HDPE or Glass	≤ 6 °C	14 days
Ammonia (N-NH_3)	HDPE or Glass	≤ 6 °C; H_2SO_4 to pH < 2	28 days
Anions	HDPE	≤ 6 °C	28 days (Br^-, F^-, Cl^-, SO_4^{2-})
BOD, CBOD	HDPE or Glass	≤ 6 °C	48 hours
COD	HDPE or Glass	≤ 6 °C; H_2SO_4 to pH < 2	28 days
Color	HDPE or Glass	≤ 6 °C	48 hours
Conductivity	HDPE or Glass	≤ 6 °C	28 days
Cyanide	HDPE or Glass	≤ 6 °C; NaOH to pH > 12	14 days
Chromium (VI)	HDPE or Glass	≤ 6 °C	Refer to SOP for holding time
Dissolved Oxygen	Glass	None required	Analyze immediately
Metals (except Cr^{6+}, Hg)	HDPE or Glass	HNO_3 to pH < 2	180 days
Mercury (CVAA, ICP/MS)	HDPE or Glass	HNO_3 to pH < 2	28 days
Mercury (CVAFS)	Glass	5 mL 12N HCl	90 days
N – NO_2 / NO_3	HDPE or Glass	≤ 6 °C; H_2SO_4 to pH < 2	28 days (48 hours if unpreserved)
N – NO_3	HDPE or Glass	≤ 6 °C	48 hours
N – NO_2	HDPE or Glass	≤ 6 °C	48 hours
Nitrogen, Total Kjeldahl	HDPE or Glass	≤ 6 °C; H_2SO_4 to pH < 2	28 days
Oil & Grease	Glass	≤ 6 °C; HCl or H_2SO_4 to pH < 2	28 days
Orthophosphate	HDPE or Glass	≤ 6 °C	48 hours
pH	HDPE or Glass		Analyze immediately
Phenols	Glass	≤ 6 °C; H_2SO_4 to pH < 2	28 days
Phosphorus (Total)	HDPE or Glass	≤ 6 °C; H_2SO_4 to pH < 2	28 days
Sulfide	HDPE or Glass	≤ 6 °C; Zn acetate + NaOH to pH > 9	7 days

APPENDIX A Continued

Parameter	Container	Preservation	Maximum Holding Time
Sulfite	HDPE or Glass	≤ 6 °C; EDTA	Analyze immediately
Settleable Solids	HDPE or Glass	≤ 6 °C	48 hours
Total Organic Carbon	Glass only	≤ 6 °C; HCl or H_2SO_4 to pH < 2	28 days
Turbidity	HDPE or Glass	≤ 6 °C	48 hours
Total Dissolved Solids	HDPE or Glass	≤ 6 °C	7 days
Total Suspended Solids	HDPE or Glass	≤ 6 °C	7 days
Total Solids	HDPE or Glass	≤ 6 °C	7 days
Total Volatile Solids	HDPE or Glass	≤ 6 °C	7 days
Radon-222	Glass Vial [d]		4 days
Total Volatile Hydrocarbons	Glass Vial or jar [d]	≤ 6 °C; HCl to pH < 2 (water)	Refer to SOP for holding times
Total Petroleum Hydrocarbons	Amber Glass	≤ 6 °C	Refer to SOP for holding times
BTEX / MTBE	Glass Vial or jar [d]	≤ 6 °C; HCl to pH < 2 (water)	14 days
Organochlorine Pesticides	Glass Vial or jar [d]	≤ 6 °C; pH 5 – 9	Refer to SOP for holding times
PCBs	Amber Glass	≤ 6 °C	Refer to SOP for holding times
PAHs	Amber Glass	≤ 6 °C	Refer to SOP for holding times
BNAs (semi-volatiles)	Amber Glass	≤ 6 °C	Refer to SOP for holding times
VOAs (volatiles)	Glass Vial or jar [d]	≤ 6 °C; HCl to pH < 2 (water)	Refer to SOP for holding times
TCLP	Glass [d]	≤ 6 °C	Refer to SOP for holding times
Radchem (except Rn-222)	HDPE cube	HNO_3 to pH < 2	180 days

a. No pH adjustment for soil
b. Preservation with 0.008% $Na_2S_2O_3$ required only when residual chlorine is present.
c. Unless otherwise specified in the test SOP, complete sample preparation and analysis within holding time.
d. Teflon-lined septa or lid
e. Aqueous samples must be preserved at ≤6 °C, and should not be frozen unless data demonstrating that sample freezing does not adversely impact sample integrity is maintained on file and accepted as valid by the regulatory authority. Also, for purposes of NPDES monitoring, the specification of "≤ °C" is used in place of the "4 °C" and "< 4 °C" sample temperature requirements listed in some methods. It is not necessary to measure the sample temperature to three significant figures (1/100th of 1 degree); rather, three significant figures are specified so that rounding down to 6 °C may not be used to meet the ≤6 °C requirement. The preservation temperature does not apply to samples that are analyzed immediately (less than 15 minutes).

APPENDIX B Utah BLI Certificate and List of Certified Parameters

State of Utah
JON HUNTSMAN Jr.
Governor
GARY HERBERT
Lieutenant Governor

Utah Department of Health
David N. Sundwall, MD
Executive Director

Epidemiology and Laboratory Services
Patrick F. Luedtke, MD, MPH.
Director of Public Health Laboratories

Bureau of Laboratory Improvement
David B Mendenhall, MPA, MT (ASCP)
Bureau Director

NELAP
Recognized

STATE OF UTAH
DEPARTMENT OF HEALTH

ENVIRONMENTAL LABORATORY CERTIFICATION PROGRAM

CERTIFICATION

is hereby granted to

ACZ Laboratories, Inc.

2773 Downhill Drive
Steamboat Springs CO 80487

Scope of accreditiation is limited to the
State of Utah Accredited Fields of Accreditiation
Which accompanies this Certificate

Continued accredited status depends on successful
Ongoing particitpation in the program

EPA Number: CO00028
Expiration Date: 4/30/2010

Patrick F. Luedtke, MD, MPH.
Director of Public Health Laboratories
Deputy Director of Epidemiology and Laboratory Services

Utah Department of Health

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Utah! Where ideas connect

State of Utah
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Governor
GREGORY S BELL
Lieutenant Governor

Utah Department of Health
David N. Sundwall, MD
Executive Director

Disease Control and Prevention
Patrick F. Luedtke, MD, MPH.
Director Unified State Labs - Public Health

Bureau of Laboratory Improvement
David B Mendenhall, MPA, MT (ASCP)
Bureau Director

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12/3/2009

ACZ Laboratories, Inc.
Audrey Stover
2773 Downhill Drive
Steamboat Springs CO 80487

ID # ACZ
EPA ID: CO00028

Director,

On the basis of your most recent Proficiency Testing results and continuing compliance with the ELCP requirements, the laboratory listed is certified for environmental monitoring under the Clean Water Act and authorized to perform the following methods, for the analytes and matrix listed:

Non-Potable Water

Inorganics and Metals

160.4 [1971]	Residue, Volatile (Gravimetric, Ignition at 550-C)
1631 E	Mercury in Water by Oxidation, Purge and Trap, and Cold Vapor Atomic Fluorescense Spectrometry
1664 A [1999]	Oil & Grease and Total Petroleum Hydrocarbons
180.1 [1993]	Turbidity
200.7 [1994]	Aluminum
200.7 [1994]	Antimony
200.7 [1994]	Arsenic
200.7 [1994]	Barium
200.7 [1994]	Beryllium
200.7 [1994]	Boron
200.7 [1994]	Cadmium
200.7 [1994]	Calcium
200.7 [1994]	Chromium
200.7 [1994]	Cobalt
200.7 [1994]	Copper
200.7 [1994]	Iron
200.7 [1994]	Lead
200.7 [1994]	Lithium
200.7 [1994]	Magnesium
200.7 [1994]	Manganese
200.7 [1994]	Molybdenum
200.7 [1994]	Nickel
200.7 [1994]	Potassium
200.7 [1994]	Selenium
200.7 [1994]	Silica
200.7 [1994]	Silver
200.7 [1994]	Sodium
200.7 [1994]	Strontium
200.7 [1994]	Tin

The expiration for the laboratory's certification is 4/30/2010. The Utah Environmental Laboratory Certification Program (ELCP) encourages clients and data users to verify the most current certification letter for the authorized method. For further assistance please call 801-538-9370.

UTAH DEPARTMENT OF HEALTH

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Clean Water Act
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Inorganics and Metals

200.7 [1994]	Titanium
200.7 [1994]	Vanadium
200.7 [1994]	Zinc
200.8 [1994]	Aluminum
200.8 [1994]	Antimony
200.8 [1994]	Arsenic
200.8 [1994]	Barium
200.8 [1994]	Beryllium
200.8 [1994]	Cadmium
200.8 [1994]	Chromium
200.8 [1994]	Cobalt
200.8 [1994]	Copper
200.8 [1994]	Lead
200.8 [1994]	Manganese
200.8 [1994]	Mercury
200.8 [1994]	Molybdenum
200.8 [1994]	Nickel
200.8 [1994]	Selenium
200.8 [1994]	Silver
200.8 [1994]	Thallium
200.8 [1994]	Thorium
200.8 [1994]	Uranium
200.8 [1994]	Vanadium
200.8 [1994]	Zinc
2310 B [20th ED]	Acidity (Nephelometric) [SM 20th ED]
2320 B [20th ED]	Alkalinity (Titration) [SM 20th ED]
2340 B [20th ED]	Hardness (Calculation) [SM 20th ED]
245.1 [1994]	Mercury
2510 B [20th ED]	Conductivity (Laboratory) [SM 20th ED]
2540 B [20th ED]	Total Solids Dried at 103-105-C [SM 20th ED]
2540 C [20th ED	Total Dissolved Solids Dried at 180-C [SM 20th ED]
2540 D [20th ED	Total Suspended Solids Dried at 103-105-C [SM 20th ED]
2540 F [20th ED]	Settleable Solids [SM 20th ED]
300.0 [1993]	Bromide
300.0 [1993]	Chloride
300.0 [1993]	Fluoride
300.0 [1993]	Sulfate
3114 B [19th ED]	Selenium [SM 19th ED]
335.4 [1993]	Cyanide, Total
350.1 [1993]	Nitrogen, Ammonia
3500 (Cr) D [19t	Chromium VI (Colorimetric) [SM 19th ED]
351.2 [1993]	Nitrogen, Total Kjeldahl
353.2 [1993]	Nitrogen, Nitrate-Nitrite
353.2 [1993]	Nitrogen, Nitrite
353.2 [1993]	Nitrogen, Nitrate
365.1 [1993]	Phosphorous, Total
365.1 [1993]	Ortho-Phosphate
375.4 [1978]	Sulfate
410.4 [1993]	Chemical Oxygen Demand
420.4 [1993]	Phenolics, Total
4500 (Cl-) E [19t	Chloride (Ferricyanide, Automated) [SM 19th ED]
4500 (CN-) I [20t	Weak Acid Dissociable Cyanide [SM 20th ED]
4500 (F-) C [20th	Fluoride (Ion-Selective Electrode) [SM 20th ED]
4500 (H+) B [20t	pH (Electrometric) [SM 20th ED]

The expiration for the laboratory's certification is 4/30/2010. The Utah Environmental Laboratory Certification Program (ELCP) encourages clients and data users to verify the most current certification letter for the authorized method. For further assistance please call 801-538-9370.

UTAH DEPARTMENT OF HEALTH

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Inorganics and Metals

4500 (SO42-) D [	Sulfate (Gravimetric, Drying of Residue [SM 20th ED]
5210 B [20th ED]	Biochemical Oxygen Demand 5-Day Test [SM 20th ED]
5210 B [20th ED]	Carboneous Biochemical Oxygen Demand (CBOD) [SM 20th ED]
5310 B [20th ED]	Total Organic Carbon (Combustion-Infrared) [SM 20th ED]
D-516 (02)	Sulfate, Turbidimetric

Organics

624	Purgeables
624	Benzene
624	Bromodichloromethane
624	Bromoform
624	Bromomethane
624	Carbon Tetrachloride
624	Chlorobenzene
624	Chloroethane
624	2-Chloroethylvinyl Ether
624	Chloroform
624	Chloromethane
624	Dibromochloromethane
624	1,2-Dichlorobenzene
624	1,3-Dichlorobenzene
624	1,4-Dichlorobenzene
624	1,1-Dichloroethane
624	1,2-Dichloroethane
624	1,1-Dichloroethene
624	trans-1,2-Dichloroethene
624	1,2-Dichloropropane
624	cis-1,3-Dichloropropene
624	trans-1,3-Dichloropropene
624	Ethylbenzene
624	Dichloromethane (DCM, Methylene chloride)
624	1,1,2,2-Tetrachloroethane
624	Tetrachloroethylene
624	Toluene
624	1,1,1-Trichloroethane
624	1,1,2-Trichloroethane
624	Trichloroethene
624	Trichlorofluoromethane
624	Vinyl Chloride
624	Xylenes, total
624	ortho-xylene
624	meta-xylene
624	para-xylene
625	Base/Neutrals and Acids
625	Acenaphthene
625	Acenaphthylene
625	Anthracene
625	Benzo(a)anthracene
625	Benzo(b)fluoranthene
625	Benzo(k)fluoranthene
625	Benzo(g,h,i)perylene
625	Benzo(a)pyrene
625	Benzyl Butyl Phthalate
625	bis(2-Chloroethyl)ether
625	bis(2-Chloroethoxy)methane

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Organics	
625	bis(2-Ethylhexyl)phthalate
625	bis(2-Chloroisopropyl)ether
625	4-Bromophenyl Phenyl Ether
625	2-Chloronaphthalene
625	4-Chlorophenyl Phenyl Ether
625	Chrysene
625	Dibenz(a,h)anthracene
625	Di-n-butylphthalate
625	3,3'-Dichlorobenzidine
625	Diethyl phthalate
625	Dimethyl phthalate
625	2,4-Dinitrotoluene
625	2,6-Dinitrotoluene
625	Di-n-octylphthalate
625	Fluoranthene
625	Fluorene
625	Hexachlorobenzene
625	Hexachlorobutadiene
625	Hexachlorocyclopentadiene
625	Hexachloroethane
625	Indeno(1,2,3-cd)pyrene
625	Isophorone
625	Naphthalene
625	Nitrobenzene
625	N-Nitrosodimethylamine
625	N-Nitrosodi-n-propylamine
625	N-Nitrosodiphenylamine
625	Phenanthrene
625	Pyrene
625	1,2,4-Trichlorobenzene
625	4-Chloro-3-methylphenol
625	2-Chlorophenol
625	2,4-Dichlorophenol
625	2,4-Dimethylphenol
625	2,4-Dinitrophenol
625	2-Methyl- 4,6-dinitrophenol
625	2-Nitrophenol
625	4-Nitrophenol
625	Pentachlorophenol
625	Phenol
625	2,4,6-Trichlorophenol
Radiological	
900.0	Gross Alpha
900.0	Gross Beta
901.1	Photon Emitters
901.1	cesium-134
901.1	cesium-137
903.0	Radium
903.0	radium-226
903.1	radium-226
904.0	radium-228

UTAH DEPARTMENT OF HEALTH

The expiration for the laboratory's certification is 4/30/2010. The Utah Environmental Laboratory Certification Program (ELCP) encourages clients and data users to verify the most current certification letter for the authorized method. For further assistance please call 801-538-9370.

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The effective date of this certificate letter is: 6/1/2009.

The analytes by method which a laboratory is authorized to perform at any given time will be those indicated in the most recent certificate letter. The most recent certification letter supersedes all previous certification or authorization letters. It is the certified laboratory's responsibility to review this letter for discrepancies. The certified laboratory must document any discrepancies in this letter and send notice to this bureau within 15 days of receipt. This certification letter will be recalled in the event your laboratory's certification is revoked.

All laboratories are required to submit a Corrective Action Report for all failed PT Audit Results to the Bureau of Laboratory Improvement.

Respectfully,

Patrick F. Luedtke, MD, MPH.
Director of Public Health Laboratories
Deputy Director of Epidemiology and Laboratory Services

UTAH DEPARTMENT OF HEALTH

The expiration for the laboratory's certification is 4/30/2010. The Utah Environmental Laboratory Certification Program (ELCP) encourages clients and data users to verify the most current certification letter for the authorized method. For further assistance please call 801-538-9370.

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Utah Department of Health
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Director Unified State Labs - Public Health

Bureau of Laboratory Improvement
David B Mendenhall, MPA, MT (ASCP)
Bureau Director

State of Utah
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Governor
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Lieutenant Governor

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11/19/2009

ACZ Laboratories, Inc.
Audrey Stover
2773 Downhill Drive
Steamboat Springs CO 80487

ID # ACZ
EPA ID: CO00028

Director,

On the basis of your most recent assessment, Proficiency Testing results and continuing compliance with the ELCP requirements, the laboratory listed is certified for environmental monitoring under the Resource Conservation and Recovery Act and authorized to perform the following methods, for the analytes and matrix listed:

Characteristics

	Solid	Non-Potable Water	
1010 A	☑	☑	Ignitability
1311	☑	☑	Toxicity Characteristic Leaching Procedure Metals
1311	☑	☑	Toxicity Characteristic Leaching Procedure Semi-Volatiles
1311	☑	☑	Toxicity Characteristic Leaching Procedure Volatiles
1312	☑	☑	Synthetic Precipitation Leaching Procedure (TCLP Approval)

Inorganics

	Solid	Non-Potable Water	
9012 B	☑	☑	Total and Amenable Cyanide
9013 A	☑	☐	Cyanide Extraction Procedure for Solids and Oils
9040 C	☐	☑	pH
9045 D	☑	☐	Soil and Waste pH
9070 A	☐	☑	Total Recoverable Oil and Grease
9071 B [199	☑	☐	Oil and Grease Extraction Method for Sludge and Sediment Samples

Metal Digestion

	Solid	Non-Potable Water	
3005 A	☐	☑	Acid Digestion Total Recoverable or Dissolved Metals
3010 A	☐	☑	Acid Digestion for Total Metals
3050 B	☑	☐	Acid Digestion of Sediments, Sludges and Soils
3051 A	☑	☐	Microwave Acid Digestion of Sediment, Sludges, Soils & Oils
3052	☑	☐	Microwave Acid Digestion of Silliceous and Organic Matrixes
3060 A	☑	☐	Alkaline Digestion for Hexavalent Chromium

Metals

	Solid	Non-Potable Water	
6010 B	☑	☑	Aluminum

The expiration for the laboratory's certification is 4/30/2010. The Utah Environmental Laboratory Certification Program (ELCP) encourages clients and data users to verify the most current certification letter for the authorized method. For further assistance please call 801-538-9370.

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ACZ Laboratories, Inc.
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Metals

	Solid	Non-Potable Water	
6010 B	☑	☑	Antimony
6010 B	☑	☑	Arsenic
6010 B	☑	☑	Barium
6010 B	☑	☑	Beryllium
6010 B	☑	☑	Boron
6010 B	☑	☑	Cadmium
6010 B	☑	☑	Calcium
6010 B	☑	☑	Chromium
6010 B	☑	☑	Cobalt
6010 B	☑	☑	Copper
6010 B	☑	☑	Iron
6010 B	☑	☑	Lead
6010 B	☑	☑	Lithium
6010 B	☑	☑	Magnesium
6010 B	☑	☑	Manganese
6010 B	☑	☑	Molybdenum
6010 B	☑	☑	Nickel
6010 B	☑	☑	Potassium
6010 B	☑	☑	Selenium
6010 B	☑	☑	Silica
6010 B	☑	☑	Silicon
6010 B	☑	☑	Silver
6010 B	☑	☑	Sodium
6010 B	☑	☑	Strontium
6010 B	☑	☐	Thallium
6010 B	☑	☑	Tin
6010 B	☑	☑	Titanium
6010 B	☑	☑	Vanadium
6010 B	☑	☑	Zinc
6020 [1994]	☑	☑	Aluminum
6020 [1994]	☑	☑	Antimony
6020 [1994]	☑	☑	Arsenic
6020 [1994]	☑	☑	Barium
6020 [1994]	☑	☑	Beryllium
6020 [1994]	☑	☑	Cadmium
6020 [1994]	☑	☑	Chromium
6020 [1994]	☑	☑	Cobalt
6020 [1994]	☑	☑	Copper
6020 [1994]	☑	☑	Lead
6020 [1994]	☑	☑	Manganese
6020 [1994]	☑	☑	Molybdenum
6020 [1994]	☑	☑	Nickel
6020 [1994]	☑	☑	Selenium
6020 [1994]	☑	☑	Silver
6020 [1994]	☑	☑	Thallium
6020 [1994]	☑	☑	Uranium
6020 [1994]	☑	☑	Vanadium
6020 [1994]	☑	☑	Zinc
7196 A	☑	☑	Chromium, Hexavalent (Chromium, VI)
7470 A	☐	☑	Mercury
7471 A	☑	☐	Mercury

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Metals

	Solid	Non-Potable Water	
7473	☑	☐	Mercury in Solids and Solutions by Thermal Decomposition, Amalgamation, and AA Spectrophotometry

Organic Extraction

	Solid	Non-Potable Water	
3510 C	☐	☑	Separatory Funnel Liquid-Liquid Extractions
3520 C	☐	☑	Continuous Liquid-Liquid Extraction
3540 C	☑	☐	Soxhlet Extraction
3550 C	☑	☐	Ultrasonic Extraction
3580 A	☑	☐	Waste Dilution

Organic Instrumentation

	Solid	Non-Potable Water	
8015 D	☑	☑	Diesel Range Organics (DROs)
8015 D	☑	☑	Gasoline Range Organics (GROs)
8015 D	☑	☑	Nonhalogenated Organics Using GC/FID
8021 B	☑	☑	Aromatic and Halogenated Volatiles
8021 B	☑	☑	Benzene
8021 B	☑	☑	Ethylbenzene
8021 B	☑	☑	meta-Xylene
8021 B	☑	☑	ortho-Xylene
8021 B	☑	☑	para-Xylene
8021 B	☑	☑	Toluene
8021 B	☑	☑	Xylenes, Total
8260 B	☑	☑	1,1,1,2-Tetrachloroethane
8260 B	☑	☑	1,1,1-Trichloroethane
8260 B	☑	☑	1,1,2,2-Tetrachloroethane
8260 B	☑	☑	1,1,2-Trichloroethane
8260 B	☑	☑	1,1-Dichloroethane
8260 B	☑	☑	1,1-Dichloroethylene (-ethene)
8260 B	☑	☑	1,1-Dichloropropene
8260 B	☑	☑	1,2,3-Trichlorobenzene
8260 B	☑	☑	1,2,3-Trichloropropane
8260 B	☑	☑	1,2,4-Trichlorobenzene
8260 B	☑	☑	1,2,4-Trimethylbenzene
8260 B	☑	☑	1,2-Dibromo-3-chloropropane (DBCP, Dibromochloropropane)
8260 B	☑	☑	1,2-Dibromoethane (EDB, Ethylene dibromide)
8260 B	☑	☑	1,2-Dichlorobenzene
8260 B	☑	☑	1,2-Dichloroethane
8260 B	☑	☑	1,2-Dichloropropane
8260 B	☑	☑	1,3,5-Trimethylbenzene
8260 B	☑	☑	1,3-Dichlorobenzene
8260 B	☑	☑	1,3-Dichloropropane
8260 B	☑	☑	1,4-Dichlorobenzene
8260 B	☑	☑	2,2-Dichloropropane
8260 B	☑	☑	2-Chloroethyl Vinyl Ether
8260 B	☑	☑	2-Chlorotoluene
8260 B	☑	☑	2-Hexanone
8260 B	☑	☑	4-Chlorotoluene
8260 B	☑	☑	4-Methyl-2-pentanone (MIBK, Isopropylacetone, Hexone)
8260 B	☑	☑	Acetone

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Organic Instrumentation

	Solid	Non-Potable Water	
8260 B	☑	☑	Acrylonitrile
8260 B	☑	☑	Benzene
8260 B	☑	☑	Bromobenzene
8260 B	☑	☑	Bromochloromethane
8260 B	☑	☑	Bromodichloromethane
8260 B	☑	☑	Bromoform
8260 B	☑	☑	Carbon Disulfide
8260 B	☑	☑	Carbon Tetrachloride
8260 B	☑	☑	Chlorobenzene
8260 B	☑	☑	Chlorodibromomethane [Dibromochloromethane]
8260 B	☑	☑	Chloroethane
8260 B	☑	☑	Chloroform
8260 B	☑	☑	cis-1,2-Dichloroethene (-ethylene)
8260 B	☑	☑	cis-1,3-dichloropropene
8260 B	☑	☑	Dibromomethane
8260 B	☑	☑	Dichlorodifluoromethane
8260 B	☑	☑	Dichloromethane (DCM, Methylene chloride)
8260 B	☑	☑	Ethylbenzene
8260 B	☑	☑	Hexachlorobutadiene
8260 B	☑	☑	Isopropylbenzene
8260 B	☑	☑	meta-Xylene
8260 B	☑	☑	Methyl bromide [Bromomethane]
8260 B	☑	☑	Methyl chloride [Chloromethane]
8260 B	☑	☑	Methyl Ethyl Ketone (MEK, 2-Butanone)
8260 B	☑	☑	Methyl-t-Butyl Ether (MTBE)
8260 B	☑	☑	Naphthalene
8260 B	☑	☑	n-Butylbenzene
8260 B	☑	☑	n-Propylbenzene
8260 B	☑	☑	ortho-Xylene
8260 B	☑	☑	para-Xylene
8260 B	☑	☑	sec-Butylbenzene
8260 B	☑	☑	Styrene
8260 B	☑	☑	tert-Butylbenzene
8260 B	☑	☑	Tetrachloroethylene (Perchloroethylene -ethene)
8260 B	☑	☑	Toluene
8260 B	☑	☑	trans-1,2-Dichloroethylene (-ethene)
8260 B	☑	☑	trans-1,3-Dichloropropylene (-propene)
8260 B	☑	☑	Trichloroethene (Trichloroethylene)
8260 B	☑	☑	Trichlorofluoromethane
8260 B	☑	☑	Vinyl Acetate
8260 B	☑	☑	Vinyl Chloride
8260 B	☑	☑	Volatile Organic Compounds
8260 B	☑	☑	Xylenes, Total
8270 C	☑	☑	1,2,4-Trichlorobenzene
8270 C	☑	☑	1,2-Dichlorobenzene
8270 C	☑	☑	1,3-Dichlorobenzene
8270 C	☑	☑	1,4-Dichlorobenzene
8270 C	☑	☑	2,4,5-Trichlorophenol
8270 C	☑	☑	2,4,6-Trichlorophenol
8270 C	☑	☑	2,4-Dichlorophenol
8270 C	☑	☑	2,4-Dimethylphenol

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Organic Instrumentation

	Solid	Non-Potable Water	
8270 C	☑	☑	2,4-Dinitrophenol
8270 C	☑	☑	2,4-Dinitrotoluene (2,4-DNT)
8270 C	☑	☑	2,6-Dinitrotoluene (2,6-DNT)
8270 C	☑	☑	2-Chloronaphthalene
8270 C	☑	☑	2-Chlorophenol
8270 C	☑	☑	2-Methyl-4,6-dinitrophenol (4,6-Dinitro-2-methylphenol)
8270 C	☑	☑	2-Methylnaphthalene
8270 C	☑	☑	2-Methylphenol (o-cresol, 2-Hydroxytoluene)
8270 C	☑	☑	2-Nitroaniline
8270 C	☑	☑	2-Nitrophenol
8270 C	☑	☑	3,3'-Dichlorobenzidine
8270 C	☑	☑	3-Methylphenol (m-cresol, 3-Hydroxytoluene)
8270 C	☑	☑	3-Nitroaniline
8270 C	☑	☑	4-Bromophenyl Phenyl Ether
8270 C	☑	☑	4-Chloro-3-methylphenol
8270 C	☑	☑	4-Chloroaniline
8270 C	☑	☑	4-Chlorophenyl Phenyl Ether
8270 C	☑	☑	4-Methylphenol (p-cresol, 4-Hydroxytoluene)
8270 C	☑	☑	4-Nitroaniline
8270 C	☑	☑	4-Nitrophenol
8270 C	☑	☑	Acenaphthene
8270 C	☑	☑	Acenaphthylene
8270 C	☑	☑	Anthracene
8270 C	☑	☑	Azobenzene
8270 C	☑	☑	Benzo(a)anthracene
8270 C	☑	☑	Benzo(a)pyrene
8270 C	☑	☑	Benzo(b)fluoranthene
8270 C	☑	☑	Benzo(g,h,i)perylene
8270 C	☑	☑	Benzo(k)fluoranthene
8270 C	☑	☑	Benzoic Acid
8270 C	☑	☑	Benzyl alcohol
8270 C	☑	☑	bis(2-chloroethoxy)methane
8270 C	☑	☑	bis(2-Chloroethyl)ether
8270 C	☑	☑	bis(2-chloroisopropyl)ether
8270 C	☑	☑	bis(2-Ethylhexyl) phthalate (DEHP)
8270 C	☑	☑	Butyl Benzyl Phthalate
8270 C	☑	☑	Chrysene
8270 C	☑	☑	Dibenzo(a,h)anthracene
8270 C	☑	☑	Dibenzofuran
8270 C	☑	☑	Diethyl Phthalate
8270 C	☑	☑	Dimethyl Phthalate
8270 C	☑	☑	Di-n-butyl phthalate
8270 C	☑	☑	Di-n-octyl Phthalate
8270 C	☑	☑	Fluoranthene
8270 C	☑	☑	Fluorene
8270 C	☑	☑	Hexachlorobenzene
8270 C	☑	☑	Hexachlorobutadiene
8270 C	☑	☑	Hexachlorocyclopentadiene
8270 C	☑	☑	Hexachloroethane
8270 C	☑	☑	Indeno(1,2,3-cd)pyrene
8270 C	☑	☑	Isophorone

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Organic Instrumentation

	Solid	Non-Potable Water	
8270 C	☑	☑	Naphthalene
8270 C	☑	☑	Nitrobenzene
8270 C	☑	☑	n-Nitrosodimethylamine
8270 C	☑	☑	n-Nitroso-di-n-Propylamine
8270 C	☑	☑	n-Nitrosodiphenylamine
8270 C	☑	☑	Pentachlorophenol
8270 C	☑	☑	Phenanthrene
8270 C	☑	☑	Phenol
8270 C	☑	☑	Pyrene
8270 C	☑	☑	Semivolatile Organic Compounds

Radiochemistry

	Solid	Non-Potable Water	
903.1	☑	☐	Radium-226
9310	☑	☑	Gross Alpha and Gross Beta
9315	☑	☑	Alpha Emit Radium Isotope
9320	☑	☑	Radium 228

Volatile Organic Preparation

	Solid	Non-Potable Water	
5030 C	☐	☑	Purge-and-Trap for Aqueous Samples
5035A	☑	☐	Purge-and-Trap and Extraction for Volatile Organics

The effective date of this certificate letter is: 6/1/2009.

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Respectfully,

Patrick F. Luedtke, MD, MPH.
Director of Public Health Laboratories
Deputy Director of Epidemiology and Laboratory Services

The expiration for the laboratory's certification is 4/30/2010. The Utah Environmental Laboratory Certification Program (ELCP) encourages clients and data users to verify the most current certification letter for the authorized method. For further assistance please call 801-538-9370.

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State of Utah
GARY R HERBERT
Governor
GREGORY S BELL
Lieutenant Governor

Utah Department of Health
David N. Sundwall, MD
Executive Director

Disease Control and Prevention
Patrick F. Luedtke, MD, MPH.
Director Unified State Labs - Public Health

Bureau of Laboratory Improvement
David B Mendenhall, MPA, MT (ASCP)
Bureau Director

NELAP
Recognized

11/19/2009

ACZ Laboratories, Inc.
Audrey Stover
2773 Downhill Drive
Steamboat Springs CO 80487

ID # ACZ
EPA ID: CO00028

Director,

On the basis of your most recent assessment, Proficiency Testing results and continuing compliance with the ELCP requirements, the laboratory listed is certified for environmental monitoring under the Safe Drinking Water Act and authorized to perform the following methods, for the analytes and matrix listed:

Drinking Water

Inorganics and Metals

180.1 [1993]	Turbidity
200.7 [1994]	Aluminum
200.7 [1994]	Calcium
200.7 [1994]	Iron
200.7 [1994]	Magnesium
200.7 [1994]	Manganese
200.7 [1994]	Silica
200.7 [1994]	Sodium
200.7 [1994]	Strontium
200.7 [1994]	Zinc
200.8 [1994]	Antimony
200.8 [1994]	Arsenic
200.8 [1994]	Barium
200.8 [1994]	Beryllium
200.8 [1994]	Cadmium
200.8 [1994]	Chromium
200.8 [1994]	Nickel
200.8 [1994]	Selenium
200.8 [1994]	Silver
200.8 [1994]	Thallium
200.8 [1994]	Uranium
2320 B [20th ED]	Alkalinity - Titration Method [20th ED]
2340 B [20th ED]	Hardness by Calculation (CaCO3) [20th ED]
245.1 [1994]	Mercury
2510 B [20th ED]	Conductivity by Laboratory Method [20th ED]
2540 C [20th ED	Total Dissolved Solids [20th ED]
300.0 (1993)	Bromide
300.0 (1993)	Chloride
300.0 (1993)	Fluoride
335.4 [1993]	Cyanide

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ACZ Laboratories, Inc.
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Inorganics and Metals	
4500 (F-) C [20th	Fluoride by Ion-Selective Method [20th ED]
4500 (H+) B [20t	pH [20th ED]
5310 B [20th ED]	TOC by Combustion-Infrared Method [20th ED]
Nitrate	
353.2 [1993]	Nitrate
353.2 [1993]	Nitrate/Nitrite
Nitrite	
353.2 [1993]	Nitrite
Pb/Cu	
200.8 [1994]	Copper
200.8 [1994]	Lead
Radionuclides	
900.0	Gross Alpha & Beta Radioactivity in Drinking Water Evaporation Technique
900.0	Gross Alpha
900.0	Gross Beta
903.0	Alpha-Emitting Radium Isotopes in Drinking Water
903.0	Radium 226
903.1	Radium 226 in Drinking Water Radon Emanation Technique
904.0	Radium 228 in Drinking Water Radiochemical Technique
Sulfates	
300.0 (1993)	Sulfate

The effective date of this certificate letter is: 6/1/2009.

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Respectfully,

Patrick F. Luedtke, MD, MPH.
Director of Public Health Laboratories
Deputy Director of Epidemiology and Laboratory Services

UTAH DEPARTMENT OF HEALTH

The expiration for the laboratory's certification is 4/30/2010. The Utah Environmental Laboratory Certification Program (ELCP) encourages clients and data users to verify the most current certification letter for the authorized method. For further assistance please call 801-538-9370.

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APPENDIX C AZDHS Certificate and List of Certified Parameters

Arizona Department of Health Services

ENVIRONMENTAL LABORATORY LICENSE

Issued to:

Laboratory Director: **Audrey J. Stover**
Owner/Representative: **Brad Craig**

ACZ Laboratories, Inc.
AZ0102

is in compliance with Environmental Laboratory's applicable standards for the State of Arizona and maintains on file a List of Parameters for which the laboratory is certified to perform analysis.

PERIOD OF LICENSURE FROM: 06/03/2009 TO: 06/02/2010

GREAT SEAL OF THE STATE OF ARIZONA 1912

Steven D. Baker, Chief
Office of Laboratory Services
Bureau of State Laboratory Services

Arizona Department of Health Services
Office of Laboratory Licensure, Certification & Training
250 North 17th Avenue, Phoenix, AZ 85007

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Thursday, August 13 2009

AZ License: AZ0102

Lab Director: Ms. Audrey J. Stover

Lab Name: ACZ Laboratories, Inc.
Phone: (970) 879-6590
Fax: 815 301-3857

Program HW

Parameter	EPA Method	Billing Code	Cert Date
Alkline Digestion For Hexavalent Chromium	EPA 3060A	PREP2	05/09/07
Alpha-Emitting Radium Isotopes	EPA 9315	RADIO	09/23/97
Aluminum	EPA 6010B	MTL3	06/03/98
Aluminum	EPA 6020	MTL7	04/12/04
Antimony	EPA 6010B	MTL3	05/09/02
Antimony	EPA 6020	MTL7	02/24/97
Aromatic & Halogenated Vocs	EPA 8021B	VOC1	01/15/03
Arsenic	EPA 6010B	MTL3	05/09/02
Arsenic	EPA 6020	MTL7	02/24/97
Barium	EPA 6010B	MTL3	06/03/98
Barium	EPA 6020	MTL7	02/24/97
Beryllium	EPA 6010B	MTL3	05/01/92
Beryllium	EPA 6020	MTL7	02/24/97
Boron	EPA 6010B	MTL3	04/04/06
Cadmium	EPA 6010B	MTL3	06/03/98
Cadmium	EPA 6020	MTL7	02/24/97
Calcium	EPA 6010B	MTL3	06/03/98
Chromium, Hexavalent	EPA 7196A	MTL4	04/12/04
Chromium, Total	EPA 6010B	MTL3	06/03/98
Chromium, Total	EPA 6020	MTL7	02/24/97
Closed System Purge And Trap Extract. Vocs	EPA 5035A	PREP2	12/05/06
Cobalt	EPA 6010B	MTL3	06/03/98
Cobalt	EPA 6020	MTL7	02/24/97
Continious Liquid-Liquid Extraction	EPA 3520C	PREP2	05/09/02
Copper	EPA 6010B	MTL3	06/03/98
Copper	EPA 6020	MTL7	02/24/97
Corrosivity Ph Determination	EPA 9040C	HAZ1	12/05/06
Cyanide	EPA 9012B	MISC7	12/05/06
Cyanide Extractions For Solids And Oils	EPA 9013A	PREP3	12/05/06
Dissolved In Water	EPA 3005A	PREP1	05/09/02
Gross Alpha And Beta	EPA 9310	RADIO	09/23/97
Hem For Aqueous Samples	EPA 9070A	MISC6	05/09/07
Hem For Sludge,Sediment And Solid Samples	EPA 9071B	MISC6	05/14/09
Hydrogen Ion (Ph)	EPA 9045D	NIA6	12/05/06
Ignitability (Flash Point)	EPA 1010A	HAZ2	12/05/06
Iron	EPA 6010B	MTL3	06/03/98
Lead	EPA 6010B	MTL3	06/03/98
Lead	EPA 6020	MTL7	02/24/97
Lithium	EPA 6010B	MTL3	06/26/02

Arizona Department of Health Services
Office of Laboratory Licensure, Certification & Training
250 North 17th Avenue, Phoenix, AZ 85007

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Thursday, August 13 2009

AZ License: AZ0102 **Lab Name: ACZ Laboratories, Inc.**

Program HW

Parameter	EPA Method	Billing Code	Cert Date
Magnesium	EPA 6010B	MTL3	06/03/98
Manganese	EPA 6010B	MTL3	06/03/98
Manganese	EPA 6020	MTL7	02/24/97
Mercury	EPA 7470A	MTL5	06/02/97
Mercury	EPA 7471A	MTL5	05/01/92
Mercury	EPA 7473	MTL10	08/07/09
Microwave Assisted Digestion	EPA 3052	PREP1	07/21/09
Microwave Assisted Digestions	EPA 3051	PREP1	06/12/03
Molybdenum	EPA 6010B	MTL3	06/03/98
Nickel	EPA 6010B	MTL3	05/01/92
Nickel	EPA 6020	MTL7	02/24/97
Nonhalogenated Organics Using Gc/Fid	EPA 8015D	VOC4	12/05/06
Paint Filter Liquids Test	EPA 9095B	MISC17	12/05/06
Potassium	EPA 6010B	MTL3	06/03/98
Purge And Trap For Aqueous Samples	EPA 5030C	PREP2	12/05/06
Radium 228	EPA 9320	RADIO	06/26/02
Sediments, Sludges And Soils	EPA 3050B	PREP1	05/09/02
Selenium	EPA 6010B	MTL3	06/24/08
Semivolatile Compounds By Gc/Ms	EPA 8270C	SOC16	06/03/98
Separatory Funnel Liquid-Liquid Extraction	EPA 3510C	PREP2	05/09/02
Silica	EPA 6010B	MTL3	04/04/06
Silver	EPA 6010B	MTL3	06/03/98
Silver	EPA 6020	MTL7	02/24/97
Sodium	EPA 6010B	MTL3	06/03/98
Soxlhet Extraction	EPA 3540C	PREP2	05/09/02
Splp	EPA 1312	HAZ6	02/15/96
Strontium	EPA 6010B	MTL3	05/09/02
Tclp	EPA 1311	HAZ5	05/01/92
Thallium	EPA 6010B	MTL3	06/26/02
Thallium	EPA 6020	MTL7	02/24/97
Tin	EPA 6010B	MTL3	06/03/98
Titanium	EPA 6010B	MTL3	04/04/06
Total Metals	EPA 3010A	PREP1	05/09/02
Total Recoverable In Water	EPA 3005A	PREP1	05/09/02
Ultrasonic Extraction	EPA 3550B	PREP2	05/09/02
Vanadium	EPA 6010B	MTL3	06/24/08
Vocs By Gc/Ms	EPA 8260B	VOC8	06/03/98
Waste Dilution	EPA 3580A	PREP2	05/12/03
Zinc	EPA 6010B	MTL3	06/03/98
Zinc	EPA 6020	MTL7	02/24/97

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AZ License: AZ0102 **Lab Name: ACZ Laboratories, Inc.**

Program HW

Parameter	EPA Method	Billing Code	Cert Date
Total Licensed Parameters in this Program: 79			

Program SDW

Parameter	EPA Method	Billing Code	Cert Date
Alkalinity	SM 2320B	NIA1	04/10/03
Aluminum	EPA 200.7	MTL3	04/10/03
Antimony	EPA 200.8	MTL7	04/10/03
Arsenic	EPA 200.8	MTL7	04/10/03
Barium	EPA 200.8	MTL7	04/10/03
Beryllium	EPA 200.8	MTL7	04/10/03
Bromide	EPA 300.0	NIIIA1	04/10/03
Cadmium	EPA 200.8	MTL7	04/10/03
Calcium	EPA 200.7	MTL3	04/10/03
Carbon, Total Organic	SM 5310B	MISC1	04/10/03
Chloride	EPA 300.0	NIIIA1	04/10/03
Chromium Total	EPA 200.8	MTL7	04/10/03
Copper	EPA 200.8	MTL7	04/10/03
Cyanide	EPA 335.4	MISC7	06/26/02
Cyanide	SM 4500 CN F	MISC7	04/10/03
Fluoride	EPA 300.0	NIIIA1	04/10/03
Fluoride	SM 4500-F C	NIB9	04/10/03
Gross Alpha	EPA 900	RADIO	05/12/03
Gross Beta	EPA 900	RADIO	04/10/03
Hardness	SM 2340B	MTL3	05/09/02
Hydrogen Ion (Ph)	SM 4500-H B	NIA6	05/09/07
Iron	EPA 200.7	MTL3	04/10/03
Lead	EPA 200.8	MTL7	04/10/03
Magnesium	EPA 200.7	MTL3	04/10/03
Manganese	EPA 200.7	MTL3	04/10/03
Mercury	EPA 245.1	MTL5	04/10/03
Nickel	EPA 200.8	MTL7	04/10/03
Nitrate	EPA 353.2	NIB1	04/10/03
Nitric Acid/Hydrochloric Acid	SM 3030F	PREP1	06/24/08
Nitrite	EPA 353.2	NIIB4	06/26/02
Orthophosphate	EPA 365.1	NIIB5	04/10/03
Preliminary Filtration	SM 3030B	PREP1	12/24/03
Radium 226	EPA 903.1	RADIO	04/10/03
Radium 228	EPA 904	RADIO	04/10/03
Residue, Filterable (Tds)	SM 2540C	NIIA8	04/10/03
Selenium	EPA 200.8	MTL7	04/10/03
Silica	EPA 200.7	MTL3	04/10/03

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AZ License: AZ0102 **Lab Name: ACZ Laboratories, Inc.**

Program SDW

Parameter	EPA Method	Billing Code	Cert Date
Silver	EPA 200.8	MTL7	04/10/03
Sodium	EPA 200.7	MTL3	04/10/03
Specific Conductance	SM 2510B	NIA7	04/10/03
Strontium	EPA 200.7	MTL3	04/10/03
Sulfate	EPA 300.0	NIIIA1	04/10/03
Thallium	EPA 200.8	MTL7	04/10/03
Turbidity, Ntu: Nephelometric	EPA 180.1	NIA9	04/10/03
Uranium	EPA 200.8	MTL7	04/13/05
Zinc	EPA 200.7	MTL3	04/10/03

Total Licensed Parameters in this Program: 46

Program WW

Parameter	EPA Method	Billing Code	Cert Date
Acidity	SM 2310B	NIIA1	06/26/02
Alkalinity, Total	SM 2320B	NIA1	06/26/02
Aluminum	EPA 200.7	MTL3	10/16/95
Aluminum	EPA 200.8	MTL7	04/12/04
Ammonia	EPA 350.1	NIIB1	05/01/92
Antimony	EPA 200.7	MTL3	05/09/02
Antimony	EPA 200.8	MTL7	02/24/97
Arsenic	EPA 200.7	MTL3	05/09/02
Arsenic	EPA 200.8	MTL7	02/24/97
Barium	EPA 200.7	MTL3	10/16/95
Barium	EPA 200.8	MTL7	02/24/97
Base/Neutrals And Acids Excluding Pesticides	EPA 625	SOC16	05/12/03
Beryllium	EPA 200.7	MTL3	10/16/95
Beryllium	EPA 200.8	MTL7	02/24/97
Biochemical Oxygen Demand	SM 5210B	DEM1	05/09/07
Boron	EPA 200.7	MTL3	05/01/92
Bromide	EPA 300.0	NIIIA1	09/27/01
Cadmium	EPA 200.7	MTL3	10/16/95
Cadmium	EPA 200.8	MTL7	02/24/97
Calcium	EPA 200.7	MTL3	05/25/94
Chemical Oxygen Demand	EPA 410.4	DEM3	05/01/92
Chloride	EPA 300.0	NIIIA1	05/25/94
Chloride	SM 4500-CL E	NIA2	05/09/07
Chromium Total	EPA 200.7	MTL3	10/16/95
Chromium Total	EPA 200.8	MTL7	02/24/97
Chromium, Hexavalent	SM 3500-CR D	MTL8	05/09/02
Cobalt	EPA 200.7	MTL3	10/16/95
Cobalt	EPA 200.8	MTL7	02/24/97

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Program WW

Parameter	EPA Method	Billing Code	Cert Date
Copper	EPA 200.7	MTL3	10/16/95
Copper	EPA 200.8	MTL7	02/24/97
Cyanide, Total	EPA 335.4	MISC7	05/08/07
Fluoride	EPA 300.0	NIIIA1	05/09/02
Fluoride	SM 4500-F C	NIB3	05/09/02
Gross Alpha	EPA 900	RADIO	04/10/03
Gross Beta	EPA 900.0	RADIO	04/10/03
Hardness	SM 2340B	NIA5	01/12/06
Hydrogen Ion (Ph)	SM 4500-H B	NIA6	05/09/07
Iron	EPA 200.7	MTL3	10/16/95
Kjeldahl Nitrogen	EPA 351.2	NIIB3	05/09/02
Lead	EPA 200.7	MTL3	10/16/95
Lead	EPA 200.8	MTL7	02/24/97
Lithium	EPA 200.7	MTL3	04/10/03
Magnesium	EPA 200.7	MTL3	05/25/94
Manganese	EPA 200.7	MTL3	10/16/95
Manganese	EPA 200.8	MTL7	02/24/97
Mercury	EPA 1631E	MTL10	04/10/03
Mercury	EPA 245.1	MTL5	10/16/95
Molybdenum	EPA 200.7	MTL3	10/16/95
Molybdenum	EPA 200.8	MTL7	02/24/97
Nickel	EPA 200.7	MTL3	10/16/95
Nickel	EPA 200.8	MTL7	02/24/97
Nitrate-Nitrite (As N)	EPA 353.2	NIB1	05/01/92
Nitric Acid/Hydrochloric Acid	SM 3030F	PREP1	06/24/08
Nitrite	EPA 353.2	NIIB4	05/09/07
Oil And Grease, Tph	EPA 1664A	MISC6	12/05/06
Orthophosphate	EPA 365.1	NIIB5	05/01/92
Phenols	EPA 420.4	MISC8	05/09/07
Phosphorus Total	EPA 365.1	NIIB6	05/01/92
Potassium	EPA 200.7	MTL3	05/25/94
Preliminary Filtration	SM 3030B	PREP1	06/24/08
Purgeables	EPA 624	VOC8	05/12/03
Radium 226	EPA 903.1	RADIO	04/10/03
Residue Nonfilterable	SM 2540D	NIIA5	12/05/06
Residue Total	SM 2540B	NIIA4	12/05/06
Residue Volatile	EPA 160.4	NIIA7	05/01/92
Residue, Filterable	SM 2540C	NIA8	12/05/06
Residue, Settleable Solids	SM 2540F	NIIA6	05/01/92
Selenium	EPA 200.7	MTL3	05/09/02
Selenium	EPA 200.8	MTL7	02/24/97

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AZ License: AZ0102 **Lab Name: ACZ Laboratories, Inc.**

Program WW

Parameter	EPA Method	Billing Code	Cert Date
Selenium	SM 3114B	MTL6	05/09/02
Silica, Dissolved	EPA 200.7	MTL3	05/01/92
Silver	EPA 200.7	MTL3	10/16/95
Silver	EPA 200.8	MTL7	02/24/97
Sodium	EPA 200.7	MTL3	05/25/94
Specific Conductance	SM 2510B	NIA7	05/24/07
Strontium	EPA 200.7	MTL3	05/09/02
Sulfate	EPA 300.0	NIIIA1	05/25/94
Sulfate	SM 4500-SO4 D	NIB3	05/18/05
Thallium	EPA 200.8	MTL7	02/24/97
Tin	EPA 200.7	MTL3	05/09/02
Titanium	EPA 200.7	MTL3	07/21/09
Total Organic Carbon	SM 5310B	MISC1	05/09/07
Total Radium	EPA 903.0	RADIO	07/21/09
Turbidity	EPA 180.1	NIA9	05/01/92
Uranium	EPA 200.8	MTL7	02/24/97
Vanadium	EPA 200.7	MTL3	10/16/95
Vanadium	EPA 200.8	MTL7	02/24/97
Zinc	EPA 200.7	MTL3	10/16/95
Zinc	EPA 200.8	MTL7	02/24/97

Total Licensed Parameters in this Program: 89

Instruments	Quantity	Date
RADIATION COUNTING INSTRUMENT	10	04/28/09
GAS CHROMATOGRAPH/MASS SPEC- OTHER THAN HI RESOL	4	04/28/09
AUTOMATED AUTOANALYZER	4	04/28/09
GAS CHROMATOGRAPH	3	05/29/08
INDUCTIVELY COUPLED PLASMA SPECTROMETER	3	05/29/08
ATOMIC ABSORPTION SPECTROPHOTOMETER	3	04/28/09
INDUCTIVELY COUPLED PLASMA/MASS SPECTROMETER	3	05/29/08
ION CHROMATOGRAPH	1	05/29/08
MERCURY ANALYZER	1	05/29/08

Softwares
AGILENT - ICP/MS
PERKIN ELMER - AA
LEEMAN HYDRA - MECURY ANALYZER
TJA TRACE-ICP
ENVIROQUANT - HPLC

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- LEEMAN - AA
- LEEMAN - ICP
- BERTHOLD LB770 - COUNTER FOR RADIOACTIVITY
- CANBERRA XLB - COUNTER FOR RADIOACTIVITY
- CHROMELEON (DIONEX) - IC
- OMNIONIC (LACHAT)
- ENVIROQUANT/CHEMSTATION

APPENDIX D – Forms for Management Review of the Quality System

ACZ Laboratories, Inc.
2773 Downhill Drive
Steamboat Springs, CO 80487

DEPARTMENT REPORT FOR MANAGEMENT REVIEW OF THE QUALITY SYSTEM

Department:_____ Quarter Ending:_____

1) **OPERATIONS:**
EVALUATE ALL OPERATIONS FROM LOG-IN TO REPORTING AS IT PERTAINS TO YOUR DEPT.

   a. What company wide operations-related issues has the department encountered during the last quarter? Were any of the issues reoccurring?

   b. What actions were taken to resolve the issues?

   c. What actions can be taken to reduce/eliminate these issues in the future?

2) **RESOURCES & PERSONNEL:**
EVALUATE RESOURCES & PERSONNEL AS THEY PERTAIN TO THE DEPARTMENT

   a. Did the department have adequate resurces (supplies, instrumentation, facilitied, etc.) and properly trained staff for the volume of work?

   b. What resources must be available for the work expected next quarter?

   c. What obstacles do employees within the department routinely experience that hinder efficiency/productivity?

3) **QUALITY ASSURANCE & QUALITY CONTROL:**
EVALUATE QA/QC AS THEY PERTAIN TO THE DEPARTMENT

   a. Are any failed QC indicators reoccurring? If so, describe.

   b. Were any changes to policies/procedures implemented during the past quarter as a result of corrective and/or preventive actions? If yes, were they effective? If no, what changes would be effective?

4) **CLIENT COMPLAINTS/ FEEDBACK**

   a. What client feedback has the department encountered during the last quarter? Where any of the issues reoccurring?

5) **MISC: PROVIDE ADDITIONAL FEEDBACK**

FRMQA041.11.08.03

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Steamboat Springs, CO 80487

MANAGEMENT REVIEW OF THE QUALITY SYSTEM

DATE OF REVIEW: _____

Attendees:

SUITABILITY OF POLICIES & PROCEDURES: **SUMMARY OF MEETING**
(REVIEW FRM QA041 SECTIONS 1A, 1B, 1C, 2A, 2C, 3A, 3B, 4A)

- Do ACZ's policies and procedures accurately reflect management's Quality Policy Statement?
- Are ACZ's policies and procedures effective? If no, what changes are necessary?

REVIEW OF STAFF RESOURCES & TRAINING:
(REVIEW FRM QA041 SECTIONS 2A, 2C)

- Did ACZ have appropriate staff to handle the volume of work received during the past quarter?
- Was all staff properly trained and was training documented before independently analyzing client samples?

Geochemistry

Clean Room / Prep

Inorganic Inst / Prep

Wet Chemistry Instrument

Wet Chemistry Manual

Organics

Radiochemistry

Log-In

Client Services (Sales / PMs)

Document Control

Information Systems

REVIEW OF INSTRUMENTATION / EQUIPMENT, SUPPLIES & CONSUMABLES:
(REVIEW FRM QA041 SECTIONS 1A, 2B) (COMPARE EXPENSES TO REVENUE)

- Did ACZ have necessary and properly functioning instrumentation and equipment to perform the volume of work received last quarter?
- Did ACZ have adequate supplies and consumables on hand to perform the volume of work?

ACZ Laboratories, Inc.
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MANAGEMENT REVIEW OF THE QUALITY SYSTEM

Geochemistry

Clean Room / Prep

Inorganic Inst / Prep

Wet Chemistry Instrument

Wet Chemistry Manual

Organics

Radiochemistry

Log-In

Client Services (Sales / PMs)

Document Control

Information Systems

REVIEW OF RECENT INTERNAL AUDITS: — QA OFFICER

(REVIEW FRM QA041 SECTIONS 3A, 3B)

- Did the QA/QC department adhere to its internal audit schedule?
- Did any department(s) have significant issues?
- Were corrective actions completed properly and within the agreed time frame?
- Was follow-up completed for all corrective actions?

REVIEW OF RECENT EXTERNAL AUDITS: — QA OFFICER

- Did the audit report(s) cite any repeat deficiencies?
- Did any department(s) have significant issues?
- Were all corrective actions completed properly and within the agreed time frame?
- Was follow-up completed for all corrective actions?

REVIEW OF RECENT PROFICIENCY TESTING STUDIES: — QA OFFICER

A) Were all analyte values reported for each study?

WP	NA ☐	Yes ☐	No ☐
WS	NA ☐	Yes ☐	No ☐
RAD	NA ☐	Yes ☐	No ☐
Soil/UST	NA ☐	Yes ☐	No ☐

B) Did ACZ passed 2 out of the 3 most recent PT studies for each analyte?

WP	NA ☐	Yes ☐	No ☐
WS	NA ☐	Yes ☐	No ☐
RAD	NA ☐	Yes ☐	No ☐
Soil/UST	NA ☐	Yes ☐	No ☐

C) Were corrective actions completed within the agreed time frame for all studies?

WP	NA ☐	Yes ☐	No ☐
WS	NA ☐	Yes ☐	No ☐
RAD	NA ☐	Yes ☐	No ☐
Soil/UST	NA ☐	Yes ☐	No ☐

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MANAGEMENT REVIEW OF THE QUALITY SYSTEM

REVIEW OF RECENT CORRECTIVE / PREVENTATIVE ACTIONS: **QA OFFICER**

- What corrective / preventive actions were implemented during the past quarter?
- What trends are apparent?
- Were corrective actions completed within the agreed time frame?
- Have changes resulting from corrective / preventive actions been implemented? Are they effective?

REVIEW OF CLIENT COMPLAINTS/FEEDBACK:
(REVIEW FRM QA041 SECTIONS 4A)

- Did ACZ receive client feedback (positive or negative) during the past quarter?
- For complaints received, did ACZ adhere to its client complaint policy?
- Were complaints handled in a manner satisfactory to the client?
- Were all complaints resolved?
- What quality indicators are repeated?

REVIEW OF CHANGES IN VOLUME / TYPE OF WORK:
(REVIEW FRM QA041 SECTIONS 1A, 1B, 1C, 2A, 2B)

- Did ACZ experience a significant change in volume and/or type of work last quarter? How did we do?
- What improvements can be made?
- Is ACZ prepared for volume and/or type of work expected next quarter?

REVIEW OF ETHICS PROGRAM:

- Were all Ombudsman issues addressed in a timely manner?
- Were any data intergrity issues/concerns brought to the attention of the Ombudsman issues or dilemmas?
- Were all employees trained on ACZ's Ethics and Proactive Prevention Program (SOPAD039)?
- Was follow-up training conducted within the time frame stated in SOPAD039?

REVIEW OF DEPARTMENTS:

Geochemistry

Clean Room / Prep

Inorganic Inst / Prep

Wet Chemistry Instrument

Wet Chemistry Manual

Organics

Radiochemistry

Log-In

Client Services (Sales / PMs)

Document Control

Information Systems

APPENDIX E REFERENCES UTILIZED BY ACZ

- "NELAC Standards," National Environmental Laboratory Accreditation Conference, (current version).
- "Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act," USEPA, Federal Register Vol. 67, No. 205, October 23, 2002.
- "Manual for the Certification of Laboratories Analyzing Drinking Water," USEPA, (current version).
- "Methods for the Chemical Analysis of Water and Wastes," USEPA, EPA-600/4-79-020, March 1983.
- "Test Methods for Evaluating Solid Waste," USEPA, SW-846 Third Edition, Update IV, January 2008.
- "Guidelines in Establishing Test Procedures for the Analysis of Wastewater Pollutants," Code of Federal Regulations 40, Parts 136, 141, 143.
- "Quality Assurance of Chemical Measurements," Taylor, J., Lewis Publishers, Michigan, 1987
- "Annual Book of Standards, Water Analysis," ASTM, 1989.
- "Quality Control in Analytical Chemistry," Kateman, G., Vol. 60, 1985.
- "Principles of Environmental Analysis, Analytical Chemistry," Keith, L.H., et al., Vol. 55, 1983.
- "Handbook for Analytical Quality Control in Water and Wastewater Laboratories," USEPA, 1979.
- "Guidance for the Data Quality Assessment: Practical Methods for Data Analysis," USEPA, EPA 600/R-96-084, July 2000.
- "Methods for the Determination of Metals in Environmental Samples," USEPA, EPA 600/4-91-010, June 1991.
- "Methods for the Determination of Metals in Environmental Samples," Supplement I [to EPA 600/4-91-010], USEPA, EPA 600/R-94-111, May 1994.
- "Methods for the Determination of Inorganic Substances in Environmental Samples," USEPA, EPA 600/R-93-100, August 1993.
- "Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater," USEPA, EPA 821/B-96-005, December 1996.
- "Prescribed Procedures for Measurement of Radioactivity in Drinking Water," USEPA, EPA 600/4-80-032. August 1980.
- "Determination of Lead-210, Thorium, Plutonium and Polonium-210 in Drinking Water: Methods 909, 910, 911, 912," 01A0004860 (Region 1 Library), March 1982.
- "Good Automated Laboratory Practices - Principles and Guidance to Regulations for Ensuring Data Integrity in Automated Laboratory Operations" USEPA, 2185, 1995.

APPENDIX F DEFINITIONS OF TERMS

Acceptance Criteria: specified limits places on characteristics of an item, process, or service defined in requirement documents.

Accreditation: verification by a competent, disinterested, third party that a laboratory possesses the capability to produce accurate test data, and that it can be relied upon in its day-to-day operations to maintain high standards of performance.

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

Analytical Spike (AS): an aliquot of client sample to which a known amount of target analyte is added and that demonstrates the absence or presence of interference in the matrix. The AS is prepared exactly the same way as the LFB, only spiking into sample instead of reagent blank, and is not prepped (digested) prior to analysis. The AS may also be referred to as a post-digestion spike.

Analytical System: the combination of events, techniques, and procedures used to generate analytical results.

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

Batch: environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one to 20 environmental samples of the same matrix, meeting the above criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An **analytical batch** is composed of 20 or less prepared environmental samples (extracts, digestates or concentrates) that are analyzed together as a group.

All required QC samples must be prepared and/or analyzed with each batch at the frequency required by the method, even if there are less than 20 client samples in the batch. If the workgroup has more than 20 samples, then sufficient batch QC must be analyzed for additional samples. Every batch of environmental samples is assigned a unique (i.e. traceable) six-digit numerical identifier called the LIMS Workgroup number.

Blank: a sample that has not been exposed to the analyzed sample stream utilized to monitor contamination during sampling, transport, storage, or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. See also Equipment Blank, Field Blank, Instrument Blank, Method Blank, Reagent Blank. Refer to §11.3 for types of blanks.

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

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

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

Case Narrative: Additional documentation provided in the client report that describes any abnormalities and deviations that may affect the analytical results and summarizes any issues in the data package that need to be highlighted for the data user to help them assess the usability of the data.

Chain of Custody Form: a legal record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; the collector; time of collection; preservation; and requested analyses.

Continuing Calibration Blank (CCB): the same solution as the calibration blank, it detects baseline drift in the calibration of the instrument. When specified by the method, analyze a CCB immediately after each CCV, including the final CCV.

Continuing Calibration Verification (CCV): a solution of method analytes of known concentrations used to confirm the continued calibration of the instrument. The CCV is analyzed at the frequency indicated in the test SOP.

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

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

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

Demonstration of Capability (DOC): a procedure to establish the ability of the analyst to generate acceptable accuracy [and precision, if applicable].

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

Document Control: the act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly, and controlled to ensure use of the correct version at the location where the prescribed activity is performed.

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

False Positive (Type I or alpha error): concluding that a substance is present when it truly is not.

False Negative (Type II or beta error): concluding that a substance is not present when it truly is.

Field Blank: a blank prepared in the field by filling a clean container with Type I water and appropriate preservative, if any, for the specific sampling activity being undertaken.

Holding Time (Maximum Allowable Holding Time): the maximum time that samples may be held prior to analysis and still be considered valid or not compromised.

Initial Calibration Blank (ICB): a solution identical to the calibration blank and confirms the absence of background contamination in the calibration blank. When specified by the method, an ICB is analyzed immediately after the ICV.

Initial Calibration Verification (ICV): a solution of method analytes of known concentrations intended to determine the validity of the instrument calibration. The ICV must be analyzed immediately after each calibration and must be prepared from a source independent of the calibration standards, preferably purchased from a different manufacturer.

Instrument Blank: an aliquot of Type I water or solvent processed through the instrument steps of the measurement process; used to determine presence of instrument contamination.

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

Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample): a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

Laboratory Fortified Blank (LFB): a reagent blank spiked with a known concentration of analyte. The LFB is analyzed exactly like a sample and determines whether the methodology is in control and whether the laboratory is capable of making accurate and precise measurements.

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

Linear Dynamic Range (LDR): concentration range over which the instrument response to analyte is linear.

Matrix Duplicate (DUP): a second aliquot of a client sample that is prepared and analyzed in the same manner as all other samples in the same workgroup. The DUP demonstrates the precision of the method.

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

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

Maximum Contamination Limit (MCL): the numerical value expressing the maximum permissible level of contaminant in water that is delivered to any user of a public water system.

May: denotes permitted action, but not required action.

Method Blank: a sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as client samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for the sample analyses.

Method Detection Limit: the minimum concentration of an analyte, in a given fortified matrix, that can be measured and reported with 99% confidence that the concentration is greater than zero.

Must: denotes a requirement.

The NELAC Institute (TNI): a voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories.

Outlier (Statistical): an observation or data point that deviates markedly from other members of the population.

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

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

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

Protocol: a detailed written procedure [SOP] for laboratory operation that must be strictly followed.

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

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

Quality Manual [QAP]: a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.

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

Quantitation Limit [Reporting Limit, Practical Quantitation Limit]: level, concentration, or quantity of a target variable (i.e. target analyte) below which data is reported as estimated. The quantitation limit may or may not be statistically determined, or may be an estimate that is based upon analyst experience or judgment.

Raw Data: any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for reconstructing and evaluating the report of the activity or study.

Reagent Blank (method reagent blank): a sample consisting only of Type I water and reagent(s) without the target analyte(s) or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps.

Reference Method: a method of known and documented accuracy and precision issued by an organization recognized as competent to do so (EPA, etc.). The reference method is included on the client report.

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

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

Shall: denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there is no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled.

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

Signal to Noise Ratio (S/N): a dimensionless measure of the relative strength of an analytical signal (S) to the average strength of the background instrumental noise (N) for a particular sample.

Spike: a known amount of target analyte added to a blank sample or client sub-sample; used to determine the recovery efficiency or for other quality control purposes.

Standard Deviation: the measure of the degree of agreement (precision) among replicate analyses of a sample. The population standard deviation (n degrees of freedom) should only be used for more than 25 data points; otherwise, when referenced, standard deviation implies sample standard deviation (n-1 degrees of freedom).

Standard Operating Procedure (SOP): a written document which details the manner in which an operation, analysis, or action is performed. The techniques and procedures are thoroughly prescribed in the SOP and are the accepted process for performing certain routine or repetitive tasks.

Supervisor [however named]: the individual designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees, supply and instrument adequacy

and upkeep, quality assurance/quality control duties and ascertaining that technical employees have the required balance of education, training, and experience to perform the required analyses.

Surrogate (SURR): a substance with properties that mimic the analyte of interest. It is unlikely to be found in environmental samples and is added to them for quality control purposes.

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

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

APPENDIX G TECHNICAL DIRECTORS

Name	Department	Degree
James Rhudy	Organics	BA, Molecular Biology; BA, Biochemistry
Steve Pulford	Metals	BS, Chemical Engineering
Billy Grimes	Metals,Wet Chemistry Manual	BA, Biology
Carol Poirot	Wet Chemistry Instrument, Radiochemistry	BS, Physics; MS, Material Sciences
Audrey Stover	Geochemistry	BS, Agricultural Land Resources

Appendix 1.A.E

Laboratory Data Review and Validation Checklist

LABORATORY DATA REVIEW AND VALIDATION CHECKLIST – GREENS CREEK PROJECT

Sample Point(s):	Laboratory #(s):
Parameter list requested:	Date Samples Collected:
	Date Samples Received by Lab:

Category		Yes	No	N/A	Comments
Reported Data					
1. COC & other field documents included?					
2. All reporting requirements satisfied?					
3. Parameters reported match parameters requested?					
4. Methods reported match methods requested?					
5. Reporting limits and units as requested?					
6. Electronic file matches hard copy?					
Sample Analysis					
1. Analysis holding times met?					
Laboratory QA/QC Requirements					
1. Blanks	proper frequency?				
	acceptance criteria met?				
2. LCSs	proper frequency?				
	acceptance criteria met?				
3. Spikes	proper frequency?				
	acceptance criteria met?				
4. Duplicates	proper frequency?				
	acceptance criteria met?				
General *Note any additional comments/observations on back of sheet.*					
1. Are sample results consistent with historical data for specific sample point(s)?					

Reviewed by: **Date:**

FIELD DATA REVIEW AND VALIDATION CHECKLIST – GREENS CREEK PROJECT

Sample Point(s):	Date Collected:			
	Date Shipped to Lab:			
	Collected By:			
Category	**Yes**	**No**	**N/A**	**Comments**
Reported Data				
1. Are all appropriate data fields filled out?				
2. Are water level data measurements calculated and recorded correctly?				
3. Are flow measurements calculated and recorded correctly?				
General				
1. Are sample results for field measurements consistent with historical data for specific sample point(s)?				

2. Note additional comments/observations (use back of sheet if necessary):

Reviewed by: **Date:**

CORRECTIVE ACTION FORM

Sample I.D.(s)_____ **Date Sampled** _____

Laboratory Job Number(s)_____ **Date Analyzed** _____

Reviewed By_____

Describe the deficiency:
Document all correspondence involved:
(Include date and time of the communication(s), as well as the name and position of all individuals contacted. Also include a synopsis of each communication, attach extra pages as necessary)

Define a corrective action:

Explain the resolution: