FINAL
QUALITY ASSURANCE PROJECT PLAN
RADIOLOGICAL BACKGROUND STUDY
SANTA SUSANA FIELD LABORATORY
VENTURA COUNTY, CALIFORNIA

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LIST OF ACRONYMS AND ABBREVIATIONS

AgPRG	Agricultural Preliminary Remediation Goal
bgs	below ground surface
BTV	background threshold values
°C	degrees Celsius
CA	corrective action
CFR	Code of Federal Regulations
CLP	Contract Laboratory Program
COB	close of business
COC	chain-of-custody
COI	conflict of interest
DM	Data Manager
DMP	Data Management Plan
DOE	Department of Energy
DOT	Department of Transportation
DQO	data quality objective
DTL	distance test location
EDD	electronic data deliverable
EPA	U.S. Environmental Protection Agency
FSP	Field Sampling Plan
ft	feet
GIS	Geographic Information System
GPS	Global Positioning System
HGL	HydroGeoLogic, Inc.
HSP	Health and Safety Plan
IDW	investigation-derived waste
MARLAP	Multi-Agency Radiological Laboratory Analytical Protocols Manual
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
MDC	minimum detectable concentration
MS/MSD	matrix spike/matrix spike duplicate
No.	Number
%	percent
%R	percent recovery

PASI	Pace Analytical Services, Inc.
PE	performance evaluation
PRG	preliminary remediation goal
QA	quality assurance
QAMS	Quality Assurance Management Section
QAPP	Quality Assurance Project Plan
QC	quality control
RAC	Remedial Action Contract
RBRA	Radiological Background Reference Area
SAP	Sampling and Analysis Plan
SEDD	staged electronic data deliverable
SOP	standard operating procedure
SSFL	Santa Susana Field Laboratory
TPC	The Palladino Company, Inc.
WA	work assignment
WAM	Work Assignment Manager

FINAL
QUALITY ASSURANCE PROJECT PLAN
RADIOLOGICAL BACKGROUND STUDY
SANTA SUSANA FIELD LABORATORY
VENTURA COUNTY, CALIFORNIA

The Quality Assurance Project Plan (QAPP) details the Quality Assurance (QA)/Quality Control (QC) measures that will be used to ensure that the data collected are of acceptable quality and sufficient quantity to support decision making. This QAPP has been reviewed and approved by the Region 9 Quality Assurance Management Section (QAMS) program. However, HydroGeoLogic, Inc. (HGL) is performing its work on the project under HGL's contract with the U.S. Environmental Protection Agency (EPA) Region 3.

HGL will perform the full scope of services required in the Remedial Action Contract EP-S3-07-05, work assignment (WA) number 021TATA09QL, to support the EPA Region 3. The contents and organization of this QAPP are in accordance with the HGL *Generic QAPP for Region 3 Remedial Action Contract (RAC) 2 Work Assignments* (HGL, 2007) and is based on *Requirements for Quality Assurance Project Plans*, EPA QA/R-5, Interim Final, March 2001 (EPA, 2001). The Generic QAPP was developed to present information that is expected to remain unchanged for all projects that HGL supports under its EPA Region 3 program, allowing EPA reviewers to focus review and comment efforts on the project-specific information presented in project QAPPs. Each project-specific QAPP is intended to be used in conjunction with the Generic QAPP and notes where the contents of the Generic QAPP are incorporated by reference. The requirements in project-specific QAPPs take precedence in cases where the requirements presented in the Generic QAPP are in conflict with project requirements.

Section 1.0 presents project management and data quality objective (DQO) information, Section 2.0 details measurement and data acquisition strategies, Section 3.0 details assessment and oversight aspects of the project, Section 4.0 describes data validation and usability, and Section 5.0 describes data management and visualization.

1.0 PROJECT MANAGEMENT

This section discusses the project organization, overall project objectives, uses of the data and DQOs.

1.1 PROJECT ORGANIZATION

Project Quality Assurance Organization and Responsibilities will be in accordance with Section 2 of HGL's *Generic QAPP for Region 3 Remedial Action Contract (RAC) 2 Work Assignments* (HGL, 2007). The Palladino Company, Inc. (TPC) is the team subcontractor for this project and will provide general radiological consulting services and gamma survey support. The EPA will be responsible for approving all site-related activities. Table 1.1

identifies the personnel responsibilities specific to this WA. Table 1.2 describes project-specific communication pathways.

1.2 BACKGROUND AND PURPOSE

Site background information is provided in Section 2 of the Sampling and Analysis Plan (SAP). The purpose and objectives of this project are identified in Section 1 of the SAP. The purpose of this QAPP is to provide guidance to ensure that all data collection procedures and measurements are scientifically sound, are of known, acceptable, and documented quality, and are conducted in accordance with the requirements of the project.

1.3 PROBLEM DEFINITION

Table 1.3 outlines the Problem Definition. The ultimate goal of the project is to establish representative background radionuclide concentrations for the two surface geological formations at the Santa Susana Field Laboratory (SSFL), which are the Santa Susana and the Chatsworth Formations. The project will be conducted to achieve two objectives, as described in Section 1.1 of the SAP:

- The primary objective is to determine surface and subsurface soil radionuclide background concentrations at the three radiological background reference areas (RBRA).
- The secondary objective is to determine whether surface soils at the RBRAs have been impacted by atmospheric releases from the SSFL.

To accomplish this primary objective, surface and subsurface soil samples will be collected at three RBRAs located outside the SSFL property boundary. Two of these areas overlie the Chatsworth Formation and one area overlies the Santa Susana Formation.

To accomplish this secondary objective, surface soil samples will be collected in areas that are located greater than 10 miles from the SSFL. These locations are referred to as distance test locations (DTL). These samples will be analyzed for a targeted group of radionuclides, which would likely be found in SSFL atmospheric releases. Surface soil samples will also be collected at the three RBRAs and analyzed for the same targeted list of radionuclides. A statistical analysis will be conducted to determine whether the radionuclide concentrations in surface soil at the individual RBRAs are higher than the radionuclide concentrations at the DTLs.

1.4 DOCUMENTATION AND RECORDS

Documents used or generated during the course of the project will be accounted for and become a part of the project files upon completion of the task. Original records will be transferred to EPA and records will be maintained by the EPA Superfund Records Center for a minimum of 30 years. Copies of the complete project file records will be maintained in HGL's Ballston Lake, New York, office and will be updated by the Project Administrator under direction of the Project Manager. Table 1.4 shows the project records that will be generated and included in the file.

The contents of the project files, both electronic and hardcopy documentation, will be retained for a minimum of 10 years from completion of the project. The Project Administrator will be responsible for ensuring that appropriate backup of the project documentation exists in case of destruction of primary documentation (e.g., due to computer malfunction or inappropriate discarding of files). The Project Administrator will also be responsible for maintaining a current distribution list for all project planning documents and for transmitting any plan updates or amendments to all recipients.

1.4.1 Field Data

Logbooks for sampling and field investigation purposes must meet the requirements provided in Section 2.3.3. The logbook must contain sufficient information to distinguish samples from each other. Logbooks and other field-generated documentation must be bound and entries recorded in waterproof ink.

1.4.2 Laboratory Data

In addition to the documentation requirements listed in Table 1.4, the laboratory will also be responsible for providing analytical reports to HGL. These analytical reports must contain all information required to verify and validate the analytical results that are the subject of each report in accordance with the requirements presented in Section 4.1.

1.5 QUALITY OBJECTIVES AND CRITERIA FOR MEASUREMENT

The DQO process is a series of planning steps based on the scientific methods that are designed to ensure that the type, quantity, and quality of environmental data used in decision-making are appropriate for the intended purpose. This project is intended to achieve the two objectives as described in Section 1.3. The DQOs associated with the primary objective are presented in Section 1.5.3 and the DQOs associated with the secondary objective are presented in Section 1.5.4.

1.5.1 End Uses of the Data

The end use of the field and analytical data is to assist the EPA in achieving the objectives identified in Section 1.3. Background concentrations of radionuclides of potential concern will be used during investigations at SSFL. The potential activities that may use the data are as follows:

- Determine the extent of soil contamination at the SSFL;
- Assist the California Department of Toxic Substances Control (DTSC) in establishing appropriate cleanup levels;
- Provide background data to be used in human health and ecological risk assessments; and
- Establish a reference data set for characterization surveys and site closure surveys (final status surveys) in accordance with Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) guidance.

1.5.2 Data Types

Quality of analytical data is defined as either "definitive data," "screening data with definitive confirmation," or "screening data without definitive confirmation" in EPA QA/G-4, *Guidance for the Data Quality Objectives Process*, Publication No. EPA/600/R-96/055, September 1994 (EPA, 1994). The laboratory analytical data collected for this project will be used for decision-making and will be required to meet the requirements of definitive data. The field data collected for this project will not be used for decision-making and will be screening data without definitive confirmation.

1.5.3 Data Quality Objectives for the Primary Objective

The following subsections describe the development of DQOs for the determination of SSFL RBRA data sets.

1.5.3.1 State the Problem

The representative background concentration of radionuclides associated with SSFL activities has not been determined. Background concentrations are necessary for supporting future scoping and characterization surveys on SSFL, risk assessments, potential remediation activities, and to develop and complete final status surveys.

1.5.3.2 Identify the Goals of the Study

The primary objective of the study is to collect the analytical data to answer the following question (Question 1 in Table 1.3): What are the concentration population characteristics of radionuclides of potential concern in the RBRAs?

To successfully execute this phase of the study, this question will need to be answered for both the surface and subsurface soils in the Santa Susana Formation and Chatsworth Formation RBRAs. The statistical tools that will be used to evaluate project data sets to support the primary objective are presented in Appendix A.

1.5.3.3 Identify Decision Inputs

Based on the principal study question, the following information is required:

- Identification of radionuclides of potential concern;
- Potential uses of developed study data;
- Gross gamma count rate survey measurements;
- Surface soil sample analytical results; and
- Subsurface soil sample analytical results.

Only analytical results that have been determined to be usable after undergoing the data verification, validation, and evaluation process described in Section 4 will be used as decision inputs. The specific information sources associated with each of the study decision inputs identified above are presented in Table 1.5.

1.5.3.4 Define the Boundaries of the Study

The spatial boundaries of the study are:

- Gamma gross count rate measurements will be taken over the entire RBRA to determine local homogeneity.
- Surface soil samples will be collected from 0 to approximately 6-inch depth.
- Subsurface soil samples will be collected from at a depth of 3 to 10 feet (ft) below ground surface (bgs) or refusal.
- The data from each RBRA will be considered a unique data subset, pending evaluation is described in Section 1.5.3.5.

The temporal boundaries of the study are:

- Field activities will be conducted during dry season when surface soil moisture is minimal to optimize detection of gamma radiation from soil.
- Study must be completed within the project schedule (by the spring 2010).

1.5.3.5 Develop the Analytic Approach

The statistical approach for determining the radioisotope concentration population parameters for each RBRA is described in Appendix A. This approach was developed using the guidance and techniques presented in EPA's *Guidance for Comparing Background and Chemical Concentrations in Soils for CERCLA Sites* (EPA 540-R-01-003), September 2002, *Multi-Agency Radiation Survey and Site Investigation Manual* (EPA 402-R-97-016, Rev 1.), statistical software developed to support environmental applications, and technical publications. Decision rules, where applicable, will be primarily based upon guidance and calculation limitations contained and described in these documents. Professional judgment will also be used.

The following decision rules have been developed for the analysis of data obtained to address the primary objective:

- Quantitative gross gamma walkover surveys will be used at each RBRA to determine if the RBRA contains anomalies. Gamma measurements will be reviewed during the walkover survey and potential anomalies will be determined based on professional judgment. Excluding natural geometric affects, a measurement increase of greater than two will be defined as an anomaly. A location that contains anomalies is potentially unsuitable for sampling and may need to be replaced.
- Once a pool of suitable locations has been sampled in the RBRAs, the associated analytical data will be evaluated to determine the statistical characteristics of each data

set, in accordance with the decision rules presented in Table 1.5.

- For each duplicate sample, evaluate the variability to determine if affects from the matrix, sampling system, or analytical system are introducing bias or error into the measurement process and if any data points need to be excluded from the final evaluation. The decision rules for evaluating duplicate results are presented in Table 1.6.
- Evaluate the data subsets for each radionuclide to determine if data subsets can be combined, using the decision rules presented in Table 1.7 and the procedures described in Appendix A. The following data subsets will be reviewed to determine which, if any, can be combined:
  - Chatsworth Formation (surface soil);
  - Chatsworth Formation (subsurface soil);
  - Santa Susana Formation (surface soil); and
  - Santa Susana Formation (subsurface soil).

1.5.3.6 Specify Performance or Acceptance Criteria

A description of the full set of statistical tools that will be utilized to develop the population parameters of each radionuclide of concern data set at each RBRA are presented in Appendix A. These tools will incorporate statistical and graphical techniques that are classical, robust, and resistant to outliers. The use of logarithmically transformed data will be avoided due to uncertainties introduced by such transformations. Alternatives to performing logarithmic transformations will be employed when isotope populations are found to deviate from normal distribution characteristics. Non-detected results and results below detection limits will not be arbitrarily replaced by ad hoc values but will be addressed employing statistical evaluation techniques that have been designed to accurately account for the impact of non-detected results on the characterization of analyte data sets.

Once the population parameters are developed based on the data set collected from each RBRA, these populations will be evaluated to determine if they are statistically similar enough to allow for combining the data sets. The null hypothesis is that the mean concentration of a given radionuclide at each RBRA is statistically equal to the corresponding mean concentration at the other RBRAs. Decision errors may occur through two scenarios.

- A false acceptance decision error would be to conclude that the null hypothesis is true, when in fact, it is not. The consequence of this decision error would be to conclude that the data sets of each RBRA can be statistically pooled when this approach is in fact inappropriate.
- The second type of decision error is a false rejection error. The consequence of this error would be to conclude that the data sets of each RBRA could not be statistically pooled when they were in fact statistically equal.

The ultimate consequence of the false acceptance decision errors would be to use RBRA data

to develop background threshold values (BTV) that are not representative of the true background concentrations of the target isotopes. It is equally probable that the error would result in BTVs that are biased high or biased low. A BTV that is biased low would potentially lead to overly conservative estimates of risk at subsequent site investigations, causing additional expense and delay to address contamination that was in fact attributable to background. A BTV that is biased high would be less effective in protecting human health and the environment and could lead to a determination that site contamination is background when it is in fact potentially attributable to site sources.

Both types of errors are limited by the decision rules. Decisions are not based on a single data point, but rather on the entire body of data available. Consequently, a large number of data errors would have to occur across several locations to bias the decision towards a false acceptance or false rejection conclusion. The probability of simultaneous occurrences of error at a large number of measuring points and over an extended period is very low.

The requirement that decisions be based only on data that have been accepted through the data review and validation process also serves to limit the occurrence of decision errors.

1.5.3.7 Develop the Plan for Obtaining Data

The program that will be conducted to address the primary objective is summarized in the following subsections.

1.5.3.7.1 Number of Samples

Each RBRA will first undergo a surface screening in accordance with standard operating procedure (SOP) number (No.) 35 (included as an appendix to the Field Sampling Plan (FSP). This surface screening will verify that there are no localized anomalies and to reposition soil samples outside any identified anomalies. Surface soil samples will be collected from 0 to 6 inches bgs at each RBRA. Specific sample locations will be positioned in a grid pattern that is superimposed onto each RBRA. Fifty surface soil samples will be collected from the single RBRA overlying the Santa Susana Formation and a total of 50 surface samples will be collected from the two RBRAs overlying the Chatsworth Formation. The selection process used to derive the sampling locations for each area is detailed in Section 1.3.1 of the FSP. The number of QA/QC samples required is shown in Table 1.1 of the FSP. Matrix spike (MS)/matrix spike duplicate (MSD) samples will only be submitted for those tests for which they are appropriate.

Twenty subsurface soil samples will be collected within each geologic formation; these samples will be analyzed for the radionuclides of interest shown on Table 1.9. At each sampling location, a subsurface soil sample will be collected from at a depth of 3 to 10 ft bgs or from 3 ft bgs to bedrock (if less than 10 ft bgs). The number of QA/QC samples required is shown in Table 1.1 of the FSP.

As part of the sampling process, a gross gamma count rate survey will be conducted for each borehole in accordance with SOP No. 36 (included as an appendix to the FSP). This will be

conducted to identify subsurface anomalies and to characterize the natural subsurface gamma profile.

1.5.3.7.2 Analytical Methods and Detection Limits

Soil samples will be equal to or greater than 4 liters to ensure the best achievable analytical sensitivity. Table 1.9 presents the radionuclides that will be used to determine the background data sets at each of the RBRAs. This table also includes the associated analytical method, half-life, estimated best minimum detectable concentration (MDC), and EPA's agricultural Preliminary Remediation Goal (PRG) for each radionuclide. These radionuclides were selected as described in the document "Explanation of Selection of Proposed Radionuclides for Consideration, Analysis, and Distance Test Locations" dated April 15, 2009. The rationale for the selection of the target radionuclides is summarized in Appendix A of the FSP. The Agricultural PRGs have been selected as the basis for site cleanup objectives in accordance with California Senate Bill 990, which mandates the use of the PRGs in effect on January 1, 2007, as the risk range point of departure for radiological contamination at the SSFL site. For some analytes, the estimated best MDC exceeds the Agricultural PRG. The potential impact of each affected radioisotope is discussed in Appendix B.

1.5.4 Data Quality Objectives for the Secondary Objective

The following subsections describe the development of DQOs for the determination of potential impact to RBRAs and for the RBRA surface soil gamma survey.

1.5.4.1 State the Problem

The selected RBRAs may have been impacted by SSFL activities and, therefore, may not represent background concentrations of radionuclides of potential concern.

1.5.4.2 Identify the Goals of the Study

The secondary objective of the study is to collect the analytical data to answer the following question (Question 2 in Table 1.3): Are the selected RBRAs for the Santa Susana and Chatsworth Formations impacted by SSFL activities such that concentrations of radionuclides are not representative of background?

If the answer to this question is no for any RBRA, it will be rejected for use as a background reference area.

1.5.4.3 Identify Decision Inputs

Based on the principal study question, the following information is required:

- Identification of 40 suitable DTLs;
- Identification of study radionuclides;
- Quantitative gross gamma count rate survey measurements to determine the homogeneity of each DTL sampling location; and

- Surface soil samples and analytical results from each DTL sampling location and each RBRA sample data set.

Only analytical results that have been determined to be usable after undergoing the data verification, validation, and evaluation process described in Section 4.0 will be used as decision inputs. The specific information sources associated with each of the study decision inputs identified above are presented in Table 1.10.

1.5.4.4 Define the Boundaries of the Study

The spatial boundaries of the study are:

- Gamma gross count rate measurements will be taken in an approximately 50 ft by 50 ft area at each proposed DTL to determine local homogeneity.
- Surface soil samples will be collected from 0 to approximately 6-inch depth.
- The data from each RBRA will be considered a unique data subset.

The temporal boundaries of the study are:

- Field activities will be conducted during dry season when surface soil moisture is minimal to optimize detection of gamma radiation from soil.
- Study must be completed within the project schedule (by the spring of 2010).

1.5.4.5 Develop the Analytic Approach

Performance criteria and decision rules for achieving the primary objective have been developed using the same procedures and guidance presented in the documents referenced in Section 1.5.3.5. The following decision rules have been developed for the analysis of data collected to achieve the secondary objective:

- Quantitative gross gamma surveys will be conducted at each sampling location at each DTL to determine if the sampling location contains anomalies. A location that contains anomalies is potentially unsuitable for sampling and may need to be replaced. The decision rules for determining if a specific location is suitable for sampling are presented in Table 1.11.
- Once a pool of suitable locations has been sampled in the DTLs, the associated analytical data will be evaluated to determine the statistical characteristics of each data set, in accordance with the decision rules presented in Table 1.12.
- For each duplicate sample, evaluate the variability to determine if affects from the matrix, sampling system, or analytical system are introducing bias or error into the measurement process and if any data points need to be excluded from the final evaluation. The decision rules for evaluating duplicate results are presented in Table 1.6.
- An evaluation to determine if the central tendency of each RBRA data set is comparable to the DTL data set will be performed. In addition, the RBRA mean for

each analyte will be compared to the range of the DTL. Table 1.13 summarizes the decision rules for these comparisons.

1.5.4.6 Specify Performance or Acceptance Criteria

A description of the full set of statistical tools that will be utilized for evaluating whether data sets meet the acceptance criteria are presented in Appendix A. This paper describes the null hypotheses, the alternative hypotheses, and the acceptable limits on the Type I Error rate, α (alpha), and the Type II Error rate, β (beta). The same restrictions on data transformation described in Section 1.5.3.6 will apply to evaluating the data sets collected for achieving the secondary objective. The null hypothesis for the secondary objective is that the mean concentration of a given radionuclide at an RBRA is greater than the mean concentration in the corresponding DTL. Decision errors may occur through two scenarios.

- A false acceptance decision error would be to conclude that the null hypothesis is true, when in fact, it is not. The consequence of this decision error would be to conclude that an RBRA was not representative of background conditions when in fact it was. This scenario would cause project delays as alternative background locations were evaluated and tested. This alternative program would provide no better background locations than the originally selected ones and may provide worse as the best candidate locations have already been selected for investigation in the current study.
- The second type of decision error is a false rejection error. The consequence of this error would be to assume that an RBRA was representative of background conditions when in fact it was not.

The ultimate consequence of both decision errors would be to use RBRA data to develop BTVs that are not representative of the true background concentrations of the target isotopes. The false rejection error would lead to a high bias in the calculated BTVs. High bias would also be the most likely indirect consequence of the false acceptance error. A BTV that is biased high would be less effective in protecting human health and the environment and could lead to a determination that site contamination is background when it is in fact potentially attributable to site sources.

Both types of errors are limited by the decision rules. Decisions are not based on a single data point, but rather on the entire body of data available. Consequently, a large number of data errors would have to occur across several locations to bias the decision towards a false acceptance or false rejection conclusion. The probability of simultaneous occurrences of error at a large number of measuring points and over an extended period is very low.

The requirement that decisions be based only on data that have been accepted through the data review and validation process also serves to limit the occurrence of decision errors.

1.5.4.7 Develop the Plan for Obtaining Data

The data collection plan (sampling program) is described in detail in Section 1.0 of the FSP.

The program that will be conducted to address the secondary objective is summarized in the following subsections.

1.5.4.7.1 Number of Samples

Forty DTLs were identified as potential sampling locations with 10 DTLs per compass quadrant; i.e., 10 locations in the northeast quadrant, 10 locations in the northwest quadrant, 10 locations in the southeast quadrant, and 10 locations in the southwest quadrant. These DTLs were selected based on the criteria presented in Table 1.10. A random number generator will be used to select six of the 10 DTLs in each quadrant. A gross gamma surface soil survey will be performed in accordance with SOP No. 35 at each selected DTL to determine if the location has been impacted by radiological contamination. If anomalous measurements are found, the location will be rejected and a new location will be selected from the four remaining locations in that quadrant, using a random number generator.

A single surface soil sample will be collected from 0 to 6 inches bgs at each of the six selected DTLs in each quadrant. The specific sampling locations at each DTL will be selected based on professional judgment. Locations will be selected in areas where there is no evidence of soil erosion or soil/sediment accumulation. Samples will not be collected within topographic depressions or areas where there is evidence of surface water runoff (e.g., gullies). A random number generator will be used to select five of the six samples collected from each quadrant for laboratory analysis. The sixth sample will be archived as a backup sample for future analysis if one of the five sample results is determined to be invalid for use in the data set. The potential causes for rejection are numerous, such as data rejected during the validation process due to a quality control issue or a value determined to be an outlier. Two field duplicates and one MS/MSD pair will be collected and analyzed for QA/QC purposes.

1.5.4.7.2 Analytical Methods and Detection Limits

Soil samples are expected to be greater than 4 liters to ensure that requested detection limits can be met; the final required mass will be determined after a commercial analytical laboratory has been selected and the laboratory has provided the project team with their mass requirement. Table 1.13 presents the radionuclides that will be used to determine the potential for SSFL activities to have affected the proposed RBRAs. This table also includes the associated analytical method, half-life, estimated best MDC, and EPA's agricultural PRG for each radionuclide. These radionuclides were selected as described in the document "Explanation of Selection of Proposed Radionuclides for Consideration, Analysis, and Distance Test Locations" dated April 15, 2009; the rationale for selection is summarized in Appendix A of the FSP.

1.5.5 Data Measurement Quality Objectives

The QC elements associated with laboratory operations associated with this project are presented in Table 1.14. These tables also include the data quality evaluation criteria associated with each QC element. The principal tool for evaluating QC elements is the Z-score.

This value is calculated using the following formula:

$$Z = \frac{M - E}{\sqrt{\mathrm{TPU}_{\mathrm{M}}^2 + \mathrm{TPU}_{\mathrm{E}}^2}}$$

where:

M	=	value of the measured results;
E	=	value of the expected results; and,
TPU	=	reported total propagated error associated with M and E

The Z-score for a measured parameter is used to evaluate the significance of the difference between the measured value and the expected value. The Z-score is also known as the normalized difference. A positive value for a Z-score indicates a high bias and a negative value for a Z-score indicates a negative bias. In some cases, the absolute value of the Z-score, or the normalized absolute difference, is used to evaluate a QC element. In this case, the absolute value of the numerator is used in the calculation.

The null hypothesis for the evaluating Z-score is that M and E do not differ significantly. A Z-score of 1.96 represents a 5 percent (%) chance of incorrectly rejecting the null hypothesis and a Z-score of 2.58 represents a 1% chance of incorrectly rejecting the null hypothesis. These values of 1.96 and 2.58 are incorporated into several QC element evaluation procedures presented in Table 1.14.

Note that for MS evaluation, the E and $\mathrm{TPU}_{\mathrm{E}}^2$ terms have two components. The E term consists of the parent sample result plus the spike amount; the $\mathrm{TPU}_{\mathrm{E}}^2$ term consists of the TPU^2 for the parent sample result plus the TPU^2 for the spike amount.

1.5.6 Field Measurements

The field measurements that will be taken during the investigation include surface gamma measurements and subsurface gamma measurements. These measurements will be screening quality data for comparison purposes only. Maintaining and calibrating the equipment as described in Section 2.6 will be performed to ensure that these measurement systems are operating in accordance with the manufacturer's specifications.

1.6 SPECIAL TRAINING REQUIREMENTS

Training requirements for working at the Santa Susana Radiological Background Study will comply with the *Generic QAPP for Region 3 RAC2 Work Assignments* (HGL, 2007). Prior to initiating the field work, all field personnel will receive training on the project-specific requirements and sampling procedures. This training will be completed prior to mobilizing to the field.

2.0 MEASUREMENT AND DATA ACQUISITION

2.1 SAMPLE PROCESS DESIGN

The sampling process presented in the FSP (Sections 1.0 and 2.0) was designed to meet the DQOs previously discussed in Section 1.0. Information in this section provides details related to the sample collection to ensure the data are of known and acceptable quality.

2.2 SAMPLING METHOD REQUIREMENTS

Sampling methods include EPA and HGL SOPs to ensure samples are collected in a standardized method to ensure they represent actual site conditions. The SOPs that will be used for this project are included as an appendix to the FSP. Information in this section discusses the sample container and collection requirements specific to each analytical laboratory where sample analysis will be performed.

2.2.1 Sampling Equipment and Preparation

Sampling equipment required for the field program (including environmental sampling, health and safety monitoring, equipment and personal decontamination, and general field operations) are listed in Table 4.1 of the FSP.

Field preparatory activities will include review of the SAP and pertinent SOPs by all HGL field personnel, a field planning meeting with HGL field personnel to discuss the content of the SAP, the Health and Safety Plan (HSP), and general logistics related to implementation of the field program, procurement of field equipment and supplies, and mobilization of subcontractors.

The sampling equipment that will be used for this project includes:

- Surface soil samples will be collected using a stainless steel shovel or spade.
- Subsurface soil samples will be collected with a direct-push drill rig or hand auger.
- Surface gamma scanning will be conducted using a 3-inch by 3-inch sodium iodide scintilllator gamma scanning system integrated with Global Positioning System (GPS).
- Subsurface gamma scanning will be conducted using an appropriate size sodium iodide scintillator.

2.2.2 Sample Containers

All sample containers will be pre-cleaned and traceable to the facility that performed the cleaning. Sampling containers will not be cleaned or rinsed in the field. Table 2.1 provides the sample containers, preservation requirements, and holding times for the analyses that will be conducted. Containers, coolers, and preservatives will be provided by the laboratory.

Most target analytes can be analyzed from sample aliquots collected in 1 gallon freezer bags that should not be filled over half-full to prevent bursting in transit. These samples will be

dried and ground in entirety at the laboratory to create a homogenous solid matrix. There is some concern that carbon-14, tritium (hydrogen-3), chlorine-36, iodine-129, and technetium-99 may become volatile under the sample processing conditions, and could potentially be lost prior to the analytical process. Due to this concern, separate sample aliquots will be collected for the analysis of these analytes. There will be some impact on sample homogeneity for the aliquots selected for the analyses of these isotopes; however, losses of target analytes during processing would represent a severe limitation to data usability.

2.2.3 Sample Collection for Off-Site Analysis

Sample collection procedures outlined in Section 2.0 of the FSP will be used to collect field samples and associated QC samples in the containers with appropriate preservatives as specified in Table 2.1. Documentation that will be delivered with samples includes sample labels and chain-of-custody (COC) forms as specified in the applicable SOPs and Section 2.3.

When possible, samples will be shipped to the laboratory daily via Federal Express or other overnight commercial carrier. Prior to shipping samples, the Field Team Leader will contact the laboratory to confirm that laboratory personnel are available to receive the samples when they arrive. If the samples must be held to accommodate the laboratory or field schedule, the samples will be stored in a secure, temperature and humidity controlled environment.

2.2.4 Decontamination

Sampling equipment and other field items will be decontaminated in accordance with any requirements specifically addressed in individual sampling SOPs and the general requirements of SOP #11 *Equipment Decontamination*.

- All soil sampling equipment (such as drilling equipment, shovels, and trowels) will be thoroughly cleaned and decontaminated before starting field work each day and between soil sampling locations.
- Surface gamma scanning equipment will be thoroughly cleaned and decontaminated at the beginning of each day and prior to initiating work at a new location.
- Sample preparation equipment (e.g., ball mill) will be cleaned and decontaminated after processing each sample.

2.3 SAMPLE HANDLING AND CUSTODY REQUIREMENTS

The following subsections describe the procedures that will be used to ensure that the integrity of the samples is maintained. Procedures to ensure the custody and integrity of the samples begin at the time of sampling and continue through transport, sample receipt, preparation, analysis, and storage. A discussion of corrections to documentation is also included.

Table 2.2 summarizes the Sample Handling System and personnel responsible for each task.

2.3.1 Field Sample Custody and Documentation

The purpose and description of the sample label and the COC record are discussed in the following sections. All identification and tracking procedures for samples will follow HGL SOP No. 3 *Chain of Custody*, SOP No. 4 *Sample Identification, Labeling, and Packaging*, and SOP No. 5 *Sample Location Documentation*.

2.3.1.1 Sample Labeling and Identification

An alphanumeric coding system will uniquely identify each sample accepted during the field investigation. Because the radiological samples will be sent to laboratories directly under contract to HGL, sample numbers will not be assigned an associated Routine Analytical Services or Regional Delivery of Analytical Services number. COC records will be completed in accordance with the requirements of Section 4.3 ("Non-Contract Laboratory Program [CLP] Samples") of HGL SOP No. 3.

Equipment blank(s), will be identified by an "EB" following a number indicating the date; e.g., the equipment blank collected on July 15, 2009 would be identified as "EB071509". If multiple equipment blanks are collected on the same day, each will be distinguished by a suffix starting with "A", then "B", and so on. The parent sample associated with each field duplicate will be noted in the field log books and will be provided to the data validator, but the laboratory will not be provided with the identity of the parent sample.

The location of each sample, as well as time and date of sample collections and requested analyses, will be recorded on a field sheet completed for each sample. An example field sheet is provided in the FSP.

2.3.1.2 Chain-of-Custody Requirements

Sample COC procedures will follow the requirements set forth in HGL SOP No. 3. The COC record is employed as physical evidence of sample custody and control. This record system provides the means to identify, track, and monitor each individual sample from the point of collection through final data reporting. An example COC record is included with the field forms in the FSP.

The COC record is initiated with the acquisition of the samples and remains with the sample at all times. The COC includes the name of the field personnel assuming responsibility for the samples and documents transfer of sample custody. To simplify the COC record and eliminate sample custody questions, as few people as possible will handle the samples during the investigation.

A sample is considered to be under custody if one or more of the following criteria are met:

- The sample is in the sampler's possession;
- The sample is within the sampler's view after being in possession;

- The sample was in the sampler's possession and then was locked up to prevent tampering; or,
- The sample is in a designated secure area.

In addition to the COC record, custody seals are used to maintain the custody of samples during shipment. Custody seals are adhesive seals placed on items (such as sample shipping containers) in such a manner that if the sealed item is opened, the seal would be broken. The custody seal provides evidence that no sample tampering occurred between shipment of the samples and receipt of the samples by the laboratory.

The COC will be completed for each accepted sample that will be submitted to the commercial laboratory selected for analysis. The COC will be completed by the field sampling team. The field sampler will sign off on the COC when the samples are relinquished to the sample coordinator for packaging and shipping of the samples to the laboratory.

The sample coordinator will sign the COC when accepting custody of these samples, and will relinquish custody to Federal Express or other commercial overnight carrier for shipment by noting the carrier name and the air bill number on the COC form. The COC will be shipped to the laboratory with the samples, and a copy of the COC will be maintained by HGL.

2.3.2 Sample Packaging and Shipping

Samples will be packaged and shipped promptly after collection. When sent by common carrier, packaging, labeling, and shipping of hazardous materials are regulated by the U.S. Department of Transportation (DOT) under Code of Federal Regulations (CFR) Title 49, Part 172. Samples will be handled, packed, and shipped in accordance with HGL SOP No. 4, *Sample Identification, Labeling, and Packaging*, which includes applicable DOT requirements.

Key steps for packaging samples for shipment are outlined below:

1) Wrap glass containers in bubble wrap to protect them during shipment. Enclose and seal labeled sample containers in appropriately sized plastic zip-top bags.

2) Place a large plastic garbage bag into a sturdy cooler in good repair. Pour 2 to 4 inches of Styrofoam peanuts or bubble wrap into the plastic bag. Place the sample containers in the bag with sufficient space to allow for the addition of more packing material and ice between the sample containers, depending on preservation requirements.

3) Depending on preservation requirement, place ice in large sealed, double-bagged zip-top plastic bags. Place the ice on top of and/or between the samples. Fill all remaining space between the sample containers with packing material. Enough bagged ice should be included to maintain the samples at 4 degrees Celsius (°C) until the cooler arrives at the laboratory. A temperature blank will be included in each cooler for the lab to verify the samples arrival temperature is 4 °C. Seal the top of the garbage bag with fiber or duct tape.

4) Complete shipping/sample documentation including air bill shipment forms for each cooler. Seal traffic report/COCs inside a waterproof plastic bag and tape the bag inside the shipping container lid. Include a return address for the cooler.

5) Close the shipping container, affix signed and dated custody seals, and seal the cooler with nylon fiber strapping tape.

All samples will be shipped by an overnight delivery service to the designated laboratory. A copy of each air bill will be retained by HGL and the air bill number will be recorded in the field logbook so the cooler can be easily tracked if mishandled.

2.3.3 Field Logbook(s) and Records

2.3.3.1 Field Logbooks

An important element of field documentation is the proper maintenance by field personnel of the site-specific field logbooks. Field logbook(s) will be maintained by the field team in accordance with HGL's SOP No. 6, *Use and Maintenance of Field Logbook*. The logbook is an accounting of the accomplishment of scheduled activities, and will duly note problems or deviations from the governing plans and observations relating to the field program. Logbooks will be kept in the field team member's possession or in a secure place when not being used. The Project QA/QC Officer, or his designee, will periodically check logbook entries to ensure the required information is present as specified in the SOP.

2.3.3.2 Field Forms

In addition to the field logbooks, field forms will be used to record sampling activities and measurements taken in the field. Field forms to be used during this project are included in the FSP. Information included on the field sheets will be repeated in the field logbook. Each completed field sheet will be referenced in the field logbook, as appropriate.

At the conclusion of site activities or when the logbook is filled, the logbook and field forms will be incorporated into the project file as part of HGL's document control procedures. Completed field sheets also will be maintained in the project file.

2.3.3.3 Photographs

Field activities and sampling events will be documented using a digital camera. For each photograph, the following items will be recorded in the applicable field logbook or noted in a photographic record:

- Date of photograph;
- Time of photograph;
- Signature of the photographer;
- Identification of the site or sample by sample number;

- General direction the photograph is oriented; and,
- Sequential number of the photograph.

2.3.4 Laboratory Custody Procedures and Documentation

Laboratory custody procedures are provided in the laboratory's QA Manual. Upon receipt at the laboratory, each sample shipment will be inspected to assess the condition of the shipping cooler and the individual samples. This inspection will include measuring the temperature of the cooler (if cooling is required) to document that the temperature of the samples is within the acceptable criteria (4 $\pm$ 2 ºC) and verifying sample integrity. The pH of preserved aqueous samples will be measured. The enclosed COC record(s) will be cross-referenced with all of the samples in the shipment. Laboratory personnel will then sign these COC records and copies provided to HGL will be placed in the project file. The sample custodian may continue the COC record process by assigning a unique laboratory number to each sample on receipt. This number, if assigned, will identify the sample through all further handling. It is the laboratory's responsibility to maintain internal logbooks and records throughout sample preparation, analysis, data reporting, and disposal.

2.3.5 Corrections to and Deviations from Documentation

The procedures for correcting erroneous field entries are described in HGL SOP No. 6, *Use and Maintenance of Field Logbooks*. If required, a single strikeout initialed and dated is required to document changes. The correct information should be entered in close proximity to the erroneous entry. The same procedure will be used on field logbooks, field sheets, and COC records.

Any deviations from the guidance documents (FSP, QAPP, HSP, SOPs) will be recorded in the appropriate field logbook. A field change request form, included in the FSP, will be completed prior to implementing the deviation. The field change request form will be signed by the Head Geologist and Project Manager. Significant deviations will additionally require signature by the EPA Work Assignment Manager (WAM) before the deviation is implemented. Completed field change request forms will be included and discussed in the field investigation report.

2.4 ANALYTICAL METHODS REQUIREMENTS

Analytical analyses will be subcontracted to the Pittsburgh, Pennsylvania, facility of Pace Analytical Services, Inc. (PASI). PASI is a qualified laboratory that does not have an unacceptable conflict of interest (COI). Assumptions include the following:

- One laboratory will be contracted to conduct all analyses.
- Analytical services will be based on the radionuclide list presented in Table 1.9, with associated MDC requirements. The laboratory QA manual is presented in Appendix C.
- Milling will be performed by the laboratory.

- Not all MDCs are achievable.
- One archive volume per sample will be prepared by the laboratory and transferred to the EPA; these archive volumes will be retained by the EPA for a minimum of 90 days after the final report is issued for the results associated with the analyzed fraction of these samples.
- One in 20 samples will be analyzed for MS/MSD, as applicable to analytical methods.
- Data packages will conform to EPA Level 4 (full validation with raw data) standards, and contain the items listed in Exhibit 2.1.

The formula that PASI will use to calculate MDCs is presented below:

$$MDC = \frac{3.29\sqrt{R_b * \left(\frac{1}{T_s} + \frac{1}{T_b}\right)} + 3 * \left(\frac{1}{T_s} + \frac{1}{T_b}\right)}{k}$$

where:

R_b = the instrument background count rate

T_s = the sample count duration

T_b = the background calibration count duration

k = the standard denominator

It is recognized that some vendor-supplied proprietary software may use a variant of the MDC formula described above, and that the lab may not have control over the exact MDC formula used. In these cases, the lab will provide documentation as to the MDC formula being used by the software. If the lab can select from a variety of MDC formulas in such a proprietary software application, the formula that most closely matches the one described above will be used.

2.4.1 Laboratory Quality Assurance Program

Samples accepted during this project will be analyzed in accordance with standard EPA and/or nationally-accepted analytical procedures. The laboratory will adhere to all applicable QA/QC requirements stated in the applicable method and the laboratory QA Plan. Applicable recommendations of the *Multi-Agency Radiological Laboratory Analytical Protocols Manual* (MARLAP) (EPA et al., 2004) and *Evaluation of Radiochemical Data Usability* (DOE, 1997) will also be followed whenever practicable. Other QA elements associated with the laboratory analysis program include:

- A one day audit of each laboratory will be performed during the analyses of project samples.
- An appropriate mass of customized performance evaluation (PE) sample will be purchased that contains as many of the radionuclides of interest as are commercially available.
- Blind PE samples will be submitted to each project laboratory for analysis by all analytical methods, including those methods for which the target analytes were not spiked into the PE sample.

2.4.2 Methods for Off-Site Laboratory Analysis

Analytical instrumentation techniques that will be used by the laboratory are shown in Table 1.9.

2.5 QUALITY CONTROL REQUIREMENTS

2.5.1 Field Quality Control Samples

Field QC samples will be used to gauge the accuracy and precision of field collection activities. QC samples will be submitted to the laboratory and include field duplicates, equipment rinsate blanks, and decontamination source water blanks. Table 1.1 and Appendix A of the FSP provide information on the number and types of analyses that will be performed, along with the number of associated QC samples that will be collected.

The conventional procedure for collection of field duplicate samples is to perform a field homogenization of the sample and submit two aliquots as separate samples. Based on the requirements of this project, field homogenization is considered inadequate to obtain representative split aliquots and field duplicate samples processed in this way would have a source of variability associated with them that would not be applicable to other samples. Field duplicates for this project will be obtained using co-located samples rather than samples homogenized and split in the field. Surface soil duplicate samples would be collected from approximately 2 feet away from the location of the parent sample. Subsurface soil duplicate samples would be collected from borings offset 2 feet from the boring advanced to collect the parent sample.

QC samples and rationale are discussed in the *Generic QAPP for Region 3 RAC2 Work Assignments* (HGL, 2007).

2.5.2 Laboratory Quality Control Samples

Laboratory QC samples will include calibration verification checks, method blanks, laboratory control samples, laboratory duplicates, and MSs are required by the analytical method.

Laboratory QC samples and rationale are discussed in the *Generic QAPP for Region 3 RAC2 Work Assignments* (HGL, 2007). The laboratory will analyze laboratory QC samples in

accordance with its in-house QA plan and method requirements.

2.6 EQUIPMENT MAINTENANCE PROCEDURES

All equipment will be maintained in accordance with the *Generic QAPP for Region 3 RAC2 Work Assignments* (HGL, 2007). Field equipment maintenance procedures are detailed in Table 2.3. Laboratory maintenance procedures are presented in the laboratory QA manuals included as Appendix C.

2.7 INSTRUMENT CALIBRATION PROCEDURES AND FREQUENCY

2.7.1 Field Equipment

Equipment handling and calibration procedures will follow the manufacturer's instructions and will be in accordance with the *Generic QAPP for Region 3 RAC2 Work Assignments* (HGL, 2007). Site-specific equipment calibration procedures are detailed in Table 2.3.

2.7.2 Laboratory Equipment

Calibration of laboratory equipment will be based on written procedures approved by laboratory management and included in the laboratory's QA manual (Appendix C). Instruments and equipment will be initially calibrated and subsequently continuously calibrated at approved intervals, as specified by either the manufacturer or more frequent requirements (e.g., methodology requirements). Calibration standards used as reference standards will be traceable to the EPA, National Institute of Standards and Technology, or another nationally recognized reference standard source. Calibration and spike standard preparation and traceability information must be presented the laboratory data reports to allow for review and evaluation during the data validation process.

Records of initial calibration, continuing calibration and verification, repair, and replacement will be maintained by the laboratory where the work is performed in accordance with the requirements in the laboratory QA manual.

2.8 ACCEPTANCE REQUIREMENTS FOR SUPPLIES

Prior to acceptance, all supplies and consumables will be inspected to ensure that they are in satisfactory condition and free of defects. If defects are noted, the item will be replaced. The field team leader or designated HGL personnel will inspect all supplies and consumables provided by subcontractors.

2.9 NONDIRECT MEASUREMENT DATA ACQUISITION REQUIREMENTS

Nondirect measurements include information from logbooks, site documents, photographs, and data from other studies that can be used to augment the data set collected under this project and assist in decision-making. All logbooks, data sheets, and photographs generated by HGL during field activities will be documented and maintained in accordance with the requirements of Section 2.3.3. Information from external sources will be evaluated for any limitations on

data use and will be incorporated into project decisions only with concurrence from the EPA. These sources will be identified in any project reporting documents and these documents will include relevant information on any such sources, including the original generator, associated quality control, and limitations on use.

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3.0 ASSESSMENT AND OVERSIGHT

3.1 ASSESSMENTS AND RESPONSE ACTIONS

Assessment and Response Actions will be in accordance with the *Generic QAPP for Region 3 RAC2 Work Assignments* (HGL, 2007). Assessment activities are outlined in Table 3.1, and procedures for handling project deviations are outlined in Table 3.2.

The HGL project management team will conduct an audit during the initial stages of this project to ensure that the procedures of this QAPP, the FSP, the HSP, and field SOPs are being performed. The HGL audit team will identify items requiring immediate corrective action and verify that the corrective action has been performed to address any deficiencies. The team will produce a report that will document findings and corrective actions.

At the discretion of EPA Region 9, the EPA will perform an oversight audit to verify that all agreed-upon procedures are being followed and that no QA discrepancies will affect the results of the investigation. Any discrepancies found will be addressed as they are identified.

3.2 REPORTS TO MANAGEMENT

Reports will be generated for all QA audits that are conducted and provided to the QA Manager. Reports will include deficiencies that were noted during the audit and corrective actions that were planned or implemented.

The EPA WAM will receive QA reports whenever major quality problems cannot be immediately corrected. A QA summary of major quality problems and their resolution will be also be provided to the EPA WAM in a timely manner. This QA summary will detail any quality issues that cause data to be provisionally rejected pending EPA review and approval (see Section 4.2.1). A summary will be provided after data validation is complete and will include all results provisionally rejected due to deficiencies in data quality. A second summary will be provided after statistical evaluation of the data sets and will include all results provisionally rejected as outliers.

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4.0 DATA VALIDATION REQUIREMENTS AND USABILITY

4.1 QUALITY CHECK OF RADIOLOGICAL DATA

Analytical data packages will be received from the laboratory in both hard copy and electronic data deliverable (EDD) format for uploading into the project database. The project manager or designee will perform a quality check of the laboratory results by reviewing sample numbers versus COCs and field sheets for consistency and completeness. HGL will subcontract data verification and validation services. The project chemist or designee will review any qualifiers added by the validator to determine usability of the results.

4.1.1 Data Validation Protocols

The data validation contractor will validate radiological analysis results. Data validation will be performed in accordance with DOE document *Evaluation of Radiochemical Data Usability* (DOE, 1997) and MARLAP (EPA et al., 2004). The data validation will be the equivalent of an EPA full validation ("Level IV") and will include examination of raw data and recalculation of results. Each data validator will be required to be a radiochemist with at least two years of experience in radiochemical separations and measurement.

Table 1.15 shows data qualification conventions for QC elements associated with the project analyses. These conventions are general, and will be supplemented by method-specific QC elements where appropriate. When analytical results are reported in association with QC results that do not meet the performance criteria, the validator will apply the appropriate qualifier as presented in Table 1.15. Alternative qualification approaches that contradict the requirements of Table 1.15 are allowed if, in the validator's judgment, the alternative is appropriate for a specific QC issue. Each instance of application of an alternative protocol must be documented in the corresponding data validation report to allow for EPA review and final approval.

4.1.2 Raw Data and Process Review

In addition to the laboratory QC elements and qualification conventions described in Table 1.15, the data validation process will also include a review of the following elements:

- Sample receipt, condition, and preservation;
- COC;
- Sample preparation documentation;
- Standard preparation and traceability;
- Required MDCs;
- Field (equipment) blank performance;
- Field duplicate performance;
- Examination of raw data to verify laboratory and instrument performance;

- Holding times;
- Nuclide identification and interferences;
- Detection decisions;
- Sample aliquot representativeness; and
- Data intercomparison between parents and daughters and gross screening results.

The validator will also be responsible for checking selected results for transcription errors from raw data to summary forms (both for representative sample and QC results) and for performing recalculation of selected reported sample and QC analysis results.

4.1.3 Equipment Blank Data Review

One equipment (rinse) blank will be collected each day by each field team. Equipment blanks will consist of decontamination water poured over or through a freshly decontaminated piece of equipment used by that team during that day's sampling activities. Each day's set of equipment blanks collected for analysis will be submitted in conjunction with a sample of the decontamination source water collected directly from the source. Each equipment blank and source water sample will be analyzed for uranium isotopes only and the results will be reported to HGL within 14 days of collection.

HGL will evaluate the results of each rinse blank and to the corresponding source water results to determine if there are substantial differences at the 99% confidence level. If substantial differences are not noted, the decontamination procedures will be considered to be effective and no additional analyses will be required for that specific rinse blank. If substantial differences are noted, it is possible that incomplete decontamination procedures could affect results by cross-contamination. The project team leader will initiate an investigation into the source of the problem and take corrective action. HGL will also instruct the laboratory to analyze the affected rinse blank and source water sample for all project parameters. In these cases, the full set of results for the equipment blank and source water blank will be required to be included in the same data report as the soil samples collected on the same day.

Validators will evaluate each rinse blank that was analyzed for the full set of parameters. For each such rinse blank, those analytes that show a substantial difference (at 99% confidence) from the corresponding source water sample will be treated as contamination and will be compared to the associated soil sample results (with adjustment for matrix differences). Soil sample results that do not differ from the corresponding rinse blank result at 99% confidence will be considered potential artifacts and qualified B.

4.1.4 Performance Evaluation Sample Review

PE samples will be analyzed for all project analytes at the required MDCs for the project. PE sample results will be evaluated against the certified values provided by the manufacturer.

The Z-score will be calculated as:

$$Z = abs(R-C)/sqrt(u_R\hat{}2+u_C\hat{}2)$$

where:

R = analysis result
u_R = 1σ CSU for the analysis result
C = analyte certified value
u_C = 1σ uncertainty in the certified value

PE sample results will have a Z-score <=2.58.

PE sample results will not be evaluated for naturally occurring radionuclides whose activity values are not certified.

PE sample results for anthropogenic radionuclides whose values are not certified will be evaluated on the assumption that C = zero and u_C = one half the requested MDC.

4.2 RECONCILIATION WITH USER REQUIREMENTS

4.2.1 DQO Reconciliation

After the data quality reviews and validation are complete as discussed in Sections 4.1, HGL will determine which data are usable for their intended purposes based on the DQOs that have been established for this project. Reconciliation with the DQOs and overall project objectives will be discussed in the data quality assessment report produced in accordance with the guidance in MARLAP (EPA et al., 2004). Rejection of any data, whether due to a discrepancy identified in the validation process or as the result of the application of statistical tests, requires explicit EPA Region 9 concurrence. Summary reports of all data provisionally rejected for decision-making and rationale for rejection will be provided to EPA for EPA's final determination of data usability (see Section 3.2).

4.2.2 Data Reduction and Tabulation

Data reduction and tabulation will be performed using the various data that have been uploaded into a project database during the course of the WA as described in Section 5.2.

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5.0 DATA MANAGEMENT AND VISUALIZATION

5.1 INTRODUCTION

The sample activities to be conducted at this site will generate fixed laboratory data from the analysis of samples from multiple media, field measurements, and other site-derived information. The resulting data will be entered into a single data management system for consistency in tracking samples; storing and retrieving data; evaluating analytical results; visualizing data; and generating data tables and reports. The data management procedures for this project are in accordance with *Generic QAPP for Region 3 RAC2 Work Assignment* (HGL, 2007).

5.1.1 Objectives of Data Management Plan

Successful data management results from coordinating data collection, control, storage, access, reduction, evaluation and reporting. This Data Management Plan (DMP) documents the methodology that will be employed during project execution to link the various data management tools, including software packages, to assure that the various data and information types to be collected are systematically obtained and managed.

The specific objectives of this DMP are:

- Standardize and facilitate the collection, formatting, and transfer of project data into the data management system and components;
- Provide a structured data system that will support the end uses of the data presented in Section 6.5.1 of the QAPP;
- Minimize the uncertainties associated with the data, data-derived products, and interpretation of results through defined QC measures and documented processes, assumptions and practices; and,
- Provide data that are adequately documented with descriptive information for technical defensibility and legal admissibility of the data.

5.1.2 Data Management Team Organization

A Data Management Team has been established for the site and the personnel comprising this team are included in Table 1.1.

5.1.3 Roles and Responsibilities of Data Management Team

The roles and responsibilities of the Data Management Team are in accordance with the *Generic QAPP for Region 3 RAC2 Work Assignments* (HGL, 2007).

5.1.4 Data Management Process

The data management process is in accordance with the *Generic QAPP for Region 3 RAC2 Work Assignments* (HGL, 2007).

5.2 DATABASE

HGL will create and maintain the project database, and will ensure that the database is organized in a fashion that can be queried to support project data reporting needs. Validated analytical data will be uploaded into the project database only after a series of QC checks have established that all appropriate qualifiers have been applied and the EDD content is complete and accurate.

5.2.1 Data Collection

All analytical sample data will be received from each laboratory following sample analysis as a Staged Electronic Data Deliverable (SEDD) for inclusion in the database. SEDDs will be received as an Extensible Markup Language (.xml) file. As results may change during data validation, all validated data will supersede the 'as-delivered' (unvalidated) results.

5.2.1.1 Data Tracking Sheets

Once data have been collected, sample result packages will be checked by the Data Manager (DM) for completion and entered onto a sample tracking sheet by the Sample Manager. A sample tracking sheet will inventory samples collected and determine which results have not been received from the laboratory. If data is missing, the DM will contact the appropriate laboratory coordinator to obtain electronic/hard copies of the missing data.

5.2.1.2 Database Log

During the data manipulation process, the DM will maintain a database log updated with project-specific assumptions and changes made.

5.2.2 Pre-Processing Non-SEDD Data

All data not received as a SEDD will be entered into a separate Excel spreadsheet in order to be loaded into the site database, rather than directly keyed into the database through the user interface. This is preformed so that the loading quality checks are uniformly applied, and to assure that all data pass through the same QC process. Data included in this step are sample collection information, field parameters, soil boring and well construction logs, survey information and investigation-derived waste (IDW) information. All hand-entered data will receive a 100% QC check before being loaded into the database.

5.2.3 Processing Staged Electronic Data Deliverables

Each SEDD will be loaded into the Excel database by the Database Administrator using the data loading tools provided in the software. Analytical data will be provided by the data validation subcontractor in SEDD format and will not require revision to perform the Automated Data Review. All data in each SEDD will be validated by other EPA contractors before receipt by HGL.

5.2.4 Post-Processing

Data will be exported from the Excel database to Environmental System Research Institute's ArcView geographic information system (GIS) for analysis and visualization. Database queries in support of the GIS will be conducted when analytical data has been validated and entered into the database.

5.2.5 Reporting

Following the one-time soil sampling event, tables of results of sample analysis, population characteristics, and population comparisons will be generated from the database after the sampling effort is completed and validated analytical results have been received. These results will be compared to the decision rules presented in QAPP Section 1.0. These tables will supplement the technical memorandum to be prepared by HGL.

At conclusion of project, the entire project database will be provided to EPA Region 9 without limitations. This database will be in a format that is usable with commercially available software; no proprietary software will be required for database access.

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6.0 REFERENCES

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U.S. Environmental Protection Agency (EPA) Office of Environmental Information, 2001. *EPA Requirements for Quality Assurance Project Plans (QA/R-5)*. Publication No. EPA/240/B-01/003. March.

EPA, 2006. *Guidance on Systematic Planning Using the Data Quality Objectives Process*, EPA QA/G4. February.

EPA, et al., 2000. *Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)*. August.

EPA, et al., 2004. *Multi-Agency Radiological Laboratory Analytical Protocols Manual (MARLAP)*. July.

EPA Region III, 1993. *Region III Modifications to the Laboratory Data Validation Functional Guidelines for Evaluating Inorganic Analyses*. April.

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TABLES

Table 1.1
Personnel Responsibilities

Name	Organization/Contact Information	Responsibility
Nicole Moutoux	USEPA Region IX 75 Hawthorne Street (SFD-8-2) San Francisco, CA 94105 (415) 972-3012	Work Assignment Manager
Mary Aycock	USEPA Region IX 75 Hawthorne Street (SFD-8-2) San Francisco, CA 94105 (415) 972-3289	Assistant Work Assignment Manager
Gregg Dempsey	Center for Environmental Restoration, Monitoring and Emergency Response Radiation and Indoor Environments National Laboratory P.O. Box 98517 Las Vegas, Nevada 89193-8517 (702) 784-8232	Technical Lead
James Clark	USEPA Region III 1650 Arch Street Philadelphia, PA 19103 (215) 814-5198	RAC 2 Contracting Officer
Jan Kool, Ph.D, P.G.	HGL 11107 Sunset Hills Road, Suite 400 Reston, VA 20190 (703) 478-5186	RAC2 Program Manager
Eric Evans, PMP	HGL Northway 10 Executive Park, 313 Ushers Road Ballston Lake, NY 12019 Phone: (518) 877-0390	Project Manager
Peter Dacyk	HGL Northway 10 Executive Park, 313 Ushers Road Ballston Lake, NY 12019 Phone: (518) 877-0390	Head Geologist
Ken Rapuano	HGL 11107 Sunset Hills Road, Suite 400 Reston, VA 20190 (703) 478-5186	Project Chemist
Jeff Martin	HGL 11107 Sunset Hills Road, Suite 400 Reston, VA 20190 (703) 478-5186	Database Manager

Table 1.1 (continued)
Personnel Responsibilities

Name	Organization/Contact Information	Responsibility
Chuck Smith	HGL 8245 Nieman Road, Suite 101 Lenexa, KS 66214 (913) 317-8860	Project QA/QC Officer
Mark McGowan	HGL 11107 Sunset Hills Road, Suite 400 Reston, VA 20190 (703) 478-5186	Corporate H&S Officer
Carl Palladino	TPC 720 Fillmore Street San Francisco, CA 94117 (415) 861-1945	Radiological Services
David C. Burns	TPC PO Box 976 Fort Collins, CO 80522 (970) 980-9792	Radiochemistry Expert
Jackie Collins	PASI-Pittsburgh 1638 Roseytown Road, Suites 2, 3, and 4 Greensburg, PA 15601 (724) 850-5600	Laboratory Project Manager
Randall Hill	PASI-Pittsburgh 1638 Roseytown Road, Suites 2, 3, and 4 Greensburg, PA 15601 (724) 850-5600	Laboratory QA Officer
Richard Kinney	PASI-Pittsburgh 1638 Roseytown Road, Suites 2, 3, and 4 Greensburg, PA 15601 (724) 850-5600	Laboratory Radiochemistry Section Manager
TBD	Project Data Validation Firm - TBD	Data Validation Project Manager

Table 1.2
Communication Pathways

Communication Drivers	Responsible Entity	Name	Phone Number	Procedure (Timing, Pathways, etc.)
Corporate project oversight and resource allocation	HGL Program Manager	Jan Kool, Ph.D, P.G.	(703) 478-5198	Evaluate project support requirements at periodic program staff meetings and at request of Project Manager.
Manages all project phases	HGL Project Manager	Eric Evans, PMP	(518) 877-0390	Interact with the Program Manager, HGL personnel, subcontractors, EPA Region 9, and stakeholders.
				Notify Region 9 WAM of field-related problems by phone, e-mail, or fax by close of business (COB) the next business day.
				Approves all real-time changes to the QAPP and coordinates obtaining EPA Region 9 WAM approval for QAPP non-time critical QAPP modifications.
				Transmit all project deliverables (including revisions) to EPA Region 9 and stakeholders.
Field sampling	Head Geologist	Peter Dacyk	(518) 877-0390	Prepare daily progress reports and fax or e-mail to HGL's Project Manager.
				Coordinate field activities with on-site contractors and HGL personnel.
				Inform Project Manager and/or QA/QC Officer of field issues requiring resolution.
				Notify Project Manager immediately if work stopped due to technical or health and safety (H&S) issues.
				Alerts PM or Project Chemist of need for real-time modification of QAPP (with EPARegion 9 WAM approval) if field conditions warrant.

Table 1.2 (continued)
Communication Pathways

Communication Drivers	Responsible Entity	Name	Phone Number	Procedure (Timing, Pathways, etc.)
Analytical program oversight	HGL Project Chemist	Ken Rapuano	(703) 736-4546	Provide guidance through memoranda, e-mail, or phone to HGL field staff, laboratory subcontractors, and data validation staff to ensure that data of required quality is obtained.
				Approves validated data for release for project use.
				Identify QAPP non-conformances and recommends corrective action to the Project Manager.
				Informs Project Manager whether real-time deviations from the QAPP can be considered single-instance or require QAPP modification (with EPA Region 9 WAM approval).
Overall project QA	HGL Project QA/QC Officer	Chuck Smith	(913) 317-8860	Communicate program QA/QC requirements to the HGL Project Manager and Project Chemist.
				Determine need to develop procedural changes to address QA/QC deficiencies.
Laboratory project management	Subcontract Laboratory	PASI	(724) 850-5600	Approve transmittal of analytical reports to the HGL Project Manager.
				Inform HGL Project Manager and/or Project Chemist of QC issues by COB next business day.
				Alert HGL Project Manager and/or Project Chemist of need to modify QAPP (with EPA Region 9 WAM approval) based on analytical conditions.
				Coordinate interaction of the laboratory manager, laboratory QA manager, and analytical staff with HGL management as needed to resolve QA/QC issues.

Table 1.3
Problem Definition

The problem to be addressed by the project: The objective of this project is to determine the background concentrations of target radionuclides in soils at each of the two geological formations (the Santa Susana and the Chatsworth) located at the SSFL.
The environmental questions being asked: Question 1: What are the concentration population characteristics of radionuclides of potential concern in the RBRAs? Question 2: Are the selected RBRAs for the Santa Susana and Chatsworth formations impacted by SSFL activities such that concentrations of radionuclides are not representative of background?
Observations from any site reconnaissance reports: Visits to the RBRAs indicate acceptable locations for collection of required data.
The possible classes of contaminants and the affected matrices: The class of contaminants is naturally occurring and man-made radionuclides; the affected matrix is soil (surface and subsurface).
The rationale for inclusion of chemical and non-chemical analyses: The rationale for the selection of target radionuclides is presented in Tables 1.5 and 1.11. Screening gamma surveys are included to assist in the identification of anomalous or impacted locations that should be excluded from the comparison or background data sets.
Information concerning various environmental indicators: During sampling activities, each site will be inspected for signs of disturbance that could cause a sampling location to be rejected as an anomaly.
Project decision conditions ("If…, then…" statements): The decision conditions used to answer Question 1 are presented in Tables 1.6 through 1.9. The decision conditions used to answer Question 2 are presented in Tables 1.6, 1.8, 1.12, and 1.13.

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Table 1.4
Project Documents and Records

Sample Collection Documents and Records	On-site Analysis Documents and Records	Off-site Analysis Documents and Records	Data Assessment Documents and Records	Other
Field notes (bound logbook)	Equipment calibration logs	Sample receipt, custody, and tracking records	Data validation reports	Project planning documents
Daily Quality Control Reports	Equipment maintenance, testing, and inspection logs	Standard traceability logs	Automated data review reports	Project deliverables
Chain-of-custody records	Field sampling data sheets	Equipment calibration logs	Database QC Spreadsheets	Telephone logs, e-mails, faxes, and correspondence
Air bills	Waste disposal records	Sample preparation logs	Telephone logs, e-mails, faxes, and correspondence	Permits
Custody seals		Analytical run logs		Site maps
Telephone logs, e-mails, faxes, and correspondence		Equipment maintenance, testing, and inspection logs		
Corrective action forms		Analytical discrepancy forms		
Photographs		Reported analytical results		
		Reported results for standards, QC checks, and QC samples		
		Data package completeness checklists		
		Sample disposal records		
		Extraction and cleanup records		
		Raw data (stored electronically)		
		Telephone logs, e-mails, faxes, and correspondence		

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Table 1.5
Decision Inputs for Determination of SSFL RBRA Data Sets

Information Needed	Information Source
Identification of radionuclides of potential concern	Criteria for selection of radionuclides: • Used or produced at SSFL. • Half-life more than 1 year (21 half-lives since 1988 when operations ceased). An exception to this criterion is if the radionuclide has a half-life of less than one year and its parent is included on the list, then it would also be retained. • The physical state of the radionuclide was not a gas. An exception to this criterion is if the radionuclide is a gas and its parent is on the list, then it would also be retained. • The SSFL Technical Workgroup elected to retain a specific radionuclide. • The radionuclide has an Agricultural Preliminary Remediation Goal (Ag PRG). Table 1.9 summarizes the list of radionuclides of potential concern that meet the selection criteria.
Potential uses of developed study data	The study data will be used as reference area data for comparison to characterization, remediation, and release (final status surveys) criteria which have not been established. Potential release criteria to be considered are as follows: • Incremental risks above background; and • The ability to distinguish from background Due to these potential future uses of the data, guidance contained in the NUREG 1575, *Multi-Agency Radiation Site Survey and Investigation Manual (MARSSIM)* and NUREG 1505, *A Nonparametric Statistical Methodology for the Design and Analysis of Final Status Decommissioning Surveys*, will be used to plan the survey.
Gross gamma count rate survey measurements	• Gross gamma count rate surface survey of each radiological reference areas. • Integrated gross count rate survey at each surface soil sample location. • Gross gamma count rate subsurface borehole survey of each borehole. A custom gamma detection system will be designed and constructed for the gross gamma count rate surface survey. An appropriate size sodium iodide scintillator detector will be used to conduct the borehole survey.

Table 1.5 (continued)
Decision Inputs for Determination of SSFL RBRA Data Sets

Information Needed	Information Source
Surface soil samples and analytical results	50 surface soil samples will be collected from 0 to an approximate 6 inch depth at each of RBRAs (one Santa Susana Formation RBRA and two Chatsworth Formation RBRAs). The samples will be collected on a grid designed in accordance with MARSSIM for a Class 1 survey unit. Field duplicates will be collected at a rate of 10%. MS/MSDs, where applicable to analytical methods, will be analyzed by the laboratory at a rate of 5%. The laboratory will process the entire sample, reserving half for analysis and transferring the other half to the EPA for archiving for contingency. Sufficient mass will be collected to ensure that the full suite of analyses can be performed on both processed fractions. Analytical results should be adequate to describe the 95% upper confidence level concentration of each radionuclide of potential concern in soil.
Subsurface soil samples and analytical results	20 boreholes from each formation will be completed to a depth not to exceed 10 feet or refusal at each of the geological formations. 1 subsurface soil sample will be collected from each borehole. This sample will consist of aliquots collected from 3 to 10 ft bgs or from 3 ft bgs to bedrock (if less than 10 ft bgs). Field duplicates will be collected at a rate of 10%. MS/MSDs, where applicable to analytical methods, will be analyzed by the laboratory at a rate of 5%. The laboratory will process the entire sample, reserving half for analysis and transferring the other half to the EPA for archiving for contingency. Sufficient mass will be collected to ensure that the full suite of analyses can be performed on both processed fractions. Analytical results should be adequate to describe the 95% upper confidence level concentration of each radionuclide of potential concern in soil.

Table 1.6
General Duplicate Quality Control Decision Rules

Parameter/Item of Interest	IF	THEN
Z-Score for Radionuclide Analysis Result	Radionuclide analysis result is available for both the parent soil sample and the duplicate QC sample.	Calculate the Z-Score as follows: $$Z = \frac{\lvert I - D \rvert}{\sqrt{TPU_I^2 + TPU_D^2}}$$ Where: Z = Z-Score I, D = value of (I)nitial and (D)uplicate/split measurement/analysis; and, TPU = reported total propagated error associated with (I) and (D) measurement/analysis; field duplicate evaluations will factor in a required level of uncertainty of 10%.
	Z-Score is greater than 1.96.	Qualify results in accordance with Table 1.14.
	Z-Score is greater than 2.58.	Qualify results in accordance with Table 1.14. Investigate sample results **AND** consider potential bias/error in sample and exclusion of data from sample data set.

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Table 1.7
Individual Radionuclide Decision Rules for Determination of SSFL RBRA Data Sets

Parameter/Item of Interest	Investigation Level	IF	THEN
Sample Population Distribution	Sample distribution is **NOT** a Normal Distribution.	Deviation from Normal Distribution identified	Apply alternative distribution evaluation[1]
Data Outliers	Identification of data Outliers	Outliers are identified	Exclude outlier data
Useful Sample Size (less excluded data)	Characterize data sets	NA[2]	NA
Mean (μ)	Characterize data sets	NA	NA
Median (M)	Characterize data sets	NA	NA
Standard Deviation	Characterize data sets	NA	NA
Standard Error	Characterize data sets	NA	NA
Background Threshold Value (BTV)	Characterize data sets	NA	NA
95% Upper Confidence Level	Characterize data sets	NA	NA
95% Upper Tolerance Limit	Characterize data sets	NA	NA
Maximum	Characterize data sets	NA	NA
Minimum	Characterize data sets	NA	NA
25th Percentile	Characterize data sets	NA	NA
75th Percentile	Characterize data sets	NA	NA
Skewness	Characterize data sets	NA	NA
Kurtosis	Characterize data sets	NA	NA

[1] The statistical approach in Appendix A identifies limitations on the usability of evaluating data sets as log-normal distributions; tests will be applied to data sets that do not show normal distribution to determine if data sets show a gamma distribution.
[2] NA refers to the applicability of an IF and THEN statement.

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Table 1.8
Combination of Individual Radionuclide Data Sets Decision Rules for Determination of SSFL RBRA Data Sets

Parameters/Item of Interest	IF	THEN
Physical, chemical, geological, and biological characteristics of the sampled media should be similar	Characteristics are reasonably similar	Proceed with comparison of data sets evaluation; else, do not compare data sets.
Equivalence of sample variances and means/medians in RBRA and DTL data sets (sample taken from same population)	Determine the distribution characteristics of the RBRA and DTL data sets	Perform statistical comparisons of the data sets appropriate for the distribution characteristics in accordance with Appendix A.
Data set combination	Data sets are determined to be comparable	Combine data sets under consideration and provide description/summary statistics; else, do not combine data sets for purposes of this study.

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Table 1.9
Radionuclides Used to Determine RBRA Background Concentrations

Symbol	Radionuclide	Pace Confirmed Method	Half-Life	Units	Ag PRG (pCi/g)	PASI MDC (pCi/g)	Ag PRG Met?
			Alpha Spectroscopy				
Am-241	americium-241	HASL Am-05 modified	432.6	Years	0.0132	0.05	No
Am-243	americium-243	HASL Am-05 modified	7,370	Years	0.0111 (+D)	0.05	No
Cm-243	curium-243	HASL Am-05 modified	29.1	Years	0.127	0.127	Yes
Cm-244	curium-244	HASL Am-05 modified	18.1	Years	0.304	TBD	TBD
Cm-245	curium-245	HASL Am-05 modified	8,500	Years	0.0922	0.0922	Yes
Cm-246	curium-246	HASL Am-05 modified	4,760	Years	0.129	0.0922	Yes
Cm-248	curium-248	HASL Am-05 modified	348,000	Years	0.00143	TBD	TBD
Np-237	neptunium-237	HASL Pu-11-RC Modified	2.144E+06	Years	0.000448 (+D)	0.0111	No
Po-210	polonium-210	HASL Po-02-RC Modified	138.376	Days	19.4	2.0	Yes
Pu-236	plutonium-236	HASL Pu-11-RC Modified	2.585	Years	0.104	0.104	Yes
Pu-238	plutonium-238	HASL Pu-11-RC Modified	87.7	Years	0.00731	0.00731	Yes
Pu-239	plutonium-239	HASL Pu-11-RC Modified	24,110	Years	0.00609	0.00609	Yes
Pu-240	plutonium-240	HASL Pu-11-RC Modified	6,563	Years	0.0061	0.00609	Yes
Pu-242	plutonium-242	HASL Pu-11-RC Modified	375,000	Years	0.00642	0.0064	Yes
Pu-244	plutonium-244	HASL Pu-11-RC Modified	8.00E+07	Years	0.00506 (+D)	TBD	TBD
Th-228	thorium-228	HASL Th-01-RC Modified	1.9116	Years	0.0338 (+D)	0.04	No
Th-229	thorium-229	HASL Th-01-RC Modified	7,880	Years	0.00171 (+D)	0.05	No
Th-230	thorium-230	HASL Th-01-RC Modified	75,400	Years	0.0105	0.05	No
Th-232	thorium-232	HASL Th-01-RC Modified	1.405E+10	Years	0.00942	0.04	No
U-232	uranium-232	HASL U-02-RC Modified	68.9	Years	0.00059	0.33	No
U-233	uranium-233	HASL U-02-RC Modified	1.592E+05	Years	0.00184	0.33	No
U-234	uranium-234	HASL U-02-RC Modified	245,500	Years	0.00187	0.04	No
U-235	uranium-235	HASL U-02-RC Modified	7.040E+08	Years	0.00181 (+D)	0.04	No
U-236	uranium-236	HASL U-02-RC Modified	2.3420E+07	Years	0.00198	0.05	No
U-238	uranium-238	HASL U-02-RC Modified	4.468E+09	Years	0.00147 (+D)	0.04	No
U-240	uranium-240	HASL U-02-RC Modified	14.1	Hours	298	TBD	TBD

Table 1.9 (continued)
Radionuclides Used to Determine RBRA Background Concentrations

Symbol	Radionuclide	Pace Confirmed Method	Half-Life	Units	Ag PRG (pCi/g)	PASI MDC (pCi/g)	Ag PRG Met?
Gas Flow Proportional Counting							
Bi-210	bismuth-210	Eichrom OTS01 Modified	5.012	Days	1340	0.2	Yes
Pb-210	lead-210+D	Eichrom OTS01 Modified	22.20	Years	0.0000642 (+D)	0.2	No
Sr-90	strontium-90	Eichrom SRW01 Modified	28.8	Years	0.00139 (+D)	0.03	No
Y-90	yttrium-90	Eichrom SRW01 Modified	64.053	Hours	9630	0.03	Yes
Gamma Spectroscopy [1]							
Ac-227	actinium-227	EPA 901.1M	21.772	Years	0.0831 (+D)	0.0831	Yes
Ac-228	actinium-228	EPA 901.1M	6.15	Hours	731	0.5	Yes
Ag-108	silver-108	EPA 901.1M	2.37	Minutes	6010000	TBD	TBD
Ag-108m	silver 108m	EPA 901.1M	418	Years	0.00629	0.01	No
Ba-133	barium-133	EPA 901.1M	10.5	Years	0.161	0.161	Yes
Ba-137m	barium-137m	EPA 901.1M	2.552	Minutes	178000	0.0012	Yes
Bi-212	bismuth-212	EPA 901.1M	60.55	Minutes	22400	0.5	Yes
Bi-214	bismuth-214	EPA 901.1M	19.9	Minutes	8190	0.5	Yes
Cd-113m	cadmium-113m	EPA 901.1M	14.1	Years	0.00526	TBD	TBD
Cf-249	californium-249	EPA 901.1M	351	Years	0.0613	0.0613	Yes
Co-60	cobalt-60	EPA 901.1M	5.275	Years	0.000901	0.000901	Yes
Cm-245	curium-245	EPA 901.1M	8,500	Years	0.0922	0.0922	Yes
Cm-246	curium-246	EPA 901.1M	4,760	Years	0.129	0.0922	Yes
Cs-134	cesium-134	EPA 901.1M	2.0652	Years	0.00747	0.0075	Yes
Cs-137	cesium-137	EPA 901.1M	30.08	Years	0.0012 (+D)	0.0012	Yes
Eu-152	europium-152	EPA 901.1M	13.537	Years	0.0376	0.0376	Yes
Eu-154	europium-154	EPA 901.1M	8.593	Years	0.0472	0.0472	Yes
Eu-155	europium-155	EPA 901.1M	4.753	Years	3.74	1.0	Yes
Ho-166m	holmium-166m	EPA 901.1M	1,230	Years	0.011	0.011	Yes
I-129	iodine-129	EPA 902.0M, 901.1M	1.57E+07	Years	0.0000276	1.0	No
K-40	potassium-40	EPA 901.1M	1.248E+09	Years	0.0445	0.0445	Yes
Na-22	sodium-22	EPA 901.1M	2.6027	Years	0.0852	0.0852	Yes

Table 1.9 (continued)
Radionuclides Used to Determine RBRA Background Concentrations

Symbol	Radionuclide	Pace Confirmed Method	Half-Life	Units	Ag PRG (pCi/g)	PASI MDC (pCi/g)	Ag PRG Met?
Nb-94	niobium-94	EPA 901.1M	2.03E+04	Years	0.0115	0.0115	Yes
Np-236	neptunium-236	EPA 901.1M	1.53E+05	Years	0.00281	0.333	No
Np-239	neptunium-239	EPA 901.1M	2.356	Days	22.6	20	Yes
Pa-231	protactinium-231	EPA 901.1M	32,760	Years	0.21	0.21	Yes
Pb-212	lead-212	EPA 901.1M	10.64	Days	80	0.5	Yes
Pb-214	lead-214	EPA 901.1M	26.8	Minutes	34900	0.5	Yes
Ra-226	radium-226	EPA 901.1M	1,600	Years	0.000632 (+D)	0.01	No
Ra-228	radium-228	EPA 901.1M	5.75	Years	0.00116 (+D)	0.01	No
Rn-220	radon-220	EPA 901.1M	55.6	Seconds	774000000	0.5	Yes
Rn-222	radon-222	EPA 901.1M	3.8235	Days	127000 (+D)	0.5	Yes
Sb-125	antimony-125	EPA 901.1M	2.7586	Years	0.46 (+D)	0.46	Yes
Sn-126	tin-126	EPA 901.1M	2.30E+05	Years	0.711	0.711	Yes
Te-125m	tellurium-125m	EPA 901.1M	57.40	Days	32	TBD	TBD
Th-231	thorium-231	EPA 901.1M	25.52	Hours	3310	100	Yes
Th-234	thorium-234	EPA 901.1M	24.1	Days	15.3	1.0	Yes
Tl-208	thallium-208	EPA 901.1M	3.053	Minutes	22600	0.5	Yes
Tm-171	thulium-171	EPA 901.1M	1.92	Years	1250	TBD	TBD
Liquid Scintillation							
C-14	carbon-14	RJ Harvey Inst. Method	5,700	Years	0.0000563	10	No
Fe-55	iron-55	HASL Fe-01-RC Modified	2.737	Years	0.821	10	No
H-3	tritium (hydrogen-3), organic	RJ Harvey Inst. Method	12.32	Years	0.16	0.16	Yes
Ni-59	nickel-59	DOE RESL Ni-1M	76,000	Years	2.15	2.15	Yes
Ni-63	nickel-63	DOE RESL Ni-1M	100.1	Years	1.01	1.01	Yes
Pu-241	plutonium-241	HASL Pu-11-RC Modified	14.290	Years	1.05	1.05	Yes
Tc-99	technetium-99	Eichrom TCS01 Modified	211,100	Years	0.00557	0.1	No

Table 1.9 (continued)
Radionuclides Used to Determine RBRA Background Concentrations

Symbol	Radionuclide	Pace Confirmed Method	Half-Life	Units	Ag PRG (pCi/g)	PASI MDC (pCi/g)	Ag PRG Met?
Removed from Program							
Be-10	beryllium-10	No method available	1.51E+06	Years	11.6	Removed	
Cd-113	cadmium-113	No method available	7.7E+15	Years	0.0028	Removed	
Cs-135	cesium-135	No method available	2.3E+06	Years	0.00509	Removed	
Gd-152	gadolinium-152	No method available	1.08E+14	Years	4.8	Removed	
In-115	indium-115	No method available	4.41E+14	Years	4.14	Removed	
Mo-93	molybdenum-93	No method available	4000	Years	1.05	Removed	
Nb-93m	niobium-93m	No method available	16.13	Years	137	Removed	
Pb-205	lead-205	No method available	1.73E+07	Years	0.153	Removed	
Pd-107	palladium-107	No method available	6.50E+06	Years	24	Removed	
Sm-146	samarium-146	No method available	1.03E+08	Years	3.57	Removed	
Sm-147	samarium-147	No method available	1.06E+11	Years	3.93	Removed	
Sm-151	samarium-151	No method available	90	Years	242	Removed	
Sn-121	tin-121	No method available	27.03	Hours	613000	Removed	
Sn-121m	tin-121m	No method available	43.9	Years	41.4	Removed	
Zr-93	zirconium-93	No method available	1.53E+06	Years	200	Removed	
To Be Determined							
Cl-36	chlorine-36	TBD	3.01E+05	Years	0.0102	TBD	TBD
Pm-147	promethium-147	TBD	2.6234	Years	669	TBD	TBD
Se-79	selenium-79	TBD	2.95E+05	Years	0.132	TBD	TBD

Ag = Agricultural
(+D) = PRG calculated for target isotope plus additional daughters
PASI = Pace Analytical Services, Inc.
MDC = minimum detectable concentration
pCi/g = picocuries per gram
PRG = Preliminary Remediation Goal
TBD = To Be Determined
(1) Radionuclides determined by gamma spectroscopy will be reported with an applicable MDC. However, additional radionuclides will be reported if detected and identified with or without an applicable MDC.

Table 1.10
Decision Inputs for Determination of Potential Impact to RBRAs

Information Needed	Information Source
Identification of 40 suitable DTLs	DTLs were selected based on the following criteria: • Distance from SSFL is greater than 10 miles; • Evenly distributed areas in all directions surrounding SSFL (10 in each compass quadrant); • No obvious industrial facility with radioactive materials nearby; • Long-term average precipitation is similar to the SSFL (within 10%); • Access is obtainable; • No indication of human activities; • Minimal evidence of animal disturbance; • Minimal evidence of erosion; and • Minimally shielded by heavy vegetation.
Identification of suitable RBRAs	RBRAs were selected based on the following criteria: • Distance from SSFL; • Site elevation; • Size of area; • Direction from SSFL; • Chatsworth or Santa Susana formation; • Access is obtainable; • Site be easily cleared for grid spacing, surveying, and sampling; • Physically accessible to get equipment to area; • Minimally shielded by surrounding mountains; • Minimally shielded by heavy vegetation; • No indication of human activities; • Sufficient depth of soil; • Minimal evidence of animal disturbance; • Minimal presence of protected animal or plants; and • Minimal evidence of erosion.
Identification of Study Radionuclides	Criteria for selection of radionuclides: • Fallout constituent; • Not naturally occurring; • Half-life greater than 1 year; and • MDA requirement is achievable.
Gross gamma count rate survey measurements to determine the homogeneity of each DTL sampling location.	Gross gamma count rate surface soil survey of each DTL sampling location. A 3-inch x 3-inch sodium iodide gamma scintillation detector will be used for the gross count rate survey.
Surface soil samples and analytical results.	One surface soil sample will be collected from 0 to an approximate 6 inch depth at each of 24 DTLs; 20 of the 24 samples will be submitted for analysis and 4 of will be reserved (see Section 1.5.5.7.1 for further details). Analytical results should be adequate to describe the range of concentration of regional background radioactivity in the surface soil.

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Table 1.11
Individual Radionuclide Data Set Decision Rules for Determination of Potential Impact to Radiological Background Reference Areas

Parameter/Item of Interest	Investigation Level	IF	THEN
Sample Population Distribution	Sample distribution is **NOT** a Normal Distribution	Deviation from Normal Distribution identified	Test for Log-normality[1]
	Sample distribution is **NOT** a Log-normal distribution	Deviation from Log-normal distribution identified	Identify distribution as non-parametric
Data Outliers	Identification of data outliers	Outliers are identified	Exclude outlier data
Useful Sample Size (less excluded data)	NA	NA[2]	NA[2]
Mean (μ)	RBRA data set is within DTL concentration range (as appropriate for normal distribution)	RBRA mean is greater than DTL mean	Investigate (perform statistical test per Table 1.13) **AND** adequately explain
		An adequate explanation is **NOT** possible	Review sampling design and determine next steps with stakeholders
Median (M)	RBRA data set is within DTL concentration range (as appropriate for normal distribution)	Sample median is greater than regional median	Investigate (perform statistical test per Table 1.13) **AND** adequately explain
		An adequate explanation is **NOT** possible	Review sampling design and determine next steps with stakeholders
Substantial Difference (S)	Sufficiently large difference in sample means or medians to warrant additional interest	Means: $\mu_1 - \mu_2 > S$ Medians: $M_1 - M_2 > S$	Sample populations means/medians are substantially different
Minimum Detectable Difference (MDD) [MMD ≈ Δ of MARSSIM – width of gray region]	Smallest resolvable difference in means/medians that statistical test can resolve	$\mu_1 - \mu_2 \leq$ MDD $M_1 - M_2 \leq$ MDD	Statistical test is not conclusive
Standard Error	NA	NA[2]	NA[2]
Background Threshold Value (BTV)	NA	NA[2]	NA[2]

Table 1.11 (continued)
Individual Radionuclide Data Set Decision Rules for Determination of Potential Impact to Radiological Background Reference Areas

Parameter/Item of Interest	Investigation Level	IF	THEN
95% Upper Confidence Level	NA	NA[(2)]	NA[(2)]
Maximum	NA	NA[(2)]	NA[(2)]
Minimum	NA	NA[(2)]	NA[(2)]
25th Percentile	NA	NA[(2)]	NA[(2)]
75th Percentile	NA	NA[(2)]	NA[(2)]
Skewness	NA	NA[(2)]	NA[(2)]
Kurtosis	NA	NA[(2)]	NA[(2)]

[(1)] The statistical approach in Appendix A identifies limitations on the usability of evaluating data sets as log-normal distributions; tests will be applied to data sets that do not show normal distribution to determine if data sets show a gamma distribution.
[(2)] NA refers to the applicability of an IF and THEN statement.

Table 1.12
Data Set Decision Rules for Determination of Potential Impact to Radiological Background Reference Areas

Parameter/Item of Interest	IF	THEN
Physical, chemical, geological, and biological characteristics of the sampled media should be similar	Characteristics are reasonably similar	Proceed with comparison of data sets evaluation. **OTHERWISE**, do not compare data sets.
Equivalence of Sample Variances and Means/Medians in RBRA and DTL Data Sets	Determine the distribution characteristics of the RBRA and DTL data sets	Perform statistical comparisons of the data sets appropriate for the distribution characteristics in accordance with Appendix A.
Comparison of the RBRA mean to the DTL range (minimum to maximum)	The RBRA mean falls within the DTL range	The RBRA is considered non-impacted.

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Table 1.13
Radionuclides Used to Determine Potential Impact on Radiological Background Reference Areas

Radionuclide	Method	Half-life (years)	Best MDA (pCi/g)	Agricultural PRG (pCi/g)
Cobalt-60 (Co^{60})	Gamma spectroscopy [1]	5.27	0.000901	0.000901
Strontium-90 (Sr^{90})	Leach and beta counting	28.8	0.00139	0.00139
Cesium-137 (Cs^{137})	Gamma spectroscopy [1]	30.1	0.0012	0.0012 [1]
Plutonium-238 (Pu^{238})	Alpha spectroscopy	87.7	0.00731	0.00731
Plutonium-239 (Pu^{239})	Alpha spectroscopy	24,110	0.00609	0.00609
Plutonium-240 (Pu^{240})	Alpha spectroscopy	6,563	0.00609	0.0061

[1] The PRG listed for "Cs-137 and daughters" is presented in this table.

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Table 1.14
General Laboratory Quality Control Procedures for Radiological Methods

QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Validator Qualification Criteria [1]
Initial calibration	Initial calibration prior to sample analysis.	Method-specific criteria presented in MARLAP Section 18.5.6.	Bring system back under control; recalibrate as required by analytical method and instrument manufacturer instructions.	Validator judgment; J or R for detected results and UJ or R for non-detected results.
Background	At the method-specific frequency presented in MARLAP Section 18.5.6.	Method-specific criteria presented in MARLAP Section 18.5.6.	Bring system back under control; recalibrate as required by analytical method and instrument manufacturer instructions.	Validator judgment; J or R for detected results and UJ or R for non-detected results.
Continuing calibration verification	At the method-specific frequency presented in MARLAP Section 18.5.6; at minimum, daily prior to sample analysis.	Within $\pm 3\ \sigma$ or 3% of the expected value of the control chart (as required by method).	Recount; if still out of tolerance, correct problem and then repeat initial calibration. If in control, recount again. If in control a second time, proceed with analysis, otherwise, treat as a failure.	Validator judgment; J or R for detected results and UJ or R for non-detected results.

Table 1.14 (continued)
General Laboratory Quality Control Procedures for Radiological Methods

QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Validator Qualification Criteria [1]
LCS for all analytes	One per preparation batch	Z between −1.96 and +1.96 OR %R within recovery acceptance limits.	Correct problem then reanalyze the LCS; if the LCS is still out of tolerance, re-prepare and reanalyze the LCS and all samples in the affected batch.	For all affected analytes in associated samples: If Z > 1.96, qualify affected detected results K. If Z > 2.58, examine other QC elements to determine if detected results require qualification of R If Z < −1.96, qualify detected results L and non-detected results UL. If Z < −2.58, examine other QC elements to determine if detected results require qualification of R; qualify non-detected results R. OR If %R > UCL, qualify affected detected results K. If %R < LCL, qualify detected results L and non-detected results UL. If %R < LCL by more than 20 percentage points, qualify detected results L and non-detected results R.
LCSD for all analytes	At laboratory's discretion, one per preparation batch	Same as LCS, plus LCS/LCSD precision meeting laboratory acceptance criteria.	Same as LCS.	Same as LCS. If LCS/LCSD precision criteria not met, qualify affected detected results K.

Table 1.14 (continued)
General Laboratory Quality Control Procedures for Radiological Methods

QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Validator Qualification Criteria [1]
Laboratory duplicate	One per preparation batch	$\lvert Z \rvert < 1.96$	Correct problem then reanalyze the laboratory duplicate; if the laboratory duplicate is still out of tolerance, re-prepare and reanalyze the laboratory duplicate and all samples in the affected batch.	For all affected analytes in associated samples: If $\lvert Z \rvert > 1.96$, qualify detected results J and non-detected results UJ. If $\lvert Z \rvert > 2.58$, examine other QC elements to determine if results require qualification of R. [Note, qualification criteria also apply to field duplicate results; see Table 1.7]

Table 1.14 (continued)
General Laboratory Quality Control Procedures for Radiological Methods

QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Validator Qualification Criteria [1]
MS/MSD	One per preparation batch	Z between −1.96 and +1.96 OR %R within recovery acceptance limits.	Correct problem then reanalyze the MS/MMSD; if still out of tolerance, re-prepare and reanalyze the MS/MSD and all samples in the affected batch.	For all affected analytes in associated samples with similar matrix properties: If Z > 1.96, qualify affected detected results K. If Z > 2.58, examine other QC elements to determine if detected results require qualification of R. If Z < −1.96, qualify detected results L and non-detected results UL. If Z < −2.58, examine other QC elements to determine if detected results require qualification of R; qualify non-detected results R. OR If %R > UCL, qualify affected detected results K. If %R < LCL, qualify detected results L and non-detected results UL. If %R < LCL by more than 20 percentage points, qualify detected results L and non-detected results R. In both cases, MS/MSD precision criteria not met, qualify affected detected results K.

Table 1.14 (continued)
General Laboratory Quality Control Procedures for Radiological Methods

QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Validator Qualification Criteria [1]
Method blank	One per preparation batch	Positive blank results: $Z_{blank} < 2.58$ [Z_{blank} = concentration/TPU]	Calculate Z_{DER} for each affected analyte in each associated sample. If $Z_{DER} < 2.58$, correct problem then re-prepare and reanalyze the method blank and all associated samples with affected analyte detections.	For affected analytes in associated samples: If $Z_{DER} > 2.58$, no qualification required. If $Z_{DER} < 2.58$, qualify affected detected results K. If $Z_{DER} < 1.96$, qualify affected detected results B.
		Negative blank results: $\lvert Z_{blank} \rvert < 2.58$	Calculate Z_{DER} for each affected analyte in each associated sample. If $Z_{DER} < 2.58$, correct problem then re-prepare and reanalyze the method blank and all associated samples with affected analyte detections.	For affected analytes in associated samples: If $Z_{DER} > 2.58$, no qualification required. If $Z_{DER} < 2.58$, qualify affected detected results L and affected non-detected results UL. If $Z_{DER} < 1.96$, qualify affected detected results L and affected non-detected results R.
Chemical yield	Each sample, as required by individual analytical methods	Chemical yield within laboratory control limits (as established by control charts), but not less than 40% for methods that employ a stable carrier or 20% for methods that employ a radioactive tracer (provided that the 1S counting uncertainty does not exceed 5% (400 counts).	Examine system and evaluate whether it is in control; correct any system problems and reanalyze affected samples.	For affected analytes in each sample: If the yield is above the upper limit, qualify detected results L and non-detected results UL. If the yield is below the lower limit, qualify detected results K. If the yield is grossly above or below the control range, evaluate the data to determine if affected results require qualification of R.

Table 1.14 (continued)
General Laboratory Quality Control Procedures for Radiological Methods

QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Validator Qualification Criteria [1]
		1S counting uncertainty < 5% (400 counts) for radioactive tracers.	Examine system and evaluate whether it is in control; correct any system problems and reanalyze affected samples.	1σ CU in radioactive tracer <5%, Validator Qualification Criteria: If the result is greater than the 2σ total propagated uncertainty, qualify J. If the result is less than the 2σ total propagated uncertainty, qualify UJ.
Analyte quantitation	NA	None	None	If a result is reported greater than 2S total propagated uncertainty but less than the MDA, consider the result detected, qualify J; if a result is reported less than 2S total propagated uncertainty, qualify U.
Negative results	None	No analytes with absolute value of negative result greater than 2S counting error.	Reanalyze sample, evaluate system for negative drift or problems with background correction.	For affected analytes in each sample: If the absolute value is between the 2S and 3S total propagated uncertainty, UL. If the absolute value is greater than 3S total propagated uncertainty, qualify R.

[1] When more than one qualifier is applicable to a sample result, the priority of qualifiers for detected results is: X > R > B > J > K or L >no qualifier; a result with both a K and L applied will have a final qualifier of J; the priority of qualifiers for results considered non-detected is: X > R > UJ > UL > U.
Note: LCSs will be processed and counted to yield the same target MDCs as in associated environmental samples in order to minimize uncertainty in these QC samples and provide appropriately rigorous control.

Table 1.15
Definitions of Data Validation Qualifiers

QUALIFIER	DEFINITION
No qualifier	Confirmed identification. The analyte was positively identified at the reported value. The reported concentration is within the calibrated range of the instrument and the result is not affected by any deficiencies in the associated QC criteria.
B	Analyte present, but not detected substantially above the level reported in laboratory or field blanks.
J	The analyte was detected at the reported concentration; the quantitation is an estimate.
K	Analyte present. Reported value may be biased high. Actual value is expected to be lower.
L	Analyte present. Reported value may be biased low. Actual value is expected to be higher.
R	The result is rejected due to serious deficiencies in the ability to analyze the sample and meet QC criteria.
U	Not considered detected. The associated number is the reported concentration.
UJ	Not considered detected. The associated number is the reported concentration, which may be inaccurate.
UL	Not considered detected. The associated number is the reported concentration, which may be inaccurate due to a low bias.
X	Excluded. The data point is associated with reanalyses or diluted analyses and is excluded because another result has been selected as the definitive result for the analyte.

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Table 2.1
Summary of Sample Containers, Preservation Techniques, Sample Volumes, and Holding Time Requirements

Analyte Group	Container	Minimum Sample Size	Preservative	Holding Time
C-14, H-3, Cl-36, I-129, and Tc-99 (soil)	4 oz jar	4 oz [1]	None	None
Other radiological Parameters (soil)	2x1 gal freezer bags (half filled)	2 L [1]	None	None
C-14, H-3, Cl-36, I-129, and Tc-99 (water QC)	1x1 L glass bottle	1 L	None	None
Other Radiological Parameters (water QC)	2x1 L plastic containers	2 L	HNO_3 to pH <2 [2]	None

[1] The soil sample size provided is sufficient to process a single sample for all analyses; generally, an additional aliquot of equal size must be collected for each archive sample associated with the original sample.
[2] Sample pH will be checked in the field to ensure readings are below 2 prior to shipment.

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Table 2.2
Sample Handling System

Sample Collection, Packaging, and Shipment
Sample Collection (Personnel/Organization): Site staff/HGL
Sample Packaging (Personnel/Organization): Site staff/HGL
Coordination of Shipment (Personnel/Organization): Site Supervisor/HGL and Courier Supervisor/Project Laboratories
Type of Shipment/Carrier: Commercial Overnight Delivery Service
Sample Receipt and Analysis
Sample Receipt (Personnel/Organization): Sample Management Staff/Project Laboratories
Sample Custody and Storage (Personnel/Organization): Sample Management Staff/Project Laboratories
Sample Preparation (Personnel/Organization): Sample Preparation Staff; Bench Chemists/Project Laboratories
Sample Determinative Analysis (Personnel/Organization): Bench Chemists/Project Laboratories
Sample Archiving
Field Sample Storage (No. of days from sample collection): Archive volumes of each sample will be retained at the laboratory for two years from collection.
Sample Extract/Digestate Storage (No. of days from extraction/digestion): For 30 days from report release
Biological Sample Storage (No. of days from sample collection): Not applicable
Sample Disposal
Personnel/Organization: Sample management staff/Project Laboratories
Number of Days from Analysis: 30 from report release; archive volumes 2 years from sample collection

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Table 2.3
Field Equipment Calibration, Maintenance, Testing, and Inspection

Field Equipment	Calibration Activity	Maintenance Activity	Testing Activity	Inspection Activity	Frequency	Acceptance Criteria	Corrective Action	Responsible Person	SOP Reference
Gamma Scanning System	Annual	Daily check	Daily QC Check; Daily Background Check	Daily Check	Daily	Source within ±10%; Background within ±10%	Re-test twice, then remove from service	Field Equipment Manager	To Be Determined
Ludlum Model 44-20 Detector and Model 44-62 or 44-2 Detector	Annual by Manufacturer	Daily Check	Daily QC Check; Daily Background Check	Daily Check	Daily	±20% of background and source check	Re-test twice, then remove from service	Field Equipment Manager	SOP #35
Ludlum Model 2221 Ratemeter	Annual by Manufacturer	Daily Check	Daily QC Check; Daily Background Check	Daily Check	Daily	Not Applicable	Not Applicable	Field Equipment Manager	SOP #35

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Table 3.1
Planned Project Assessments

Assessment Type	Frequency	Internal or External	Organization Performing Assessment	Person(s) Responsible for Performing Assessment	Person(s) Responsible for Responding to Assessment Findings	Person(s) Responsible for Identifying and Implementing Corrective Actions (CA)	Person(s) Responsible for Monitoring Effectiveness of CA
Field Audit	Once	Internal	HGL	HGL QA officer	HGL Project Manager	HGL Field Team Leader and Project Manager	HGL QA Officer
Field Audit	At EPA Discretion	External	EPA Region 9	EPA Region 9QA Department	TBD	TBD	TBD (EPA); QA Officer (HGL)
Technical Reviews (Data Verification)	Each Data Report	Internal	HGL	HGL Technical Reviewer, TBD	HGL Project Manager	HGL Project Manager	Technical Reviewer
Data Validation	Each Sampling Event	External	Subcontracted Data Validation Firm, TBD	Data Validator, TBD	Radiological Laboratory Project Manager or HGL Project Manager	Radiological Laboratory Manager or HGL Project Manager	Laboratory Director or HGL Program Manager
Provisionally Rejected Data Summary	After data validation completed and after statistical evaluation completed	Internal	HGL	HGL Project Chemist or HGL QA officer	Region 9 Project Team	HGL Project Manager	Technical Reviewer
Data Quality Assessment	Each Sampling Event	Internal	HGL	HGL Project Chemist	Radiological Laboratory Project Manager or HGL Project Manager	Radiological Laboratory Manager or HGL Project Manager	Laboratory Director or HGL Program Manager

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Table 3.2
Assessment Findings and Corrective Action Responses

Assessment Type	Nature of Deficiencies Documentation	Individual(s) Notified of Findings (Name, Title, Org.)	Contact Information	Timeframe of Notification	Nature of Corrective Action Response Documentation	Individual(s) Receiving Corrective Action Response (Name, Title, Org.)	Contact Information	Timeframe for Response
Field Audit	Written audit report	HGL Project Manager	TBD	5 business days after audit	Memo	HGL QA Officer, TBD	TBD	Field actions immediately implemented, 10 business days to address other concerns in report
Technical Review (Data Verification)	Memo	HGL Project Manager, HGL Project Chemist	TBD	5 business days after report receipt	Memo	HGL Project Manager, HGL Project Chemist	TBD	5 business days
Data Validation	Memo	HGL Project Manager, HGL Project Chemist	TBD	15 business days after report receipt	Memo	HGL Project Manager, HGL Project Chemist	TBD	5 business days
Provisionally Rejected Data Summary	Memo	Region 9 WAM	TBD	10 business days after validation completed and after statistical evaluation completed	Memo	HGL Project Manager	TBD	15 business days
Data Quality Assessment	Report section	HGL Project Manager and QA Officer	TBD	Per project report schedule	Report section	HGL Project Manager and QA Officer	TBD	5 business days

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EXHIBIT 2.1

LABORATORY DATA REPORT REQUIREMENTS

Exhibit 2.1

Laboratory Data Report Requirements

[**Bold** identifies a critical element for data validation]

1. Case Narrative

   Identify the lab, client, project, samples, and methods used. Summarize the analysis, including any unusual or notable events or observations, discussion of QA warnings and excursions, non-conforming events and corrective actions. Include a declaration of adherence to program specs and LQAP requirements, with appropriate signatures.

2. **Reported Sample Results**

   2.1. Lab Name

   2.2. Lab Sample ID

   2.3. Client Sample ID

   2.4. Matrix

   2.5. Analyte Name

   2.6. Reporting Units (e.g., pCi/g)

   2.7. Activity

   2.8. Uncertainty, w/ confidence interval

   2.9. MDC (or CL)

   2.10. Yield (if applicable)

   2.11. Yield Acceptance Criteria (if applicable)

   2.12. Sample Aliquant

   2.13. Aliquant Basis (e.g., dry/as received, filtered/unfiltered)

   2.14. Preparation Batch ID

   2.15. Analysis Batch ID

   2.16. Analysis Date & Time

   2.17. Raw Date File Name (if applicable)

   2.18. Data Qualifying Flags

   2.19. Report Date/Time

3. **QC Sample Results – same elements as above and:**

   3.1. LCS

   3.1.1. Spiking Standard Solution ID

   3.1.2. Spike Volume

3.1.3. Spike Activity Added, with reference date

3.1.4. Spike Recovery

3.1.5. Spike Recovery Acceptance Criteria

3.2. Matrix Spikes (as applicable to methods)

3.2.1. Native Sample ID

3.2.2. Sample (Native) Activity Concentration

3.2.3. Spiking Solution ID

3.2.4. Spike Volume

3.2.5. Spike Activity Added, with reference date

3.2.6. Spike Recovery

3.2.7. Spike Recovery Acceptance Criteria

3.3. Blanks

3.3.1. Requested MDC

3.3.2. Blank Acceptance Criteria

3.4. Duplicates

3.4.1. Native Sample ID

3.4.2. Sample Results (incl. activity, uncertainty, MDC)

3.4.3. Duplicate Results (incl. activity, uncertainty, MDC)

3.4.4. Duplicate Test Results (e.g., DER,NAD,RPD)

3.4.5. Duplicate Acceptance Criteria

4. Sample Gross Preparation Documentation

4.1. Drying Logs

4.2. Oven Temperature Logs

4.3. Grinding Logs

4.4. If appropriate, specify equipment ID, etc

4.5. Analyst ID

4.6. If QC, such as equipment blanks are required for grinding equipment, identify the QC samples, include all results as described for QC samples above.

5. Method Preparation Bench Sheets

5.1. Batch ID

5.2. Preparation Date and Time

5.3. Separation Dates/Times, if applicable to the method

5.4. Analyst ID

5.5. Method/Lab SOP ID

5.6. Sample IDs

5.7. Sample Aliquants

5.8. Spiking/Tracing Solution IDs, volumes

5.9. Pipette and Balance IDs

6. Pipet and Balance Calibration/Verification Logs (for all pipettes and balances used for critical measurements such as sample aliquants and spiking solutions)

6.1. Pipette / Balance ID

6.2. Pipette Setting (for adjustable pipettes)

6.3. Expected (Nominal) Value

6.4. Observed Value

6.5. Acceptance Criteria

6.6. Analyst ID

7. Instrument Raw Data

7.1. Filename

7.2. Instrument ID

7.3. Detector ID (for multiple detector systems)

7.4. Sample ID

7.5. Sample Gross Count Rate (or gross counts acquired)

7.6. Analysis Date and Time (specify count start or count end)

7.7. Count Duration

7.8. Copy of Run Log (must correlate Sample ID, Ct Date & Time, Detector ID)

7.9. As applicable,

7.9.1. Detector operating voltage

7.9.2. Window Settings/Regions of Interest/Analysis Range

7.10. For gamma spec

7.10.1. Compton bkg count rate

7.10.2. Peak background count rate

8. Instrument Calibration (Include all raw data from the calibration, as described above, as well as the following)

8.1. Instrument Operating Voltage Determinations (Plateaus), if applicable

8.2. Instrument ROI/Discriminator Setting Determinations, if applicable

8.3. Background Calibration Count Rate, with Acceptance Criteria

8.4. Efficiency Calibration Coefficients, with Acceptance Criteria

8.5. Energy Calibration Coefficients, if applicable, with Acceptance Criteria

8.6. Peak Resolution Calibration Coefficients, if applicable, with Acceptance Criteria

8.7. Source ID (except for backgrounds)

8.8. For gamma spectrometry, include the analysis library for samples, calibrations, daily performance checks, and any others used for the project.

9. Instrument Calibration Verification Data (Include all raw data from the calibration verification, as described above, as well as the following)

9.1. Calculated Results

9.2. Acceptance Criteria

10. Instrument Performance Checks

10.1. Raw data

10.2. Acceptance Criteria

11. **Standards Traceability Documentation** for all standards used for sample preparation, QC samples, instrument QC and Instrument Calibration.

11.1. Dilution Logs

11.2. NIST (or equivalent) certificates

11.3. Standard Verification data, incl. acceptance criteria and reports

12. Quality Assurance Reports

12.1. QA Summary Notes/Reports

12.2. Non-Conformance Reports w/ Corrective Action and QA Approval

13. Chain of Custody (CoC)

13.1. Sample Condition Report Form (describing condition of samples upon receipt to verify that the integrity of the sample containers, preservation, temperature, hold times, etc. are acceptable).

13.2. External / Field CoC

13.3. Internal CoC (if applicable)

At the lab's discretion, instrument calibration data and other validation elements that do not change from one report to the next may be submitted once, as a stand-alone deliverable, provided that the calibration data package is clearly and uniquely identified and that

subsequent sample data packages clearly reference the corresponding calibration data package in the case narrative, or other appropriate location.

The project will submit the lab's data for external validation. **At the request of the data validator, the lab will furnish any additional information necessary to recalculate the reported results from basic measurement outputs**, within 5 days of the initial request.

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APPENDIX A

STATISTICAL METHODS TO ADDRESS STAKEHOLDERS' CONCERNS AND STATISTICAL ISSUES DESCRIBED IN RADIOLOGICAL BACKGROUND STUDY SAMPLING AND ANALYSIS PLAN FOR SANTA SUSANA FIELD LABORATORY

STATISTICAL METHODS TO ADDRESS STAKEHOLDERS' CONCERNS AND STATISTICAL ISSUES DESCRIBED IN RADIOLOGICAL BACKGROUND STUDY SAMPLING AND ANALYSIS PLAN FOR SANTA SUSANA FIELD LABORATORY

Prepared by
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August 2009

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Statistical Methods to Address Stakeholders' Concerns and Statistical Issues Described in Radiological Background Study Sampling and Analysis Plan for Santa Susana Field Laboratory

This document describes statistical methods that will be used to address stakeholders' concerns as discussed during the April 30, 2009 Radiological Background Study (RBS) meeting held in Chatsworth, California. A brief description of the robust statistical methods is also included in this document to address some specific concerns of Mr. Dan Hirsch raised by him during a conference call held on July 28, 2009. Specifically, this document describes statistical methods which will be used to analyze and evaluate radiological background reference area (RBRA) data sets (from Santa Susana and Chatsworth geological formations) and distance test locations (DTLs) data set collected during the RBS to be conducted for the Santa Susana Field Laboratory (SSFL) Site. As described in the Sampling and Analysis Plan (SAP), 20 surface soil samples from the DTLs; and 50 surface soil and 20 subsurface soil background reference samples will be collected and analyzed from the Santa Susana formation. Two RBRAs will be used from the Chatsworth formation; and 25 surface soil and 10 subsurface soil samples will be collected from each of the two RBRAs from the Chatsworth formation, for a total of 50 surface soil and 20 subsurface soil samples. The RBRA and DTL data sets will be used to compare the concentrations of the radionuclides of concern (RNCs) of the two geological formations with the RNC concentrations of DTLs.

The representativeness of the RBRA data sets from the Chatsworth formation will be established first. Specifically, each of the two RBRA data sets from Chatsworth formation will be compared with the DTL data set separately. The statistical tests as described in Section 1.2 of this document will be used to perform these comparisons. If the two RBRA data sets from the Chatsworth formation represent non-impacted radiological background reference area locations (in comparison with the RNC concentrations of DTLs), statistical tests will be performed to compare the RNC concentrations of the two RBRA data sets collected from the Chatsworth formation. If there are significant differences between the RNC concentrations of the two RBRA data sets, an additional 25 surface and 10 subsurface soil samples will be collected to complete the RBRA data set from the Chatsworth formation at the acceptable RBRA. Once the RBRA data sets from the two formations have been validated and established, statistical tests will be used to compare RNC concentrations of the two formations. Both univariate (one radionuclide at a time) and multivariate (several radionuclides simultaneously) methods supplemented with formal graphical tests and displays will be used to address stakeholders concerns and various other statistical issues of the RBS evaluations as described in the SAP for the SSFL site.

Univariate (analyzing one radionuclide at a time) statistical methods used and described in MARSSIM (2000) and EPA guidance documents (e.g., EPA 1989, EPA 1992, EPA 2002a, EPA 2002b, and EPA 2006) will be used to address statistical issues of the evaluation studies of the RBS. Additionally, robust and resistant (to outliers) and formalized graphical methods will be used to effectively address specific concerns of stakeholders. All statistical analyses for the RBS evaluations as described in the SAP for the SSFL site will be performed using peer-reviewed EPA software packages (developed by Lockheed Martin for ORD, NERL- EPA, Las Vegas, NV): Scout 2008, Version 1.00.01 and ProUCL 4.00.04. These beta tested and peer-reviewed software packages are equipped with most of the statistical methods as described in MARSSIM and other EPA guidance documents listed above. These

software packages offer classical, robust and resistant, and graphical methods to analyze univariate and multivariate (e.g., analyzing multiple radionuclides simultaneously) data sets with and without the nondetect (ND) or below detection limit (BDL) observations. Specifically, univariate two sample parametric t-test, nonparametric Wilcoxon Rank Sum (WRS) or Wilcoxon Mann-Whitney (WMW) test, Quantile test, and Gehan test will be used to compare: RNC concentrations of the two RBRA data sets, and RNC concentrations of RBRA (individually or combined) data sets with the DTL data set. Furthermore, since many contaminants will be analyzed and compared, it is also planned to use multivariate methods to compare concentrations of the multiple radionuclides of the two RBRAs; and of RBRAs (individually or merged) and DTLs.

For verification of results and conclusions, more than one statistical method may be used on the same data set. Most statistical methods and tests will be supplemented with formalized graphical displays. Graphical displays provide added insight (e.g., presence of outliers, data distributions and patterns, mixture populations, visual comparison of two or more groups) into data sets that is not possible to visualize and understand simply by reviewing the estimates and test statistics such as Dixon and Rosner outlier test statistics, upper confidence limits (UCLs), upper tolerance limits (UTLs), upper prediction limit (UPL), t-test and WRS test statistics. Hypotheses testing approaches will be used to compare RBRA and DTL concentrations; upper percentiles, UPLs and/or UTLs will be used to establish background level contaminant concentrations also known as background threshold values (BTVs) or trigger values. Additionally, in order to address stakeholders' concerns, formalized classical and robust graphical displays will be used to compare on-site observations (single, multiple, or entire data set) with the entire RBRA data set (as a comparison to comparing on-site observations with robust upper limits such as upper percentiles, UTLs).

Outliers (if any) will be identified in the original raw scale (non-transformed data set) as the remediation and cleanup decisions need to be made using data and statistics (e.g., averages, prediction limits) in the original scale. Often, the use of a log-transformation tends to hide contamination by accommodating outlying observations (e.g., Singh, Singh, and Engelhardt, 1997, Chapter 7, ProUCL 4.00.04 Tech Guide) as part of the data set. For an example, an outlier in the raw scale may not be an outlier in the transformed space (e.g., log-scale). This does not imply that the outlier (e.g., an elevated RBRA concentration in the original scale) identified in the original scale represents a clean unimpacted location and can be included in the computation of a BTV, estimated by a UPL/UTL. Furthermore, since environmental decisions need be made based upon the values of statistics (e.g., UCL, UPL, t-test, WRS test statistic) in the original scale, all transformed test statistics computed using log-transformation need to be back-transformed in the original scale. The transformation and back-transformation process yields statistics which suffer from an unknown amount of transformation bias. It is also well known (Singh, Singh, and Engelhardt (1997)) that the use of a lognormal distribution often yields unrealistic and unstable values of upper limits such as 95% UCL, 95% UPL, 95%-90th UTLs. Therefore, in order to compute reliable statistics, derive defensible and correct conclusions, the use of lognormal distribution will be avoided, and all statistical tests including outlier tests, two sample hypotheses tests, and estimation of BTVs will be performed in the original raw scale. Some drawbacks and pitfalls of using lognormal distribution are summarized in Appendix D of this document.

Once the data sets become available from RBRAs and DTLs, those data sets will be screened for potential outliers. Outlying observations will not be included in hypotheses testing and estimation of the background level radiological concentrations. The presence of even a few (single, a couple) outliers in a background reference data set can yield distorted/inflated estimates of the BTVs and hypothesis

testing statistics. The use of those distorted/inflated statistics (e.g., upper prediction limit, t-test statistic) may yield incorrect and misleading results and conclusions. Robust statistical methods will be used to identify all potential outliers (e.g., Rousseeuw and van Zomeren (1990); Singh and Nocerino (1995)). A brief description of outlier identification procedures is given in Appendix B. Scout 2008 Version 1.00.01 software will be used to identify potential outliers present in RBRA and DTL data sets.

Statistically rigorous hypotheses testing and estimation methods (and not simple ad hoc substitution methods) will be used on data sets consisting of non-detect (ND) and below detection level (BDL) observations. The details of those methods can be found in ProUCL 4.00.04 Technical Guide (EPA, 2009), Helsel (2005), and Singh, Lee, and Maichle (2006). A brief description of statistical methods to deal with data sets consisting of nondetects is given in Appendix C.

One main disadvantage of using univariate statistical methods on multivariate data sets is that they do not take the potential correlation structure existing among the multiple contaminants (e.g., metals, radionuclides) into account. Moreover, it is hard to control the specified Type I error rate, as an error rate (e.g., = 0.1) is used for each radionuclide, which results in a cumulative error rate (for all analytes combined) much different from the specified error rate of 0.1. Due to some of these reasons, it is always desirable to use multivariate methods (e.g., Johnson and Wichern, 2002) on multivariate (consisting of multiple correlated radionuclides) data sets. The main drawback of multivariate statistical methods is that they are relatively complex to use and proper statistical training in multivariate statistics is required to adequately use them and interpret them. However, the use of multivariate robust methods often produce more accurate results leading to defensible conclusions by minimizing error rates (false positives and false negatives) that are protective of human health and the environment. Whenever applicable and appropriate (and agreed by all concerned parties), it is planned to use multivariate methods to address stakeholders concerns and statistical issues related to RBS evaluations. However, it should be pointed out that univariate methods (widely used and commonly accepted) will be used to address all statistical issues and concerns, and multivariate methods will be used to supplement and verify the results/conclusions derived using univariate methods.

1.0 Evaluations Based Upon Univariate Methods

Univariate methods that will be used to address stakeholders concerns and to analyze RBRAs and DTL data sets collected during RBS evaluations are briefly described in this section.

1.1 Goodness-of-Fit Tests to Evaluate Data Distributions

Before using parametric statistical methods on data sets generated during the RBS, normality of data sets will be assessed using Shapiro-Wilk (S-W) and Lilliefors goodness-of-fit (GOF) tests. Anderson-Darling and Kolmogorov-Smirnov GOF tests will be used to determine if a data set follows a gamma distribution, a statistical probability model. A gamma distribution is better (than lognormal distribution) suited to model positively skewed data sets originating from environmental applications (Singh, Singh, and Iaci, 2002). Another advantage of using a gamma distribution is that the gamma model can be used on the original untransformed data sets. Depending upon the data distribution, the Gamma distribution may be used to estimate BTVs. All of these GOF tests are available in EPA software packages: ProUCL 4.00.04 and Scout 2008.

1.2 Establishing Radiological Background Reference Area (RBRA) Data Sets

Three RBRA (one from the Santa Susana formation and two from the Chatsworth formation) data sets will be collected. The two RBRA data sets from the Chatsworth formation will be considered as coming from a single Chatsworth reference area population. In other words, the two RBRA data sets from the Chatsworth formation will be combined together to make a single Chatsworth RBRA data set. However, if deemed necessary, the RNC concentrations of the two Chatsworth RBRAs can also be compared using the statistical methods as described in this document.

In order to verify that the three RBRAs are not impacted by the site activities, a radiological background data set will be obtained from DTLs, over 10 miles away from the SSFL site. The main objective of this evaluation is to establish representative and defensible RBRA data sets unimpacted by the site activities. Univariate two sample hypotheses testing approaches (e.g., t-test, WRS test) supplemented with graphical displays (e.g., side-by-side boxplots, multiple Q-Q plots, histograms, formal control-chart-type graphical displays) will be used to address this objective. Background module of ProUCL 4.00.04 will be used to address some of these objectives. A brief description of the Background module of ProUCL 4.00.04 is given in Appendix A.

The following two sample parametric and nonparametric hypotheses tests (supplemented with graphical displays) will be used to compare RNC concentrations of the two RBRAs with DTL RNC concentrations; and also to compare RNC concentrations of the two RBRAs collected from Santa Susana and Chatsworth formations

***Two Sample Parametric Student's t-Test*:** This test will be used when the RBRA data sets and DTL data set all follow normal distributions, and no nondetects are present in either of the two RBRA data sets and DTL data set**.** Normality of a data set will be tested using Shapiro-Wilk (S-W) test and/or Lilliefors GOF test supplemented with a normal Q-Q plot.

Due to the reasons described above (and described in Appendix D), no attempt will be made to use log-transformation (or some other transformation) to achieve normality of the two RBRA data sets and

DTL data set. If all of the data sets do not follow normal distributions, nonparametric approaches supplemented with graphical displays will be used. The use of graphical displays (e.g., boxplots, multiple Q-Q plots (EPA 2002a), and histograms) will provide added insight about the data distributions (e.g., skewness, tails, outliers) of the RNCs from the three RBRAs and DTLs.

Two Sample Nonparametric WRS (equivalently WMW) Test: When at least one of the RBRA data sets and/or DTL data set for a certain RNC do not follow normal distributions, WRS (WMW) test will be used to compare the concentrations of RNCs of the two RBRAs; and also to compare RNC concentrations of RBRA versus DTL. This test will also be used when RBRA data sets and/or DTL data set consist of BDL observations with a single reporting limit or detection limit (DL). No ad hoc substitution methods such as replacing NDs by DL/2, DL, or estimates obtained using regression on order statistics (ROS) methods will be used in hypotheses testing process.

Two Sample Nonparametric Quantile Test: Since WRS test compares the medians (and not the mean) of two populations (e.g., two RBRAs, DTL versus RBRAs), Quantile test will also be used to compare the distributions (tails) of two RBRA data sets (e.g., EPA 2006), and to compare the distributions of RBRAs and DTLs. In other words, for defensible conclusions, both WRS test and the Quantile test will be used on the same data sets to properly determine the potential differences between the distributions of two populations (e.g., RBRA versus RBRA, and RBRA versus DTL). Concentrations of a RNC at the two formations will be considered statistically similar (comparable) if both tests lead to the conclusion that RNC concentrations of the two data sets are comparable (null hypothesis not rejected).

Two Sample Nonparametric Gehan Test: This test is used when data sets consist of BDL observations with multiple reporting or detection limits (DLs). Again, no ad hoc substitution methods such as replacing NDs by DL/2, DL, or estimates obtained using ROS method will be used in hypotheses testing process.

1.2.1 Comparing RBRA RNC Concentrations with DTL RNC Concentrations

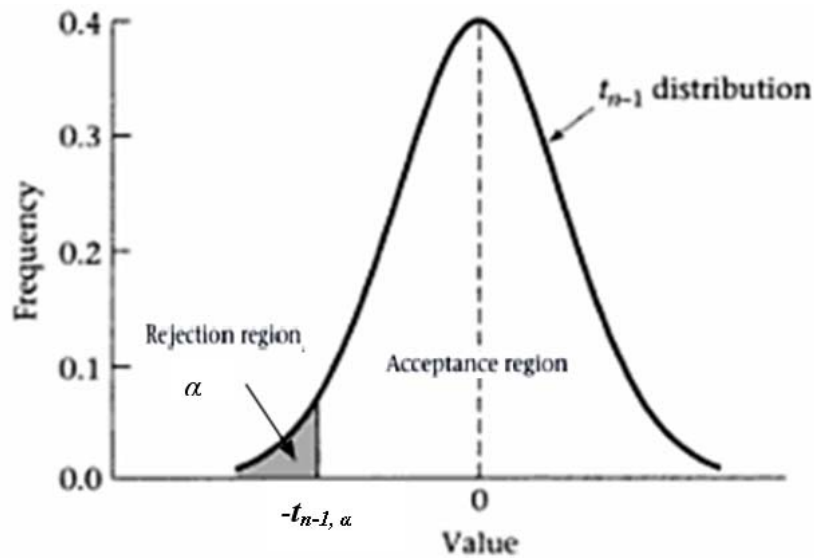
First, it will be determined if any of the three RBRAs (Santa Susana and Chatsworth) are impacted by the site activities. Univariate two sample hypothesis testing approaches (e.g., WRS test, t-test) described above will be used to compare RNC concentrations of each of the three RBRAs with those of the DTL. Background Hypothesis Test Form 2 (EPA, 2002a, ProUCL 4.00.04) will be used to compare concentrations of RBRAs versus DTLs. These statistical comparisons will be performed separately for each of the two RBRAs.

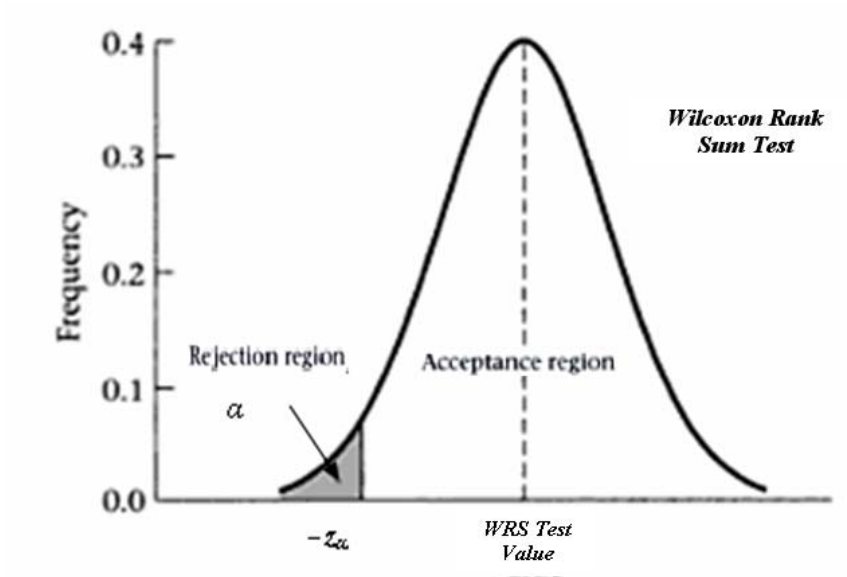
Let μ_1 represent the mean/median of a certain radionuclide at a RBRA (e.g., Santa Susana Formation), and μ_2 be the mean/median concentration of the same radionuclide at DTLs. The following null and alternative hypotheses will be considered. The allowable Type I (α) and Type II (β) errors can both be fixed at 0.1. If deemed necessary, other levels of false positive and false negatives error rates may also be considered. Background Form 2 (with substantial difference, S=0) null and alternative (left- sided, left -tailed) hypotheses are defined as follows.

1.2.1.1 Form 2 Background Hypothesis with Substantial Difference, S=0

Null Hypothesis, H_0: Mean/median, $\mu_1 \geq$ Mean/median, μ_2, versus the left-tailed (sided) Alternative hypothesis, H_1: Mean/median, $\mu_1 <$ Mean/median, μ_2

Based upon the collected data, the null hypothesis will be tested against the left-sided alternative hypothesis. These hypotheses will be tested for each RNC. Depending upon the level of significance, α (Type I error rate), and the test statistic used (e.g., t-test, WRS test), an acceptance region and a rejection region (left-tailed) for the null hypothesis will be established. For specified level of significance, α, the acceptance and rejection regions are graphically shown in the following figures for t-test and WRS test.





The conclusion regarding the acceptance or rejection of the null hypothesis is based upon the value of the test statistic (e.g., WRS test value) lying within the acceptance region or rejection region represented by intervals (and not by a single point) as shown in the above figures. If the value of the test statistic (e.g., t-test, or WRS test) falls within the acceptance region, the null hypothesis that the

mean/median concentration of a RNC at that RBRA is greater than or equal to the mean/median concentration of that RNC at DTL will be accepted, otherwise the null hypothesis will be rejected. This conclusion may also be supplemented with graphical displays such as side-by-side boxplots and Q-Q plots for further clarification and verification.

1.2.1.2 Form 2 Background Hypothesis with Substantial Difference, S > 0

Moreover, in order to determine the degree of separation between the RNC concentrations of RBRA and DTL, if deemed necessary, Form 2 Background Hypothesis with substantial difference, $S>0$ may also be used (EPA, 2002a). The appropriate values of substantial differences, S associated with various RNCs will be determined by site and radiological experts; and all parties involved such as the project management, regulators, and stakeholders. Form 2 null and alternative hypotheses are stated as follows.

Null Hypothesis, H_0: Mean/median, $\mu_1 \geq$ Mean/median, $\mu_2 + S$, versus the left-tailed (sided) Alternative hypothesis, H_1: Mean/median, $\mu_1 <$ Mean/median, $\mu_2 + S$, where $S>0$

Same statistical approaches and tests (e.g., t-test, WRS test) as described above (when $S=0$) will be used to perform Background Form 2 hypotheses with substantial difference, $S>0$. ProUCL 4.00.04 will be used to perform these hypotheses tests.

1.2.1.3 Conclusions of RBRA versus DTL RNC Concentration Comparisons

Based upon the hypotheses test statistics and associated graphical displays, if it is concluded that the concentrations of RNCs at RBRAs are not higher than those found at DTLs (Form 2 null hypothesis rejected based upon sampled data), then it would be concluded that the three RBRAs are not impacted by the site activities. The three data sets (two from Chatsworth and one from Santa Susana) consisting of unimpacted locations exhibiting concentrations comparable (not statistically significantly different) to DTL concentrations.

However, if any of the RBRAs exhibits concentrations higher than those of the DTLs (Form 2 null hypothesis not rejected), then it would be concluded that the RBRA (s) is impacted by the site activities. The RBRAs locations exhibiting RNC concentrations higher than the RNC concentrations of DTLs will be identified using formal graphical displays as described in this document. Those potentially impacted RBRA locations will not be included in establishing radiological background reference data sets for the SSFL site. It should be noted that the RBRA locations exhibiting concentrations higher than those of the DTLs can be identified using formal graphical displays as used in Examples 1 and 2 below (e.g., Figure3 and Figure4) of Section 1.2.1.4.

1.2.1.4 Graphical Comparisons of RNC Concentrations: RBRA versus DTL

In addition to statistical two sample tests described above, formal graphical Control-Chart-Type displays will also be used to compare individual observations (e.g., single or multiple on-site observations) with the entire data set (and not the average, or some upper limit of the RBRA data set). These graphical displays will be helpful to address specific concerns of stakeholders as discussed during April 30th meeting and in a conference call held on July 28th, 2009. The QA/QC module of

Scout 2008 offers both univariate and multivariate formal graphical tests to compare individual (single or multiple) observations of one group (e.g., RBRA, on-site, test set) with all observations of another group (e.g., DTL, background, training set). A couple of examples illustrating these issues are discussed next.

Example 1. A three-dimensional (lead, manganese, iron) real data set consisting of on-site and offsite background concentration data from a Superfund site has been considered to illustrate the use of graphical methods to perform comparisons of two or more groups. This data set is used again in Example 8 of Section 2 dealing with multivariate methods. Simple side-by-side boxplots and multiple Q-Q plots (EPA, 2002a) for background lead ("Lead (1)") and on-site lead ("Lead (2)") concentrations are respectively given in Figures 1 and 2.

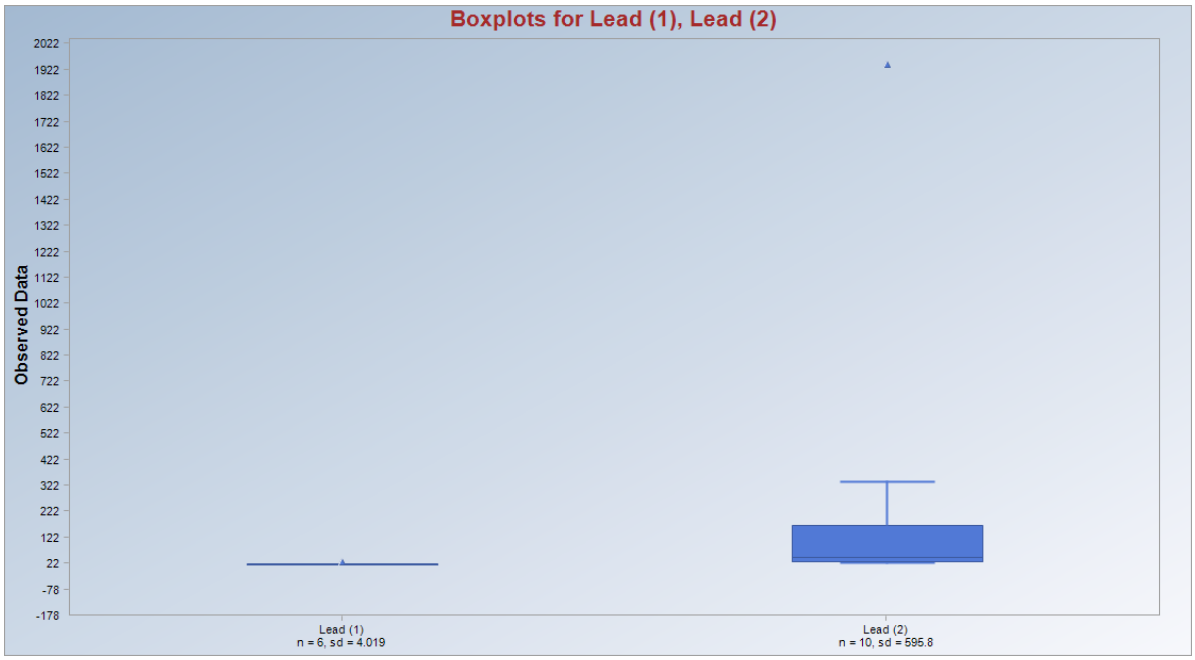


Figure 1. Side-by-side Boxplots Comparing On-site and Background Lead Concentrations

A quick look at the boxplots for lead shown in Figure1 suggests that the on-site "Lead (2)" concentrations are significantly higher than the "Lead (1)" concentrations found at background locations. A similar conclusion that on-site lead concentrations are higher than background lead concentrations can be derived from the multiple Q-Q plot graph shown in Figure 2. It should be noted that univariate two sample t-test and WRS test (results not included in this report), and graphical displays, all lead to the conclusion that the lead concentrations of the two groups (populations) are significantly different, and on-site lead concentrations are significantly higher than the background lead concentrations. Since three analytes (lead, manganese, and iron) are present in the data set, univariate analyses will be conducted for each of the three contaminants separately.

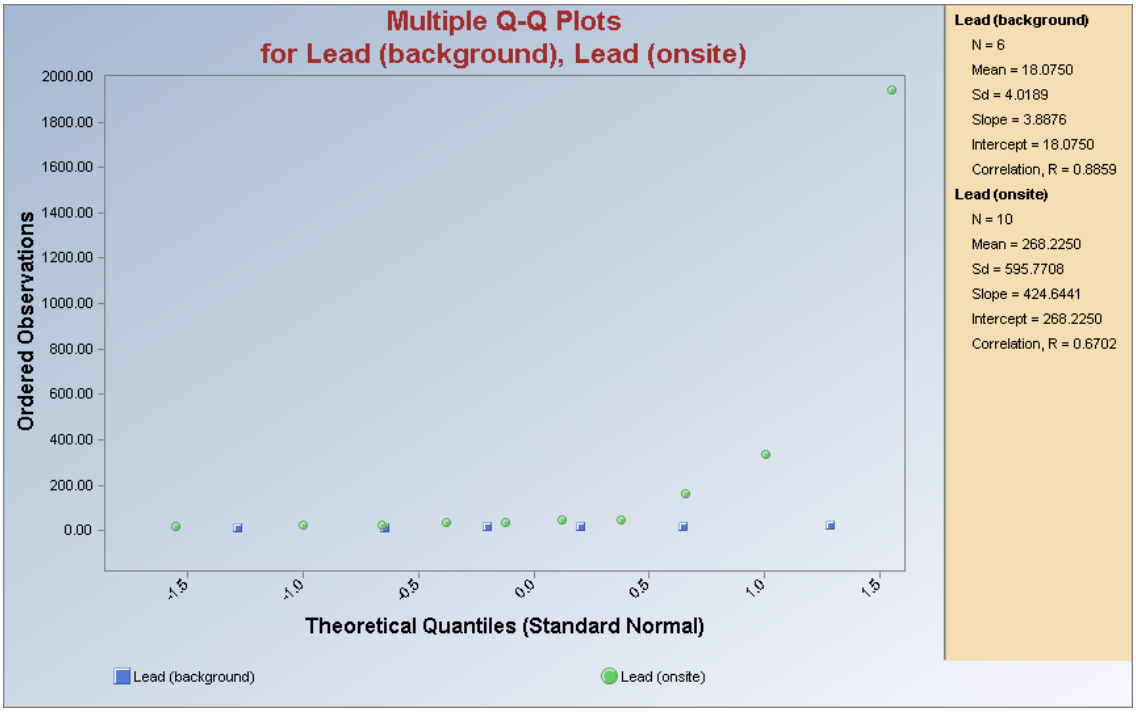


Figure 2. Multiple Q-Q Plots Comparing On-site and Background Lead Concentrations

Next, on-site and background manganese concentrations are being compared using the following *formal* graphical display.

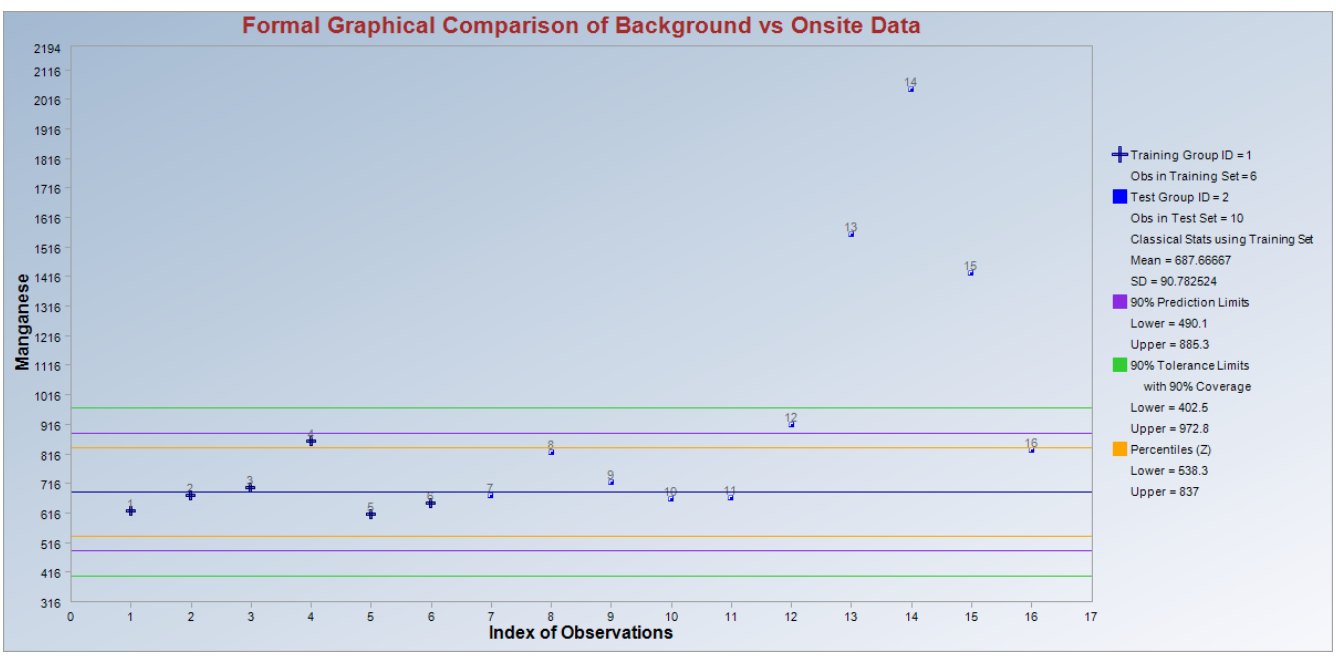


Figure 3. Formal Graphical Test to Compare Manganese Concentrations of Two Populations

From Figure 3, one can easily determine that the concentrations of the two groups (background data

denoted by bold '+', and on-site data denoted by 'square') are significantly different. Additionally, the graphical display shown in Figure 3 identifies on-site contaminated (e.g., # 13, 14, and 15) locations, which a typical test statistic such as t-test or WRS test cannot identify.

Example 2. The graphical tests can also be used to compare two data sets (e.g., on-site versus background) consisting of ND observations. A four (4) dimensional data set consisting of four analytes has been considered. The NDs are shown in red (Figure4). Using univariate methods, four different comparison graphs will be generated. One of those graphs is shown in the following Figure 4.

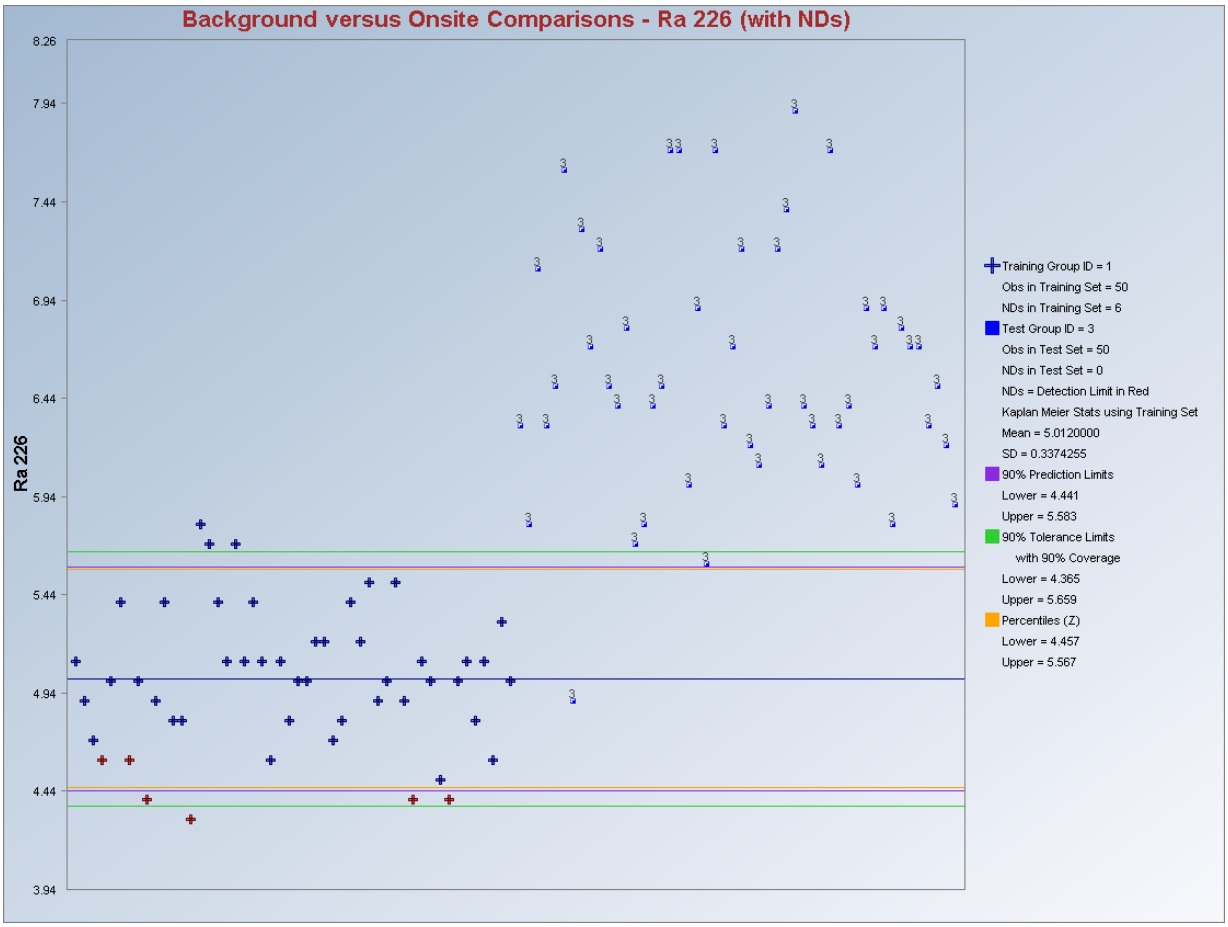


Figure 4. Graphical Test to Compare Ra 226 Concentrations of Two Groups, NDs shown in red

From Figure 4, it is easy to see that concentrations of the analyte, Ra 226, in the two groups are significantly different. Moreover, this graph also identifies all on-site ("Test Group ID = 3") locations labeled by 'squares' exhibiting significantly higher Ra 226 concentrations than those found in the background ("Training Group ID = 1") data set, labeled by bold '+'. Since, the data set consists of four analytes; this test will have to be repeated four times for each of the four variables. This data set is considered again in Example 9 (Figure 16) of Section 2 to demonstrate the needs (and advantages) for using multivariate methods on multivariate data sets consisting of multiple contaminants.

1.3 Comparing Concentrations of the Two RBRAs

Once the RBRA data sets have been established, the RNC concentrations of the two RBRAs will be compared (as described below) to determine if the two RBRA data sets can be merged together to form a single combined radiological background reference data set for all future Site versus Background comparisons. It should be noted that if RNC concentrations of the two RBRAs are comparable (e.g., with respect to mean, median, spread, and data distribution), and can be considered as coming from a single statistical population of RNC concentrations, it is desirable and recommended to compute a single estimate of the background threshold value (BTV) for that RNC.

The process of merging the two RBRA data sets (when applicable based upon statistical and graphical tests) and computing a single BTV (one for each RNC) for the two formations will result in representative and defensible estimates of the BTVs, especially when BTVs are estimated using robust and resistant methods. The use of BTV estimates computed using the merged (when applicable) RBRA data set will result in a lesser number of statistical comparisons with more manageable decision errors.

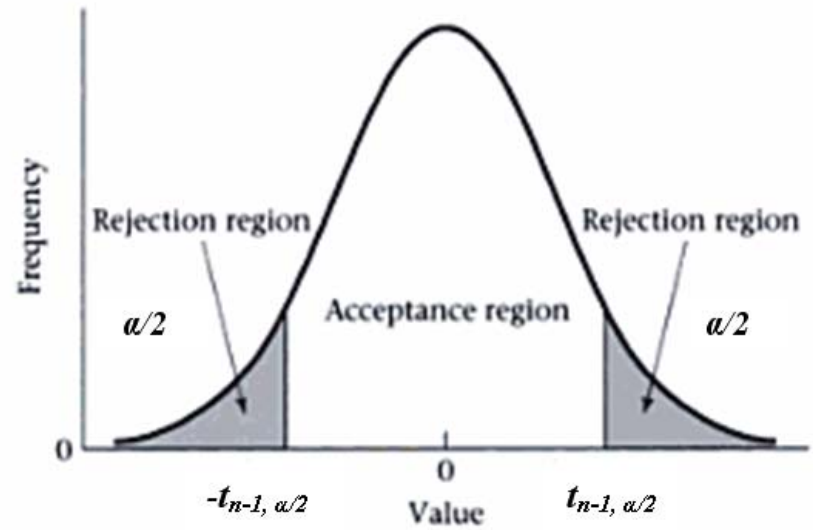
It is a common practice to merge two comparable data sets which can be considered as coming from a single statistical population. Statistics computed (e.g., BTVs) based upon the merged RBRA data sets will be statistically more robust.

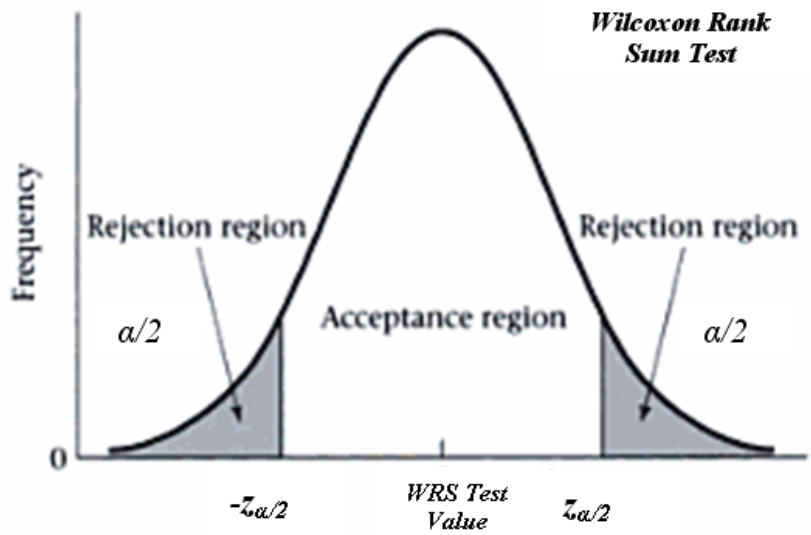
Statistical methods which will be used to compare RNC concentrations of the two RBRAs are described in this section. Since during this comparison, the objective is to determine if the concentrations of RNCs at the two geological formations are statistically similar, the use of two-sided alternative hypotheses described below will be most appropriate.

Let μ_1 represent the mean/median of a certain radionuclide at the Santa Susana RBRA, and μ_2 be the mean/median concentration of the same radionuclide at the Chatsworth RBRA. The following null and alternative hypotheses will be considered. The allowable Type I (α) and Type II (β) errors can both be fixed at 0.1. If deemed necessary, other levels of false positive and false negatives error rates will also be considered. The null and two-sided alternative hypotheses are stated as follows.

Null Hypothesis, H_0: Mean/median, μ_1 = Mean/median, μ_2, versus the two-sided (two-tailed)
Alternative hypothesis, H_1: Mean/median, $\mu_1 \neq$ Mean/median, μ_2

Based upon the collected data from the two formations, the null hypothesis will be tested against the alternative hypothesis. Depending upon level of significance, α (Type I error rate), and the test statistic used (e.g. t-test, WRS test), an acceptance region and a rejection region for the null hypothesis will be established. If the value of the test statistic (e.g., t-test, or WRS test) falls within the acceptance region, the null hypothesis that the mean/median concentrations of the two populations are similar (not statistically significantly different) will be accepted, otherwise the null hypothesis will be rejected. The acceptance and rejection regions with two sided alternative hypothesis are shown in the following figures. Note that since the alternative hypothesis is two tailed, the rejection region for the null hypothesis is also two tailed.





As mentioned before, the conclusions of hypotheses tests will be supplemented by information and patterns displayed in graphical displays (e.g., boxplots, Q-Q plots, histograms, control-chart-type displays). If hypotheses test results and graphical displays all lead to the conclusion that the RNC concentrations of the two RBRAs are statistically comparable (similar), then the two RBRA data sets (Santa Susana and Chatsworth) may be merged together to make a single RBRA data set. All interested parties including site experts, project team, regulators, and stake holders will decide how the RBRA data sets will be used in future evaluation studies. Specifically the parties involved will determine if:

1. On-site RNC concentrations from the two formations (Santa Susana and Chatsworth) will be compared separately with their respective RBRA (Santa Susana and Chatsworth) data sets; or

2. On-site RNC concentrations from the two formations will be compared with concentrations of the single merged RBRA data set, provided the statistical tests suggest that the RNC concentrations of the two RBRA data sets are not significantly different. In this case, the merged RBRA data set may be used as representative of the radiological background reference area for all future on-site versus

background comparisons.

In any case, if the RBRA data sets (merged or individually) exhibit RNC concentrations comparable (not statistically significantly different) to those of DTL data set, then those data sets will be used as background reference data sets for all future site investigations. In case the two RBRA data sets from the two formations (Santa Susana and Chatsworth) are significantly different in their RNC concentrations, then two separate reference data sets will be used in all future comparisons. Specifically, on-site versus background comparisons will be performed separately for the two geological formations of the SSFL site.

1.4 Establishing Background Level RNC Concentrations or Background Threshold Values (BTVs)

Procedures to estimate and determine the BTVs or trigger values will commence after successful completion of establishing defensible RBRA data sets. Once defensible RBRA data sets (combined RBRA data set, or two separate RBRA data sets--one for each formation) have been established, evaluations will be conducted using the procedures described in this section. The main objective of these evaluations is to identify statistical methods which will be used to compare on-site RNC concentrations (when they become available) with RNC concentrations of the RBRA data sets. Specifically, based upon the RBRA data sets, background level RNC concentrations, also known as BTVs will be computed. These BTVs may be used to compare on-site observations in future investigations. For an example, if an on-site observation exceeds a BTV, the corresponding on-site location may be considered impacted by the site activities and may require further investigations or cleanup.

Additionally, when comparing on-site concentrations with some upper limit (e.g., BTV, 90th percentile of RBRA data set) of the background data set, other formal graphical methods (e.g., shown in Figures 3 and 4) as discussed during the stakeholder meeting on April 30th will also be used to compare one or more on-site observations with the entire RBRA data set(s). Depending upon the statistical comparability of the two RBRA data sets (from two formations) and the decision made by all concerned parties: 1) on-site RNC concentrations may be compared with concentrations of the merged RBRA data set (when the two RBRA data sets exhibit statistically comparable concentrations, and decision makers agree to merge them); or 2) on-site RNC concentrations of the two formations will be compared separately with the RBRA concentration of their respective formations (when the two RBRAs are significantly different or the decision makers decide not to merge them).

1.4.1 Estimation of Background Threshold Values (BTVs)

Once defensible and representative (e.g., representing site conditions before any of the site related activities) RBRA data sets (free of outliers) have been established, BTVs will be estimated by using the documented and well established statistical procedures available in the environmental statistical literature. Typically, BTVs are estimated by upper percentiles (e.g., 90th) or upper tolerance limits (e.g., 90% upper confidence limit of the 90th percentile- 90%-90th UTL) computed based upon a pre-established reference data set (EPA 1989, 1992, 2002, Navy 1998, 2002, and ProUCL 4.00.01, 2009). Inclusion of outliers in a reference data set may yield inflated and non-representative estimates of background threshold values. As mentioned before, outliers will not be included in the computation of any of the decision making statistics including upper percentiles, upper prediction limits, and upper tolerance limits. In order to compute conservative and defensible estimates of BTVs/trigger values all statistics will be computed using original raw data set, and no log-transformation will be used. Additionally, robust and resistant methods will be used to compute upper limits based upon the RBRA data set(s). Robust estimation methods assign reduced or negligible weights to potential outlying observations (Singh (1993), Singh and Nocerino, (1995)).

The proposed robust statistical methods to estimate BTVs will provide double protection against outlying observations that potentially increase the variability of the RBRA data sets. First, the RBRA data set will be free of outliers, and second the robust and resistant methods will be used to compute the upper limits. Robust and resistant methods automatically assign reducednegligible weights to outlying observations (e.g., Rousseeuw and van Zomeren (1990), Singh and Nocerino (1997)). Estimates of BTVs thus obtained will be undoubtedly protective of human health and the environment.

1.4.1.1 Not to Use Reference Area Average to Estimate BTVs

It is recommended not to use a reference area average or its associated 95% upper confidence limit (UCL95) to estimate BTVs. Since, individual on-site observations will be compared with a trigger value, the trigger value/BTV should represent a threshold level meant for comparison of individual concentrations (and not a mean concentration). Comparing individual on-site values with reference area average value is not desirable, as that comparison will result in a high percentage of false positives without providing additional protection to human health and the environment. The comparison of individual on-site observations with reference area average value would result in the further characterization, and potentially remediation, of unimpacted, clean site locations. This kind of comparison is not supported by statistical theory. This is further illustrated in Figure 5 below based upon the data set of Example 2.

Figure 5 has the graphical display of the two-sided 90% confidence interval of the mean (showing 5% lower confidence limit and 95% upper confidence limit), the 5th and 95th percentiles, and the two-sided 90%-90th tolerance interval based on the *reference area* data set of Example 2. Since the confidence interval of the mean is meant to provide coverage for the mean (e.g., reference area mean, on-site area mean), several individual reference area values lie above the reference area mean and it's one-sided 95% upper confidence limit (UCL95) shown in Figure 5 below. If one assumes that a location with measurement lying above the reference area mean, which equals 5.012 in this example, or its UCL95, which equals 5.092 in this example, has been impacted by site-related contaminants, then several reference area locations lying above the UCL95 will also appear to be impacted by site-related contaminants. This is a fallacy because by definition contamination is always above background.

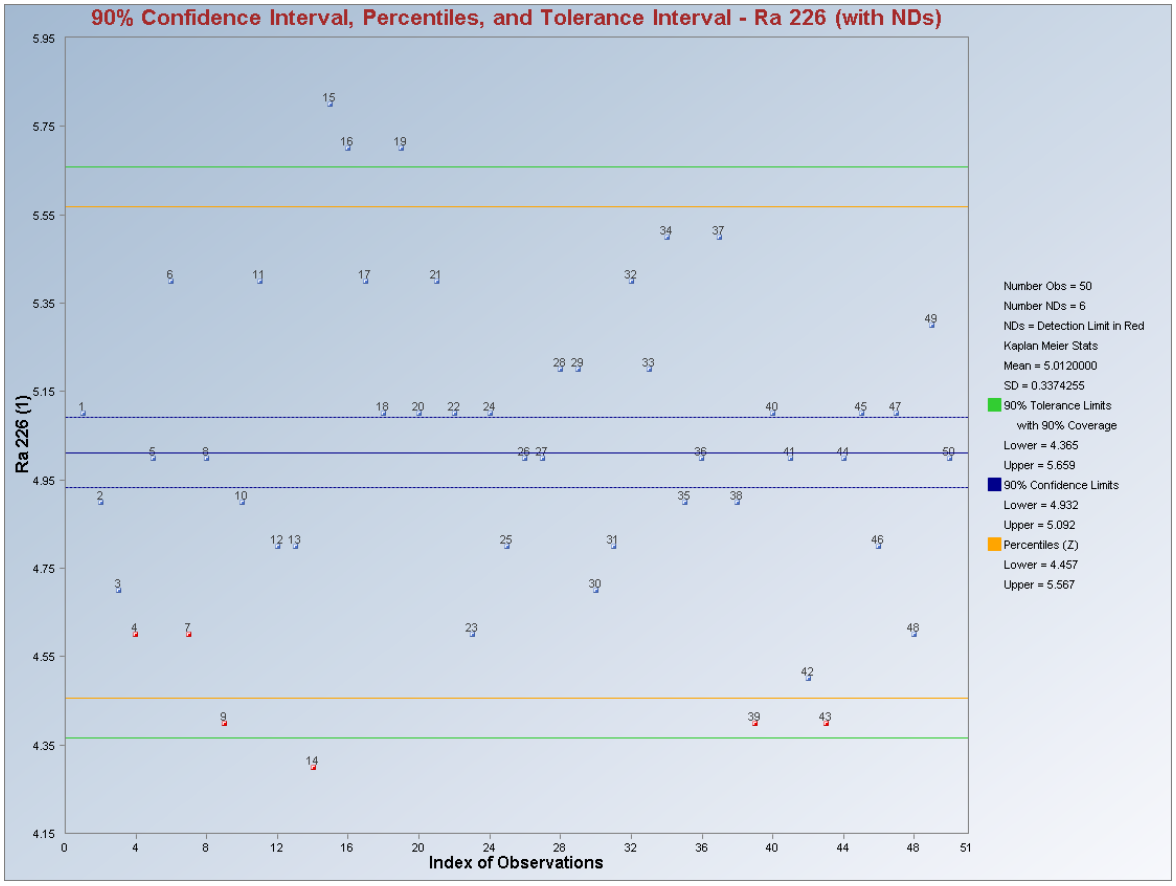


Figure5. 90% Two-sided Confidence Interval for the Mean Computed Using Reference Data Set

It is, therefore recommended to use upper limits such as 90th percentiles or 90% -90th upper tolerance limits as estimates of BTVs/trigger values.

1.4.1.2 Computing Upper Limits to Estimate BTVs

This section briefly describes statistics which will be used to estimate BTVs. The BTVs are estimated by upper percentiles (e.g., 90th) or upper tolerance limits (e.g., 90% upper confidence limit of the 90th percentile- 90%-90th UTL) computed based upon a pre-established reference data set (EPA 1989, 1992, 2002, Navy 1998, 2002, and ProUCL 4.00.01, 2009).

The relationship between the values of the statistics often used to estimate the BTVs or trigger values is given as follows:

90th percentile ≤ 90% UPL≤ 90% UTL- 90th percentile (90%-90th UTL)≤ 95% UTL- 90th percentile (95%-90th UTL)

95th percentile ≤ 95% UPL ≤ 90% UTL- 95th percentile (90%-95th UTL) ≤ 95% UTL- 95th percentile (95%-95th UTL)

The values of these upper limits are illustrated by graphical displays shown in Example 3. Furthermore, in order to illustrate how the use of robust and resistant methods yields conservative and defensible estimates of BTVs, both classical and robust estimates of BTVs are discussed in Example 4.

Example 3. A reference data set of size 20 is used to graphically display upper limits used to estimate the BTVs/trigger values. The data set does not consist of any outliers (e.g., using Dixon test and other robust outlier identification methods). Figure 6 illustrates the various classical statistics (90th percentile and 90%-90th UTL) used to estimate the BTVs; and Figure 7 has the corresponding robust and resistant upper limits. Since no outliers are present in this data set, classical and robust estimates of BTVs are in complete agreement.

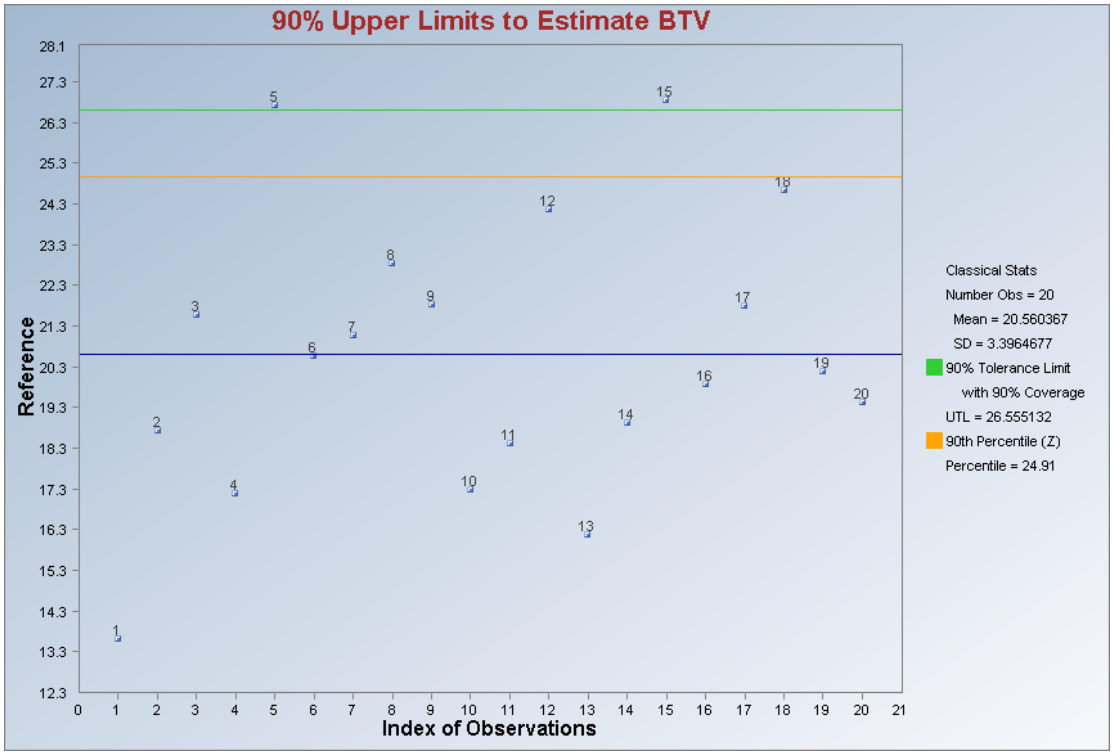


Figure 6. Graphical display of classical 90th percentile and 90% -90th UTL

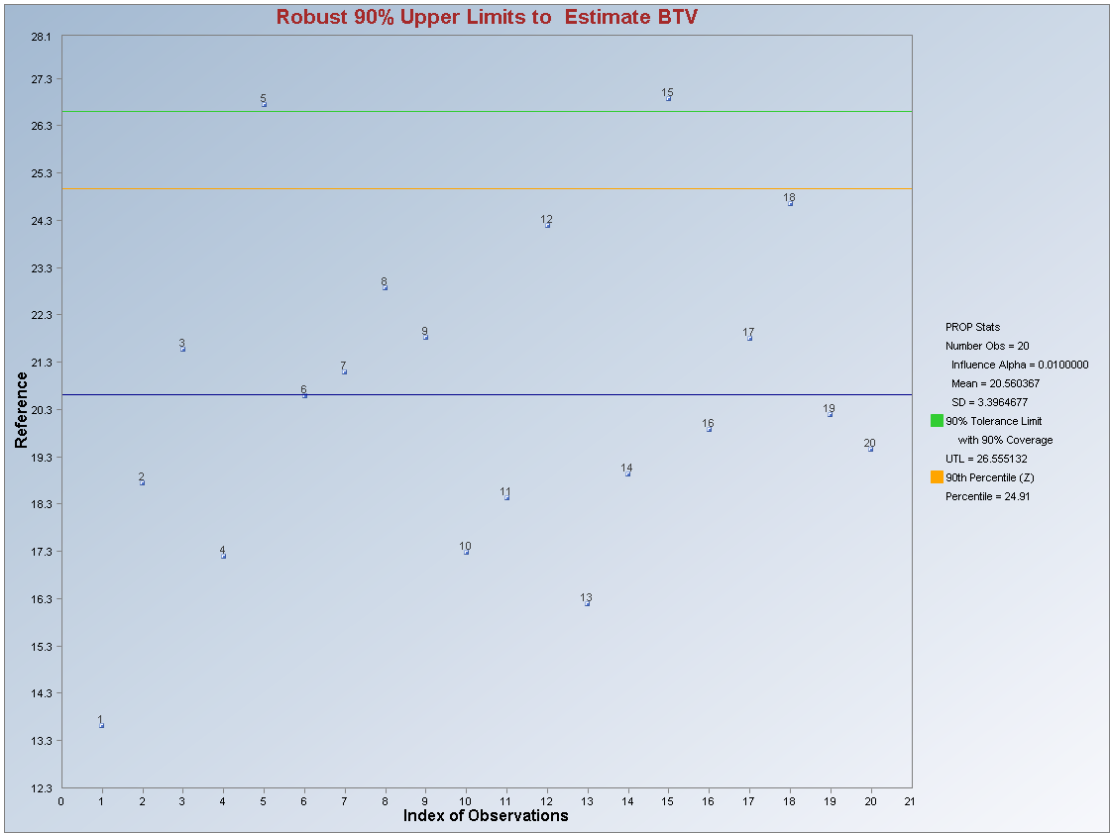


Figure 7. Graphical display of robust 90th percentile and 90% -90th UTL

This reference data set does not consist of any outliers. Therefore, both classical and robust 90th percentile and 90%-90th UTL of the reference area data set are in complete agreement. For this data set, parametric 90th percentile = 24.91 and one-sided 90%-90th UTL = 26.56. An on-site RNC observation belonging to the background population will lie at or below the 90th percentile with probability 0.90. The 90%-90th UTL represents a 90% upper confidence limit on the 90th percentile and provides coverage to the 90th percentile.

Example 4. This example uses a reference data set consisting of 9 measurements. The classical upper limits (90% percentile, 90%-90th UTL) are shown in Figure 8. From Figure 8, it appears that the observation number 4 (value of 67.72) represents a potential outlier. A simple outlier test (e.g., Dixon's test) also suggests that observation number 4 with a value of 67.72 indeed represents an outlier. Since the presence of outlier distorts classical statistics such as mean, standard deviation, percentiles, and UTLs, robust and resistant methods will be used to estimate the BTVs. The upper limits to estimate BTV based upon robust and resistant method are shown in Figure 9 and the corresponding upper limits without the outlier (observation # 4 omitted) are shown in Figure 10. It is noted that the robust limits and the limits obtained without the outlier are in close agreement (Figures 9 and 10). The values of the various limits are summarized in Table1.

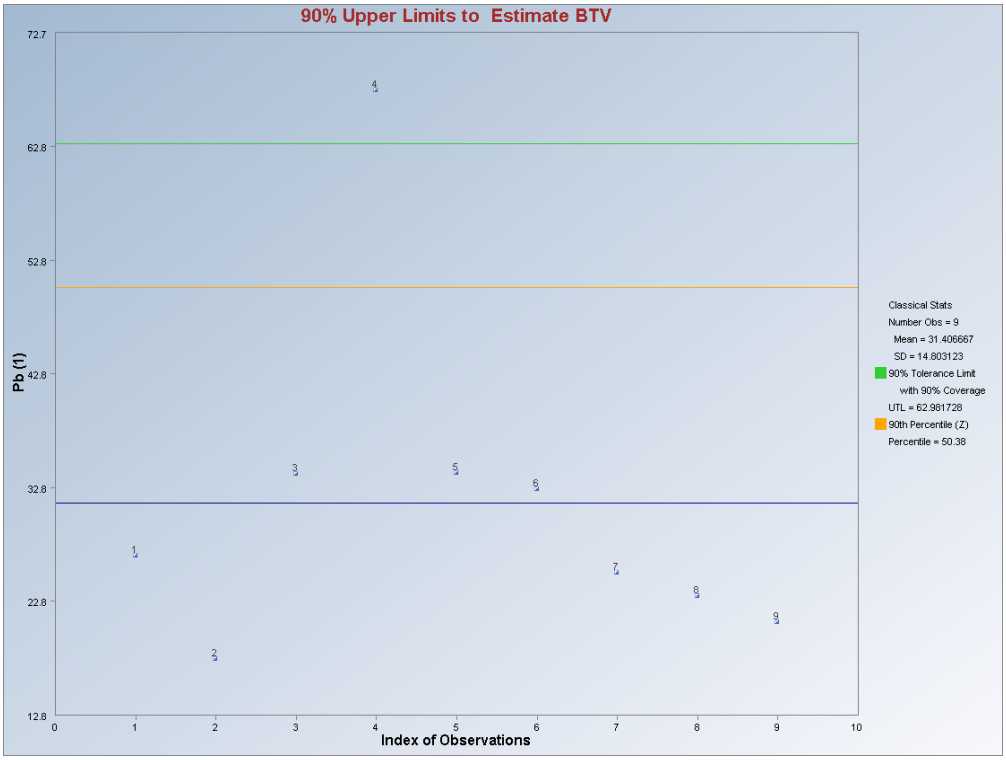


Figure 8. Graphical display of Classical 90th Percentile and 90% -90th UTL with Outlier (#4)

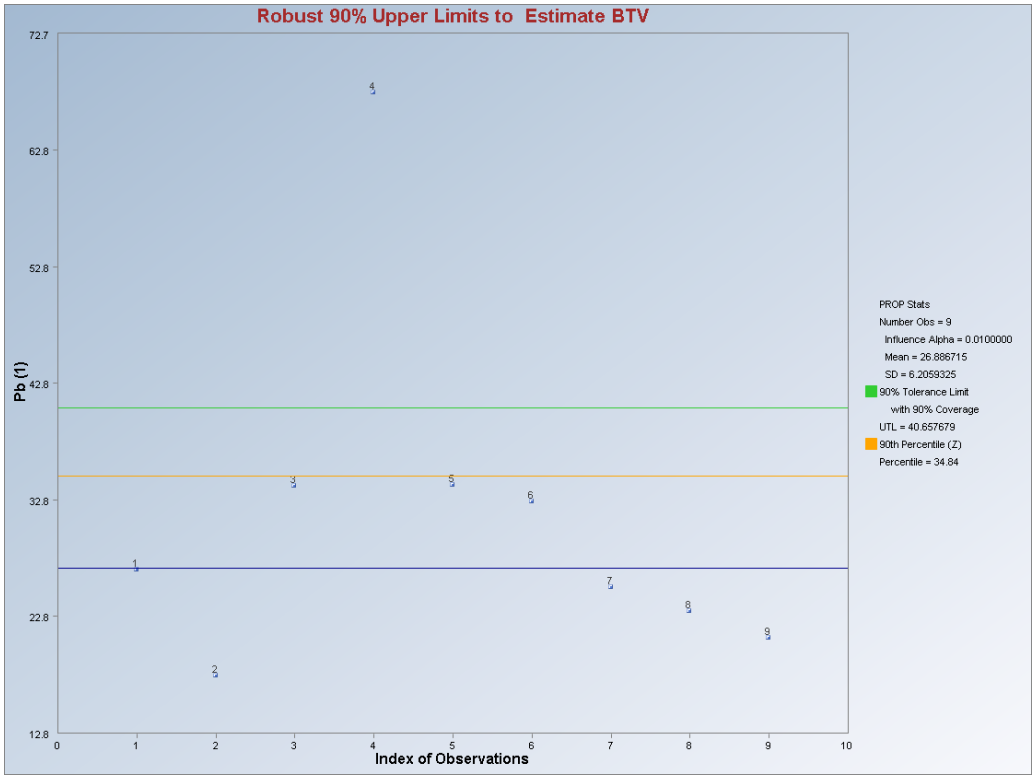


Figure 9. Graphical display of Robust 90th percentile and 90% -90th UTL with Outlier (#4)

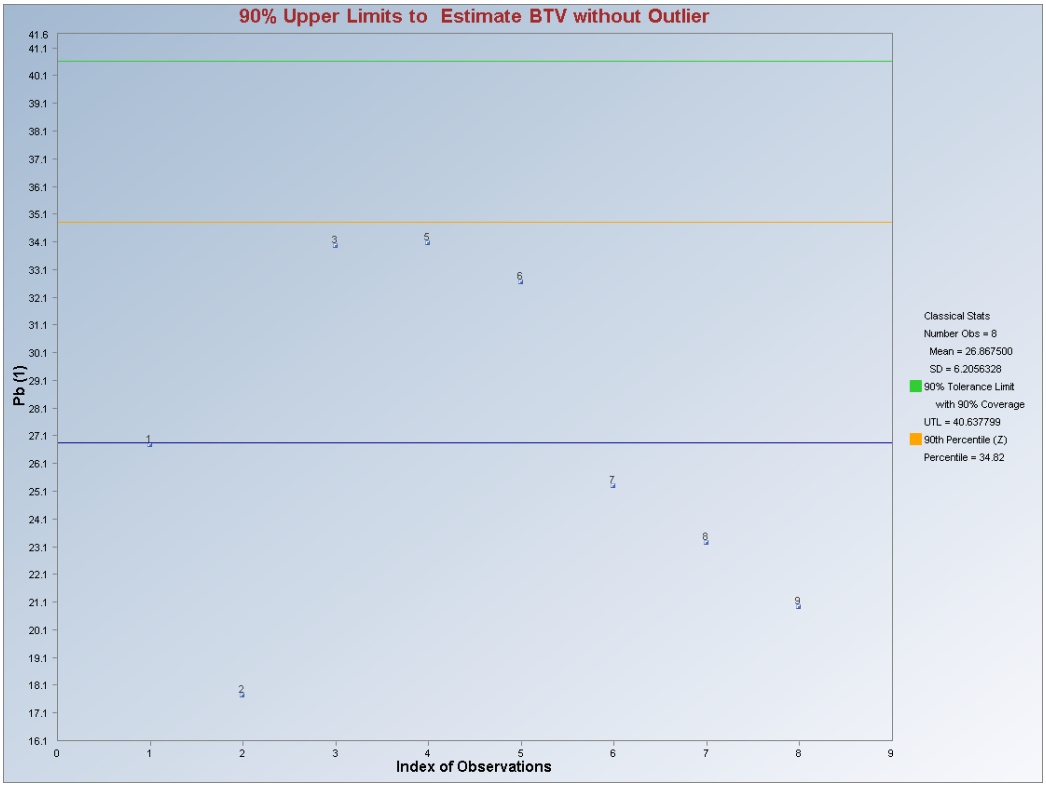


Figure10. Display of classical 90th percentile and 90% -90th UTL without Outlier (#4)

Table1. Upper Limits to Estimate BTV

Method	Mean	Standard Deviation	90th Percentile	90%-90th UTL
Classical Method with Outlier	31.41	14.80	50.38	62.98
Robust/Resistant Method with Outlier	26.89	6.21	34.84	40.66
Classical Method without Outlier	26.87	6.21	34.82	40.64

From Figures 8-10, and Table 1, it is easy to see outliers inflate the variability and distort all other statistics of interest (e.g., percentile, UTL). However, robust methods automatically assign reduced/negligible weights to outlying observations, therefore, robust and resistant (to outliers) methods yield statistics (BTVs) that are not inflated by outliers. The upper limits (to estimate BTVs) based upon the robust method (PROP influence function) and the classical methods without the outlier are in close agreement.

It should be noted that RBRA data sets will be screened for outliers before computing estimates of BTVs. Outliers will not be included in RBRA data sets. All statistics will be computed using data in original scale without using a log-transformation. Furthermore, robust and resistant methods will be used to compute upper limits to estimate BTVs. The robust statistics thus obtained will be conservative and protective of human health and the environment.

A stepwise procedure based upon *robust and resistant estimates of BTVs* can be used to determine if an on-site observation is potentially impacted by the site activities.

- If an on-site measurement falls below the robust 90th percentile of the RBRA data set, then the location of that measurement will be considered unimpacted.
- If an on-site observation lies between the robust 90th percentile and the robust 90%-90th UTL, the project team will take a closer look at the location and determine whether the corresponding location should be further investigated.
- If an on-site location exceeds the robust 90%-90th UTL, the corresponding on-site location will be considered as potentially impacted by the site activities and further investigation/evaluation will be needed.

  The stepwise procedure based upon robust estimates of BTVs described above will lead to conclusions that are statistically defensible and protective of human health and the environment.

1.4.2 Comparing On-site RNC Concentrations with Background Data Set (as a whole versus some upper limit such as UTL)

Other formal graphical displays will also be used to perform these comparisons. Specifically, one or more on-site observations will be graphically compared with the entire reference background data set. A couple of univariate graphical displays (Figures 11 and 12) illustrating these comparisons are given in Example 5.

Example 5. On-site and background chromium (Cr) concentration comparisons can also be made by using the following tolerance interval comparison graph shown in Figure 11.

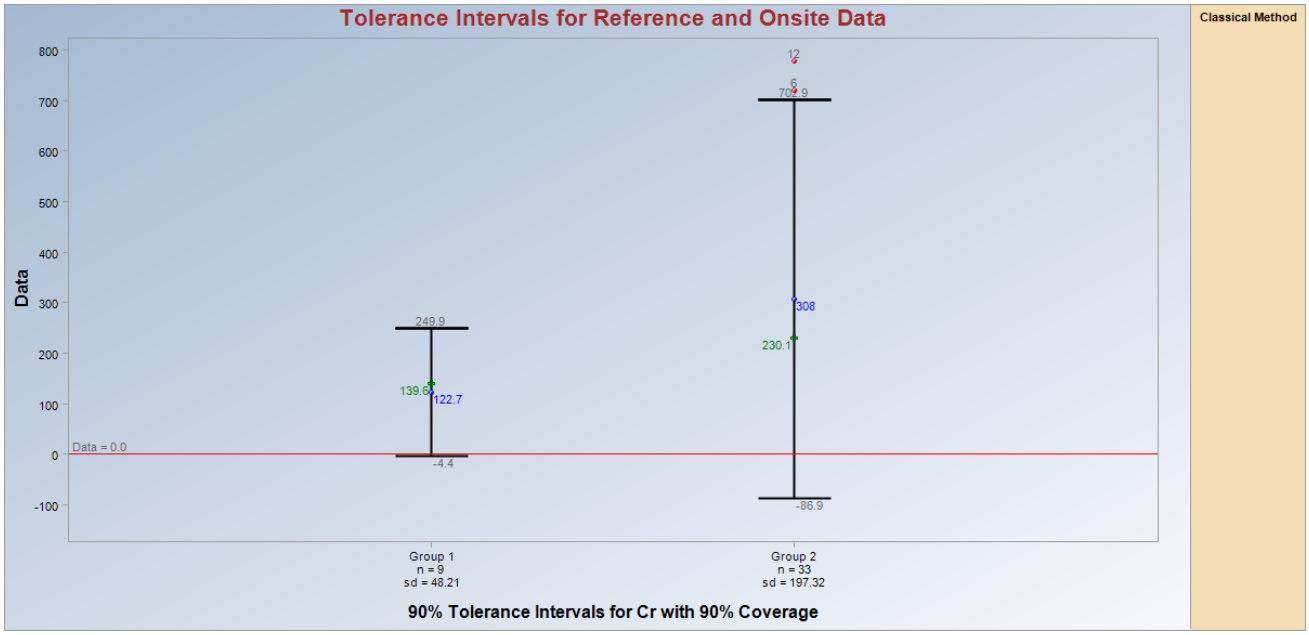


Figure 11. 90% Tolerance Intervals for Reference and On-site Chromium Concentrations

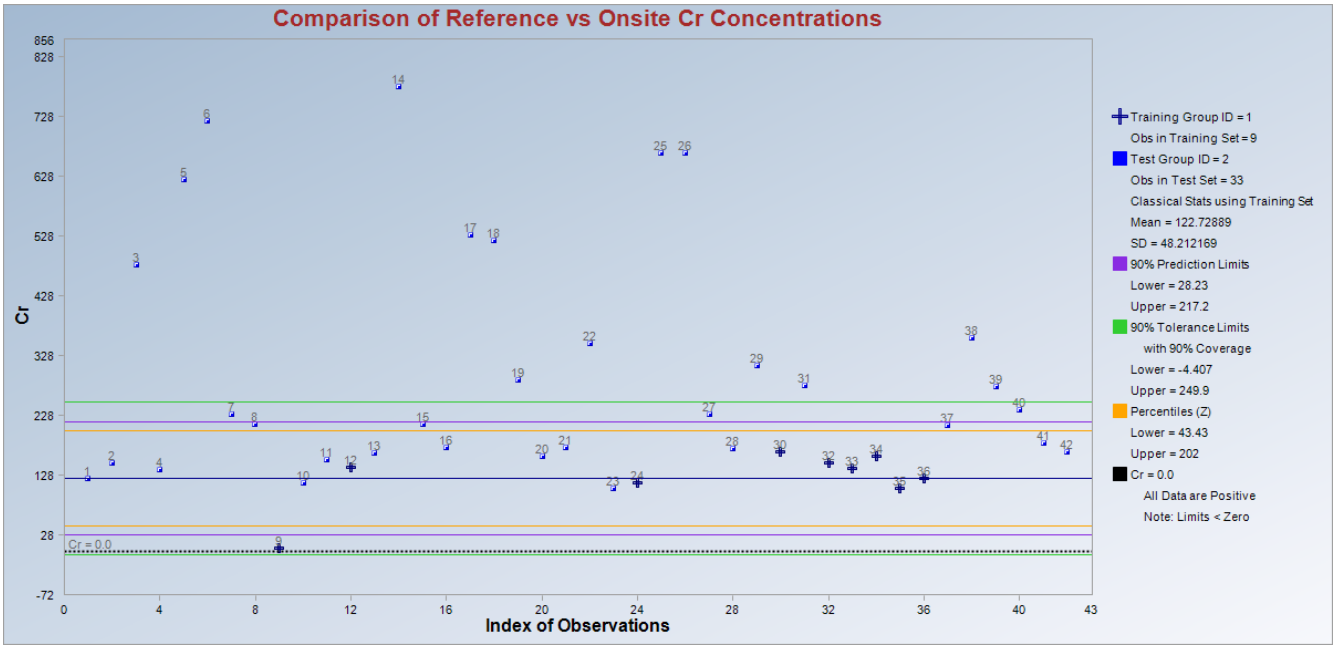


Figure 12. Formal Graphical Test to Compare Chromium Concentrations of Two Populations

From Figures 11 and 12, one can easily determine that the concentrations of the two groups (Reference data (group ID=1) denoted by bold '+', and On-site data (group ID=2) denoted by 'square') are significantly different. Actually, these formal graphs demonstrate that on-site chromium concentrations

are significantly higher than those of the reference are. The graphical display shown in Figure 12 identifies all on-site locations exhibiting chromium concentrations higher than BTVs (e.g., 95% UPL, 95th percentile, and 95%-90th UTL as shown in Figure 12). It should be noted that use of a typical t-test or WRS test can only provide the conclusion that the on-site locations exhibit concentrations significantly higher than the background locations.

2.0 Statistical Evaluations Based Upon Multivariate Methods

It is noted that many correlated constituents (e.g., radionuclides, and metals as collected by the California Department of Toxic Substances Control) will be considered in RBS evaluations. Performing statistical analyses for each constituent separately can be tedious and time consuming. Furthermore, the use of univariate methods on multivariate data sets (multiple constituents) fail to control Type I and Type II error rates (false positives and false negatives) specified in the Data Quality Objectives (DQOs). Therefore, for multivariate data sets consisting of multiple radionuclides, appropriate multivariate methods may also be used to address stakeholders' concerns and statistical issues of the RBS evaluations as described in the SAP. Multivariate methods as incorporated in Scout 2008 are based upon the peer-reviewed published research efforts of many researchers and academicians. Scout 2008 comes with a User Guide and many technical published journal articles used in the development of Scout 2008, Version 1.00.01. Multivariate robust methods (e.g., Johnson and Wichern, 2002, Rousseeuw and Leroy, 1987, Rousseeuw and van Zomeren, 1990, Singh 1993, Singh and Nocerino, 1995, 1997) are resistant to outliers and can successfully identify all potential outliers that may be present in a data set. Theoretical details of the multivariate methods used in this document can be found in the cited references.

Robust and resistant (to outliers) statistical methods will be used to identify potential outliers in univariate and multivariate data sets; and formal multivariate (based upon Mahalanobis distances (MDs)) graphical test displays (e.g., Singh and Nocerino (1995, 1997)) available in the QA/QC module of Scout 2008 will be used to determine if concentrations of RNCs of the two groups (e.g., RBRA vs. DTL, On-site vs. RBRA) differ significantly. Additionally, multivariate graphical displays will be used to determine and identify on-site (test set) observations that do not belong to the background (training set) population.

It should be noted that statistics, MDs and maximum (MDs) are multivariate in nature and are computed using all selected analytes present in a data set. Therefore, in multivariate graphs (e.g., shown in Figures 13 through 18) based upon MDs, all selected analytes are being used and included even though they are not directly shown on the graphical displays. In addition to generating graphical displays, Scout 2008 also generates Excel output sheets summarizing details about the selected variables, statistical tests, and statistics. However, in this document, only graphical displays have been used. The effectiveness and some of the advantages of using multivariate methods on multivariate data sets is illustrated in the following examples.

Example 6. Consider a 6-dimensional (e.g., 6 radionuclides) data set consisting of n=20 observations (e.g., DTLs). For the sake of illustration, assume that the data set has four outliers. The univariate Rosner outlier test (USEPA, 2006, MARSSIM, 2000) cannot be used since n<25. The univariate Dixon test could not identify any outliers. The Robust multivariate formal outlier test identified all four outliers as shown in the following Figure 13.

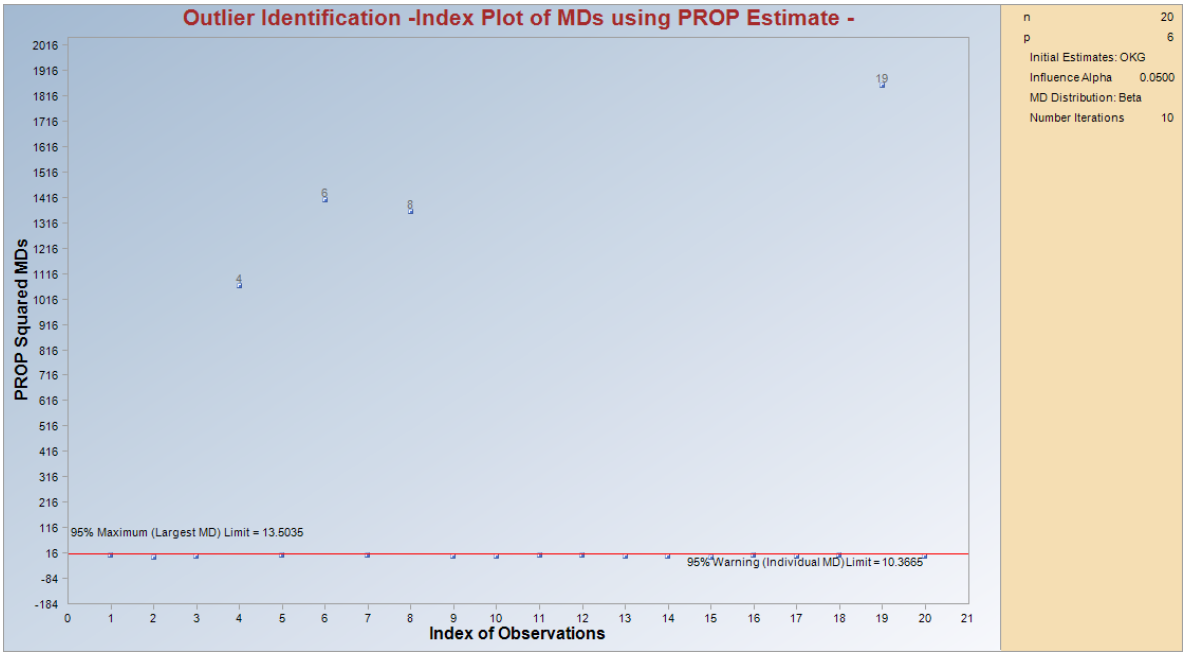


Figure 13. Identification of Outliers based upon Robust PROP Influence Function

Example 7. Effectiveness of multivariate robust outlier methods is shown by using another data set consisting of several outliers of varying degrees of extremeness. The graphical display based upon the robust outlier method not only identified all outliers successfully, but also revealed four extreme outliers (#11, 20, 30, and 34), two intermediate outliers (#7, 14), and one mild outlier as shown in Figure 14 below.

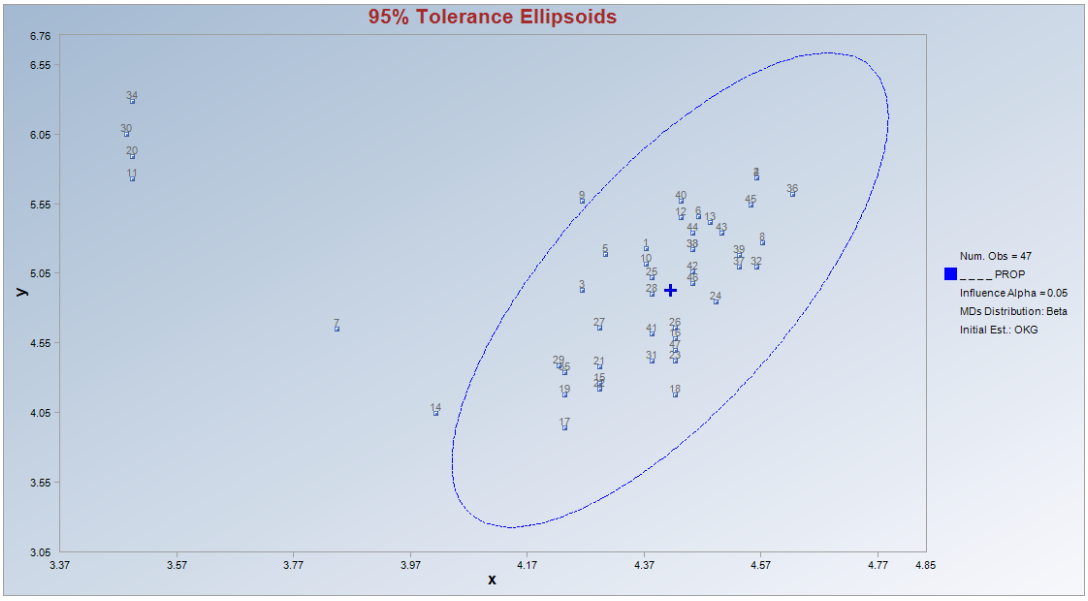


Figure 14. Identification of Outliers based upon the PROP Influence Function

Example 8. The three-dimensional (lead, manganese, iron) real data set (consisting of on-site and offsite background concentration data) from a Superfund site was used earlier in Example 1, Section 1.0 to illustrate the use of univariate graphical methods. In this example, the data set is used to illustrate the effectiveness of multivariate graphical test to determine if the metal concentrations of two populations (background versus site) differ significantly. Using the multivariate graphical test based upon MDs (representing all three contaminants), one can not only determine that there are differences between two populations (site versus background) but can also determine which of the site (e.g., test set, group 2) observations do not belong to the background population (e.g., training set, group 1). Specifically, from Figure 15, it can be determined that on-site locations 13, 14, and 15 do not belong to the background population (training set). Note that univariate manganese graphical test shown in Figure 3 also identified the same three on-site (test set) observations (13, 14, and 15) not belonging to the background (training set) population.

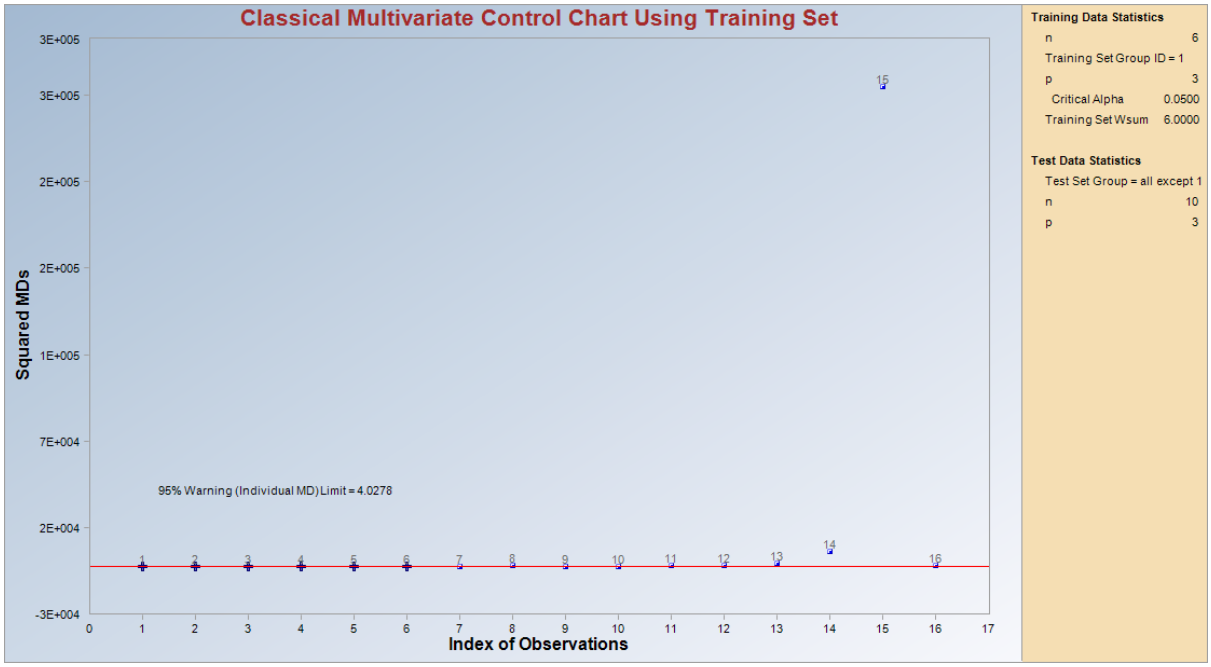


Figure15. Multivariate (three analytes) two-sample test supplemented with graphical display

Example 9. This four dimensional data set was considered earlier in Example 2. From the formal multivariate graphical test display shown in Figure 16, it is easy to conclude that the concentrations of the two groups (e.g., On-site versus Background, training set versus test set) are significantly different. No other univariate test (graphical or analytical) is needed to come to this conclusion, and the associated Type Error I rate indeed stays fixed at 0.05. Figure 16a has a similar graph comparing populations 2 and 3. Typically, on-site observations lying above the control limit ("95% Maximum (Largest MD) Limit") on the control-chart-type index plot (Figure 16) of MDs may represent impacted site observations requiring further investigation.

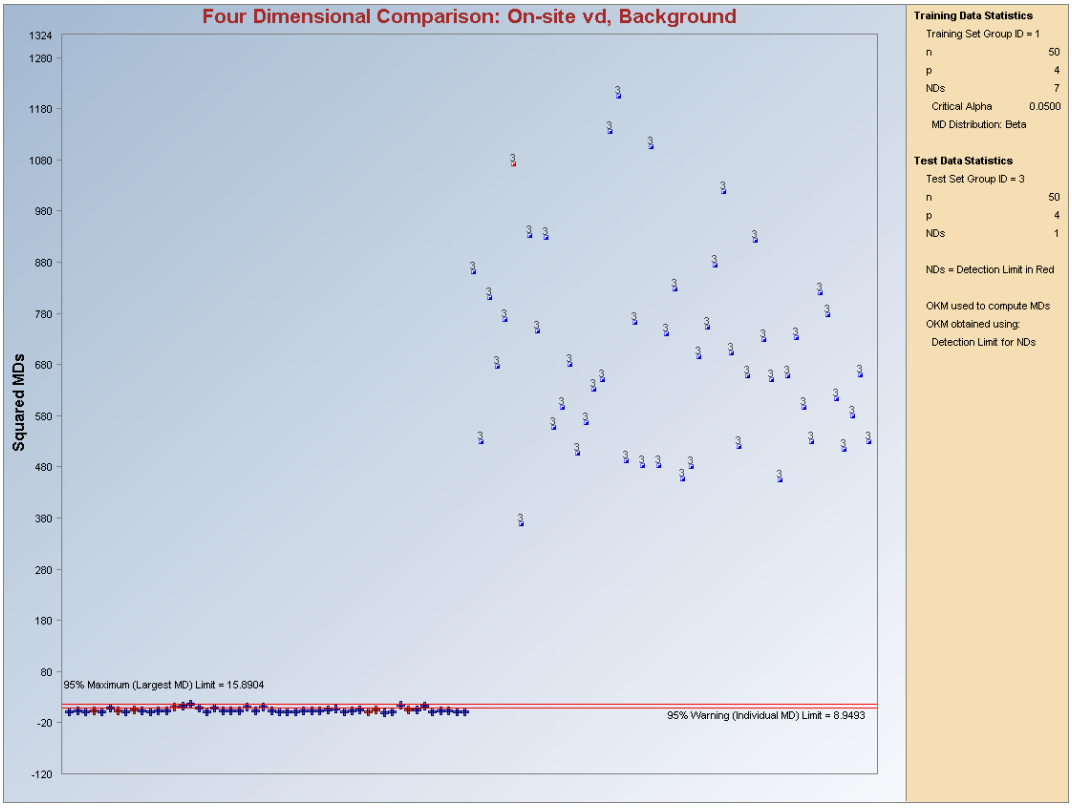


Figure 16. Multivariate (four analytes) formal graphical two-sample test

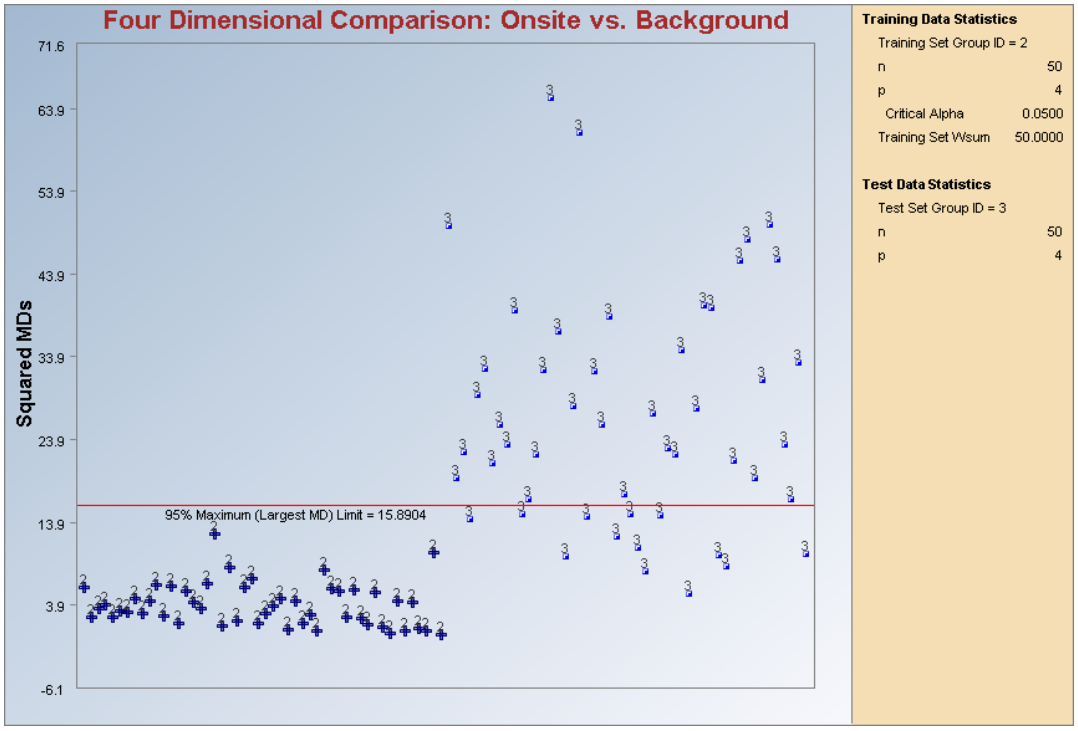


Figure 16a. Multivariate (four analytes) formal graphical two-sample test

Example 10. Another five dimensional crude oil data set from two different populations is used to illustrate the use of multivariate methods to assess and test the differences between two groups (e.g., Background versus On-site, Group 1 versus Group 2). The graph shown below in Figure 17 can be used to come to the conclusion that the bivariate (vanadium and beryllium) concentrations of the two groups (e.g., training set versus test set, group 1 versus group 2, RBRA versus DTL, On-site versus RBRA) differ significantly. Test set (Group 2) observations lying outside the tolerance ellipsoid shown in Figure 17 may be considered as not belonging to the training set (Group 1) population (e.g., background population). Multivariate graph (Figure 18) using all five metals quickly reveals that the metal concentrations of two groups are significantly different. Observations lying above the maximum limit shown on Figure 18 can be considered as not belonging to the background (training set, group 1) population.

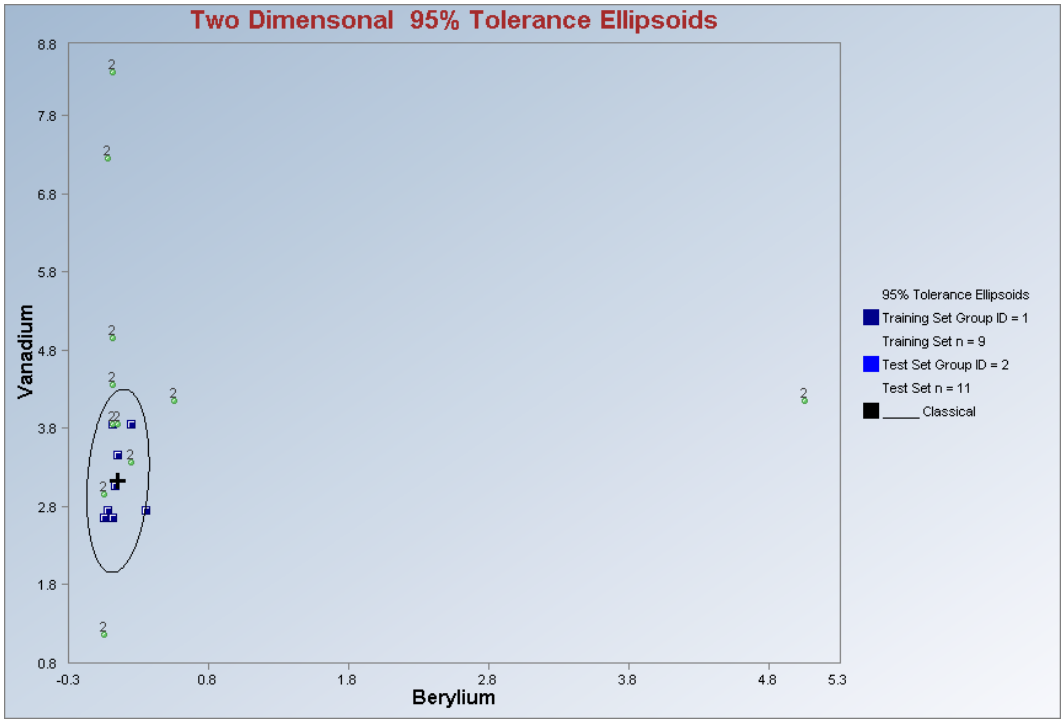


Figure17. Bivariate formal graphical two-sample test

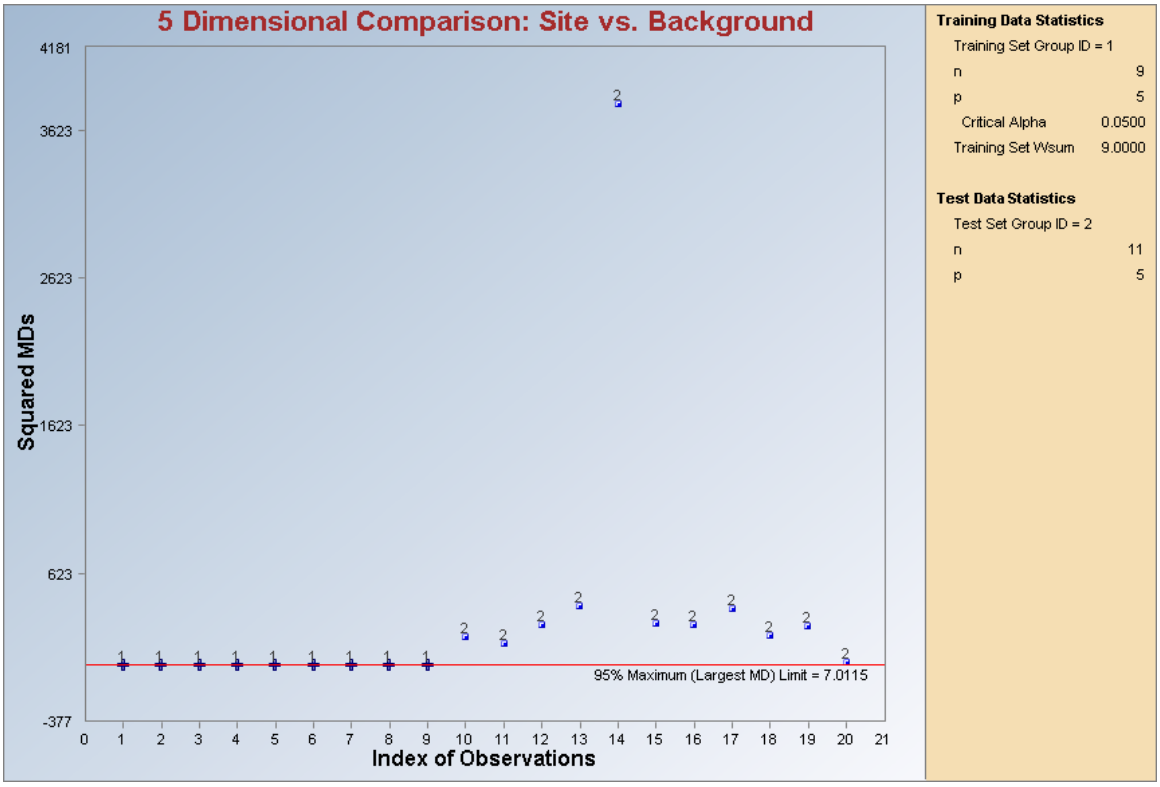


Figure18. 5-Dimensional formal two-sample test: Site (group 2) vs Background (group 1)

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Appendix A

Background Module of ProUCL 4.00.04

The background module of ProUCL 4.00.04 will be used to address most of the objectives of evaluations. The background module of ProUCL 4.00.04 (and its earlier versions) was developed to: 1) compare site concentrations data distribution to background concentrations data distribution, 2) compare point-by-point site data to some pre-established screening level such as background threshold value (BTV) or not-to-exceed value, or 3) compute background upper threshold value (BTV) based upon site-specific background data. Specifically, while comparing site data to background data, one is interested in determining whether the site concentrations can be considered as coming from (site concentrations comparable to those of background) the background population. The main objective of performing background versus site concentrations comparison is to determine if site concentration data exceed some background threshold levels (e.g., upper prediction limit, upper tolerance limit) with high confidence. Typically, in such situations, background upper threshold is estimated by a 95% upper prediction limit (95UPL), 95% upper limit for 90th, or 95th percentile (95UTL90, or 95UTL95) provided enough (e.g., at least 8-10, more are desirable) background data are available. Thus a 95% UPL or UTL is computed based upon background data, and individual point-by-point site observations are compared with the BTVs. For details refer to ProUCL 4.00.04 technical guide, which can be downloaded from the EPA website.

ProUCL 4.00.04. (2009). "ProUCL Version 4.00.04 Technical Guide." The software ProUCL 4.00.04 can be downloaded from the web site at: http://www.epa.gov/esd/tsc/software.htm.

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Appendix B

Identification of Outliers

It is noted that typically, in environmental applications (e.g., EPA, 2006), classical Rosner and Dixon outlier tests are used to identify outliers which often suffer from masking effects. However, it is well known (e.g., Singh, 1993) that classical univariate outlier tests (Dixon test, Rosner test) suffer from masking effects (e.g., extreme outliers may mask the occurrence of other intermediate outliers), it is therefore, suggested that for univariate data sets, these classical outlier tests be supplemented with graphical displays such as a box plot or a quantile-quantile (Q-Q) plot. Moreover, in order to use Rosner test, one needs to specify the number of suspected outliers, which is not known in advance. The user has to try many values (e.g., =1, 2, 3, 4,…, 10) for the number of suspected outliers. Therefore, it is always desirable to supplement analytical statistics (e.g., GOF test, Rosner test statistic) and results (as they may get inflated by outliers) with graphical displays. The use of UTLs inflated by outliers can result in inflated estimates of background threshold values (BTVs). The use of inflated BTVs is not protective of human health and the environment.

The use of robust and resistant outlier identification procedures (e.g., Singh, 1993, and Singh and Nocerino, 1995 and 1997) is recommended when multiple outliers may be present. Outliers (specifically high and extremely high values) in site data represent potentially polluted locations. These observations need to be identified using effective statistical methods. Outliers found in RBRAs and DTLs may represent observations not representative of representative background conditions. Such background locations representing outliers will not be included in statistical evaluations to address assessment objectives of the RBS. A defensible background data set should represent a "single" background population (e.g., representative of site conditions before any of the industrial site related activities) free of contaminating observations such as outliers. In a background data set, outliers may represent potentially contaminated observations from impacted site areas under study or possibly from other polluted site(s).

Furthermore, it needs to be emphasized that outliers (if any) need to be identified in the original raw scale as the remediation and cleanup decisions need to be made using data and statistics (e.g., UTL or UCL) in the original scale. An outlier in the raw scale may not be an outlier in the transformed space (e.g., log-scale). That does not imply that the elevated concentration in the original scale represents a clean location and may be included in the statistical computations such as estimation of a background threshold value (BTV). This topic has been discussed in greater detail in Chapter 7 of ProUCL 4.00.04 Technical Guide (EPA, 2009). It should be pointed out that the use of a log-transformation tends to hide contamination by accommodating outlying observations.

EPA software Scout 2008 offers many robust outlier identification and robust estimation procedures. Several of those methods will be used in evaluations of RBS data as described in the SAP for the SSFL site. The details of the robust outlier identification procedures can be found in the references used in this brief write-up. Several worked out examples using robust methods can be found in Scout 2008 User Guide.

In order to establish that when dealing with multivariate data sets (consisting of multiple radionuclides), multivariate tests are more effective to address statistical issues and in controlling decision errors (false positives and false negatives), both univariate (as commonly used) and multivariate tests supplemented with graphical displays will be used on the same data set. Results based upon two approaches will be compared, and in case of discrepancies between the conclusions derived using the two approaches, the most conservative conclusion protective of human health will be used.

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Appendix C

Analyses of Data Sets with Nondetects (NDs) and Below Detection Limit (BDL) Observations
Statistical Approaches for Data Sets with Nondetect Observations

Nondetect (ND) or below detection limit (BDL) observations are inevitable in environmental data sets. Statisticians (e.g., Helsel, 2005, Singh, Maichle, and Lee, 2006) have developed defensible statistical methods to handle data sets consisting of ND observations with single and multiple detection limits. Singh, Maichle, and Lee (EPA, 2006) studied the performances of the various upper confidence limit computation methods (e.g., Cohen, KM, bootstrap) including the simple substitution methods (such as the DL/2 and DL methods, regression on order statistics – ROS methods) for data sets with ND observations. They concluded that the upper limits obtained using the substitution methods (proxy methods), including the replacement of nondetects by respective DL/2 do not perform well even when the percentage of nondetect observations is low, such as 5%-10%. Therefore, for all statistical analyses, use of substitution methods such as the DL/2 and DL methods will be avoided. Specifically, the use of substitution methods will be avoided to perform GOF test, to perform two sample comparisons, to compute summary statistics and various other limits (e.g., UTL, UPL) used to estimate the background threshold values. For more accurate and defensible results and conclusions, statistically rigorous methods such as the Kaplan-Meier method and bootstrap methods (now available in ProUCL 4.00.04 and Scout 2008) will be used to compute UPLs and UTLs to estimate BTVs.

Also as mentioned in main body of the report, appropriate hypotheses testing approaches such as Gehan test, WRS test, and Quantile test that also handle ND observations (ProUCL.4.00.04) will be used on RBRA and DTL data sets consisting of NDs. It needs to be emphasized that the use of appropriate statistical methods is very important to derive correct and defensible conclusions. For an example, a simple WRS test used on data sets with NDs may lead to incorrect conclusions. For data sets with NDs, it is preferable to use appropriate corrected WRS test (single detection limit) and/or Gehan test (multiple detection limits). For details of these methods with examples, refer to ProUCL 4.00.04 Technical Guide (EPA, 2009).

Appropriate statistical methods (instead of simple Wilcoxon Rank Sum Test) should be used to compare surface soil and subsurface soil concentrations for data sets with nondetects. Several statistical tests (e.g., WRS test, Gehan Test, Quantile Test, Boxplots) are included in ProUCL 4.0 to compare concentrations of two populations (e.g., surface versus subsurface) based upon data sets with and without nondetect observations.

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Appendix D

Avoid the use of Log-transformation and Lognormal Distribution

Avoid the use of Transformations

The process of using statistical methods in the transformed space (e.g., log-transformed space) and then back-transforming the results in the original scale is not a straight forward process. Moreover, back-transformed statistics and estimates (e.g., from log-scale to original scale) often suffer from an unknown amount of transformation bias. The back-transformation formulae vary from transformation to transformation (log, square root, or some other Box-Cox type transformations). Therefore, in case the distributional assumptions (e.g., normality, gamma model) are not satisfied by the data set in the original scale, it is preferable to use nonparametric statistical methods such as the Mann-Whitney or Kruskal Wallis test to compare two or more populations. The nonparametric tests should be supplemented with graphical displays and various other percentiles (e.g., 25%, 50%, 75%, 90%, etc.) useful to compare data sets from two or more populations.

Avoid the use of Log-transformation and Lognormal Distribution

It should be noted that the use of lognormal distribution often tends to hide contamination by accommodating outliers. Moreover, since all decisions need be made based upon values of contaminant of potential concern (COPC) in the original scale, therefore all statistics computed using log-transformation need to be back-transformed in the original scale. Back-transformed statistics suffer from transformation bias. It is also well known that the use of lognormal distribution often yields unrealistic and unstable values of upper limits such as 95% UCL, 95% UPL, and UTLs (e.g., Singh, Singh, and Engelhardt, 1997). Therefore, in order to derive correct and defensible conclusions, the use of lognormal distribution will be avoided; and all statistical tests including outlier tests, two sample t-test and WRS test will be performed in the original raw scale. Specifically, all parametric (in case of normally distributed data sets) and nonparametric tests will be performed on original untransformed data sets.

Not to Use t-test on Log-transformed Data

Some EPA guidance documents (e.g., EPA 1989, EPA 1992, EPA QA/ G-9, 2006) suggest the use of a two sample Student's t-test on log-transformed data to compare the "means" of two skewed populations. Actually, it is observed that a lognormal model is often used as a default model (e.g., EPA RAGS document (1992)) for skewed data distribution even when the data set may not pass a lognormal goodness-of-fit test. The EPA QA/G-9 (2000) document, Section 4.6 (page 4-41) states that: "By transforming the data, assumptions that are not satisfied in the original data can be satisfied by the transformed data. For instance, a right skewed distribution can be transformed to be approximately Gaussian (normal) by using a logarithmic/square-root transformation. Then the normal-theory procedures can be applied to the transformed data. If data are lognormally distributed, then apply parametric procedures to logarithms of the data."

However, no mention of back-transformation has been stated associated with this statement. Also, no statement or guidance has been provided about how to interpret and use those test statistics obtained based upon transformed data sets. This has resulted in frequent improper use of log-transformation in many environmental applications. Specifically, the test statistics computed based upon log-transformed data are used to derive conclusions in the original scale! It should be noted that the equality of means in the transformed space does not ensure the equality of means in the original space. This is further illustrated by a simulated example discussed in the following.

When applicable (both data sets are normally distributed), parametric two sample Student's t-test will be performed on original untransformed data set. Since, the remediation and cleanup decisions have to be made using statistics and results computed in the original scale, therefore, it is recommended to perform statistical tests in the original scale. No attempt will be made to transform data using a log-transformation (or some other transformation), and perform a t-test on log-transformed data, as the equality of means in the log-scale does not imply the equality of means of two populations (e.g., Chatsworth and Santa Susana formations) in the original scale.

Improper Use of Student's t-test to Compare Means of Two Populations Using Log-transformation

Hypotheses testing for population means based upon a t-test using the raw data and log-transformed data are not equivalent procedures. Conclusions derived based upon Student's t- statistic obtained using log-transformed data can lead to incorrect conclusion regarding the equality of the means of the two populations under study (e.g., here the RBRA and DTL). Consider two data sets that follow lognormal distributions. Note that if the mean and standard deviation (SD) of log-transformed population are μ and s^2, then the mean of the lognormal distribution is given by exp ($\mu + s^2/2$). The detailed discussion about these issues can be found in Singh, Singh, and Engelhardt (1997). The mean of the lognormal population (raw) depends both upon the mean and SD of the log-transformed data - a fact often forgotten by a typical user. It should also be pointed out that comparing the medians of two populations is not equivalent to comparing the means of two populations unless the populations are normally or approximately normally (symmetrically) distributed.

For positively skewed data sets, the mean is much greater than the median. For highly skewed data sets, the actual difference between the median and mean can be enormously high. For example, the median of a lognormal population, LN (5, 4^2) is only 148.4 where as the mean is 442413.39. Obviously, for such highly skewed data sets, the cleanup decisions made based upon sample median (=148.4) can incorrectly lead to the decision that the site represented by a LN(5, 4^2) population is clean, and site concentrations are similar to those of the background population, LN(5, 1^2) with median 148.4, and mean = 244.69. Note that the medians of the lognormal populations LN (5, 1^2) (= background), LN (5, 2^2), LN (5, 3^2) and LN (5, 4^2) are all the same, but their means are significantly different. Specifically, the medians of LN (5, 1^2) and LN (5, 4^2) are the same (=148.4), but the means are very different. The population represented by LN (5, 4^2) is highly contaminated and is far different from the cleaner background population represented by LN (5, 1^2) with mean =244.69. Obviously, the equality of two medians does not imply the equality of two means.

To illustrate this issue in mathematical terminology, let a_1 and a_2 be the true means of the two lognormal distributions with the corresponding means and standard deviations of the log-transformed populations as (μ_1, s_1), and (μ_2, s_2). The means, a_1 and a_2, of the two lognormal populations (in original scale) are given by exp ($\mu_1 + s_1^2/2$) and exp ($\mu_2 + s_2^2/2$), respectively. Also note that the corresponding medians of the original lognormal populations are exp (μ_1) and exp (μ_2). Thus testing for the equality of μ_1 and μ_2 (means of log-transformed data) does not necessarily imply the equality of the means, a_1 and a_2, in the original scale. If the objective is to compare the medians (and not the means) of two populations, then one may use t-test on log-transformed data. However, as discussed above, the equality of medians is not sufficient and adequate enough to demonstrate that the site concentrations are similar to those of the background (e.g., are not impacted by the site activities). Under this scenario, many site observations can be highly contaminated, but the equality of medians can lead to the incorrect conclusion that the site and background concentrations are comparable.

In order to compare the means in the original scale, one also has to account for the standard deviations, s_1 and s_2 (which are unknown in practice and may have to be estimated using the available data) in the exponents. At best, such a t-test will provide only an approximate test for comparing two population means of approximately symmetric to mildly skewed lognormal populations (when the mean and median of lognormal populations (original scale) tend to be roughly the same). The issue that the use of a t-test on log-transformed data is not appropriate to test the equality of means of two moderately to

highly skewed lognormal populations can be very simply illustrated by writing down the hypotheses in both scales: the original scale and the log scale.

Original Scale: The main objective here is to test whether the site mean, a_2 is comparable (or significantly greater than) to the background mean, a_1, at some level of significance (say a = 0.05). Thus the null and the alternative hypotheses to be tested may be H_0: $a_1 = a_2$, vs. H_1: a_1 ¹ a_2 (or $a_1 > a_2$).

Log Scale: When a t-test is used on log-transformed data, the hypotheses in the log-scale are given by the statements: H_0: $\mu_2 = \mu_1$, vs. H_1: μ_2 ¹ μ_1 (or $\mu_2 > \mu_1$). This is not what we are trying to test, we want to compare a_1 and a_2, not μ_1 and μ_2.

As shown above, there can be a huge difference between the values of a_1 and a_2, and only a minor difference in the values of μ_1 and μ_2. Thus based upon the data sets, if it is concluded that there is no significant differences between μ_2 and μ_1 does not necessarily imply that there are no significant differences in a_1 and a_2. An example illustrating this issue is discussed as follows.

Example: Using the statistical software package, MINITAB, data sets of size 20 each are generated from two lognormally distributed populations (e.g., one background and one from a contaminated site area of concern) with means of the log-transformed data for both populations as $\mu_1 = \mu_2 = 5$ and the standard deviations as $s_1 = 2$ and $s_2 = 4$, respectively with the background population having the sd = 2, and the site area having the sd = 4. Note that the true mean, a_1, of the background population is 1096.63, and the true mean, a_2, of the contaminated site area is 442413.39. The generated data sets do follow lognormal distributions. Note that the mean of log-transformed data being 5 for both populations, therefore, the two populations have the same median = 148.4 but the means are significantly different. The objective is to test whether the means, a_1 and a_2, of the two populations in the original scale are equal. The two sample, t-test when used on the log-transformed data leads to the conclusion that there is no significant difference in the mean concentrations, $\mu_1$and μ_2, of the log-transformed data. This does not imply that the true means, a_1 and a_2 are also equal. The t-test results obtained using MINITAB on these log-transformed data are summarized as follows.

	N	Mean	StDev	SE Mean
P1(Background)	20	5.07	1.85	0.41
P2(Site)	20	5.11	4.20	0.94

95% CI for mu P1 - mu P4: (-2.15, 2.07)
T-Test mu P1 = mu P2 (vs <): T = -0.04, P = 0.48, DF = 26

For the log-transformed data, the t-value is = -0.04, which is not significant at any of the commonly used levels (= 0.05, 0.1, 0.2.). This observation leads to the conclusion that there are no significant differences in the means of the two log-transformed populations (which is true). But this does not imply that the means in the original scale are also equal - a common practice used by practitioners in environmental applications. The equality of medians is not good enough to come to the conclusion that the site concentrations are not impacted and comparable to those of the background.

A more serious problem: Using the same two sample t-test on log-transformed data to test the hypothesis H_0: a_1 ³ a_2 vs. H_1: $a_1 < a_2$, exact the same t-test statistic (= -0.04) will be obtained leading to the conclusion of not rejecting the null hypothesis and concluding (in log-scale) that the background mean may be greater than the site mean! A naive user may conclude that the background mean in original scale is also greater than the site mean - which, of course, is not true. It is, therefore, strongly recommended not to use the t-test to compare the means of two populations based upon log-transformed data for both forms of hypothesis testing, Background Form 1 and Background Form 2. It is always useful to supplement statistical tests (especially when formulated and used incorrectly) with graphical displays.

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Glossary of Terms

Accuracy of an estimate: Degree to which the estimate matches the true parameter such as mean

Below Detection Limit (BDL) or Nondetect (ND) observations: Represent those values present at low concentration/trace levels and cannot be measured below certain detection limits (DLs). For instance, assume that certain instrumentation that can only read measurements within a certain range-data obtained from this instrument may result in a left censored data sets, as measurements below the DLs cannot be measured.

Confidence coefficient/Level: The measure of probability (1- α) associated with a confidence interval (such as upper confidence limit = UCL) that the interval will include the true population parameter (e.g., population mean, μ) of interest (We can be 95% confident that this interval encloses the actual population parameter.)

Data: Information, measurements, analytical results (e.g., radionuclides) obtained from a survey, sampling experiment, investigation. Data (numerical values) are stored in a database, usually in electronic form such as Excel Spreadsheets.

Raw data: Data that has not been subjected to any sort of mathematical manipulation or statistical treatment such as grouping, coding, censoring, or transformation.

Hypothesis: A statistical hypothesis is a statement concerning the value of parameters or form of a probability distribution for a designated population or populations. More generally, a statistical hypothesis is a formal statement about the underlying mechanisms that generated some observed data. For an example, hypothesis can be stated as: Mean of Population 1 = Mean of Population 2.

Hypothesis testing: A term used to refer to testing whether observed data (sampled data, observed measurements) support a statement or hypothesis.

Null hypothesis, H_0: In general, this term relates to a particular research hypothesis being tested, as distinct from the alternative hypothesis, which is accepted if the research hypothesis is rejected. Contrary to intuition, the null hypothesis is often a research hypothesis that the analyst would prefer to reject in favor of the alternative hypothesis, but this is not always the case. For example, the null hypothesis specifies that there is no difference, no effect or no relationship.

Alternative Hypothesis, H_1: The hypothesis, which one accepts when the null hypothesis, H_0 (the hypothesis under test) is rejected. It is usually denoted by H_1.

One-tail (one-sided) test: Also known as a one-sided test, a test of a statistical hypothesis in which the region of rejection consists of either the right hand tail or the left hand tail of the sampling distribution of the test statistic. Philosophically, a one-sided test represents the analyst's a priori belief that a certain population parameter is either greater or less than a specified value. One tail tests provide more specific information and make it easier to gain statistical significance than two tailed tests.

Two-tailed (two-sided) test: A test of significance in which both directions are, a priori, equally likely.

Type I error, Alpha Level, α of significance: Alpha is the probability assigned by the analyst that reflects the degree of acceptable risk for rejecting the null hypothesis when in fact the null hypothesis is true. In other words, the level of significance, α is the probability of rejecting a null hypothesis, when it is in fact true. It is also known the probability of committing a Type I error. Erroneous rejection of the null hypothesis is known as a Type I error. Alpha, or level of significance, is pre-selected by the analyst to determine the type I error rate. The level of confidence of a particular test is given by 1 - α.

Type II error, β: If, as the result of a test statistic computed on sample data, a statistical hypothesis is accepted when it is false, i.e. when it should have been rejected, then a type II error has been made. Erroneous acceptance of the null hypothesis is known as a Type II error.
Beta is pre-selected by the analyst to determine the type II error rate. The Power of a particular test is given by 1 - β.

p = 0.05: The most common probability used as alpha level in statistical inference testing.

Data Distribution: Probability model (e.g., normal, gamma) assigned (based upon statistical goodness-of-fit tests) to the sampled data set of analytical results.

Gamma distribution: The Gamma distribution includes as special cases the chi-square distribution and the exponential distribution. This distribution is often used to model positively skewed data sets.

Normal /Gaussian distribution: The Gaussian (another name for normal) distribution is characterized by its symmetric shape and has a bell-shaped appearance. The normal distribution is the most commonly used model, and forms the cornerstone of a substantial portion of statistical theory. Gaussian distribution has the two parameters mean, mu and SD, s; when mu = 0 and s = 1, it is said to be in its standard form, and it is referred to as the standard normal distribution.

Goodness- of- Fit (GOF): Goodness- of- fit describes a class of statistics (e.g., Shapiro-Wilk statistics, Kolmogorov-Smirnov test) used to assess the fit of a model to observed/sampled data.

Interval Estimate: The estimation of a population parameter by specifying a range of values bounded by an upper and a lower limit, within which the true value is asserted to lie.

Parameter: This word occurs in its customary mathematical meaning of an unknown quantity that varies over a certain set of inputs. In statistical modeling, it most usually occurs in expressions defining frequency or probability distributions in terms of their relevant parameters (such as mean and variance of normal distribution). Of utmost importance is the notion that statistical parameters are merely estimates, computed from the sample data, which are meant to provide insight as to what the true population parameter value is, although the true population parameter always remains unknown to the analyst.

Population (or Universe): In statistical terminology, the word population is applied to any finite or infinite collection of individuals. It is important to distinguish between the populations for which statistical parameters are fixed and unknown at any given instant in time, and the sample of the population, from which estimates of the population parameters are computed. Population parameters are generally unknown because the analyst can rarely afford to measure all members of a population, and so a random sample is drawn.

Prediction interval: A prediction interval is a calculated range of values known to contain some future observation over the average of repeated trials with specific certainty (confidence coefficient, probability).

Precision: The precision or efficiency of an estimator is its tendency to have its values cluster closely around the mean of its sampling distribution. Precise estimators are preferred to less precise estimators.

Probability density functions (probability distributions): knowing the probability that a random variable takes on certain values, judgments can be made as to how likely or unlikely were the observed values.

Robustness: A method of statistical inference is said to be robust if it remains relatively unaffected when all of its underlying assumptions are not met.

Sample: A part or subset of a population, which is obtained through a recruitment or selection process, usually with the objective of understanding better the parent population. Statistics are computed on sample data to make formal statements about the population of interest. If the sample is not representative of the population, then statements made based on sample statistics will be incorrect to some degree.

Significant/Statistically significant: An effect is significant if the value of the statistic used to test it lies outside acceptable limits i.e. if the hypothesis that the effect is not present is rejected.

Skewness: Skewness is the lack of symmetry in a probability distribution. In a skewed distribution the mean and median are not coincident.

Standard normal variable: a normal distributed variable with mean 0 and standard deviation 1.

Statistic: A summary value calculated from a sample of observations; a number calculated from a sample of observed data to make an inference about the population to which the sample belongs

Statistics: The branch of mathematics that deals with all aspects of the science of decision-making and analysis of data in the face of uncertainty.

Statistical inference: statistical inference is a form of reasoning from sample data to population parameters; that is, any generalization, prediction, estimate, or decision based on a sample and made about the population. There are two schools of thought in statistical inference, classical or frequentist statistics for which R. A. Fisher is considered to be the founding father, and Bayesian inference, discovered by a man bearing the same name.

Statistical methods: Statistical methods are similar to a glass lens through which statisticians and other practitioners inspect and evaluate the phenomenon of interest such as a parameter (mean, median) or a statement about those parameters (hypotheses). The underlying mechanisms present in the population represents reality, the sample represents a snapshot of the population, and statistical methods represent a means of quantifying various aspects of the sample.

Transformation: A transformation is the change in the scale of a variable. Transformations are performed to simplify calculations, to meet specific statistical modeling assumptions, to linearize an otherwise non-linear relation with another variable, to impose practical limitations on a variable, and to change the characteristic shape of a probability distribution of the variable in its original scale.

Unbiased Estimator: An estimator whose expected value (namely the mean of the sampling distribution) equals the parameter it is supposed to estimate. In general unbiased estimators are preferred to biased estimators of population parameters. There are rare cases, however, when biased estimators are preferred because they are much more efficient than alternative estimators.

Outlier: A single or several values which lay far outside of the center of distribution. Outliers generally drastically effect (distort) all nonresistant statistics (e.g., mean, UCLs, UPLs) and parametric analyses and hence, should be investigated as to their cause. Outliers are identified as such because they "appear" to be outlying with respect to the main body of the data (dominant population). In many cases outliers can be traced to errors in data collecting, recording, or calculation, and can be corrected or appropriately discarded.

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APPENDIX B

POTENTIAL IMPACT OF RADIONUCLIDES WITH SENSITIVITIES NOT MEETING AGRICULTURAL PRGS

Several of the target radioisotopes identified in Table 1.9 are associated with MDCs that do not meet the Agricultural PRG target MDC as established by SB 990. The Agricultural PRGs have been established to correspond to a cancer risk from soil exposure corresponding to 1 x 10^{-6}, which is the lower end of the EPA target range of 1 x 10^{-4} to 1 x 10^{-6}. The effect of analytical sensitivity greater than the MDC is to raise risk factor associated with the lowest soil concentration that can be reliably detected and quantified. The affected analytes and the risk level associated with the lowest MDC achievable by PASI are shown in Table B.1.

The risk associated with the best available MDC from PASI is within the EPA target risk range of 1 x 10^{-4} to 1 x 10^{-6} for most of the isotopes where the MDC is greater than the Agricultural PRG. There are four exceptions: carbon-14, iodine-129, lead-210, and uranium-232.

Carbon-14: The carbon-14 Agricultural PRG is below the expected concentration of naturally occurring carbon-14 in uncontaminated soils. The MDC proposed by PASI is higher than those proposed by other laboratories during the subcontractor solicitation process; however, the MDCs, and corresponding method uncertainties among the laboratories, are not sufficiently different to have a practical impact on the ability to discriminate activity at the level of the agricultural PRG.

Iodine-129: PASI's proposed best MDC is comparable to the MDCs proposed by other laboratories during the subcontractor solicitation process. PASI's proposed method does not correspond to promulgated method and PASI will be required to provide method validation documentation.

Lead-210: PASI is using a promulgated method and the proposed best MDC is comparable to the MDCs proposed by other laboratories during the subcontractor solicitation process.

Uranium-232: PASI is using a promulgated method. Although the proposed best MDC is comparable to the MDCs proposed by other laboratories during the subcontractor solicitation process, several of these other laboratories proposed MDCs that were slightly superior to PASI's. In the case of uranium-232, the MDC proposed by PASI corresponds to a risk of 5.6 x 10^{-4}, which is only slightly above the EPA target range.

In all cases, there are constraints on the technical adjustments that can be made to lower MDCs. Increasing counting times can provide some improvement in sensitivity; however, sensitivity improves as a square root of the counting time under optimal conditions, and this improvement can be even less due to sample or methodological issues. Consequently, to achieve an improvement of an order of magnitude in sensitivity, a hundred-fold increase of counting time would be required. Theoretically, improvements in sensitivity are directly proportional to increases in sample quantity; however, increasing the sample quantity can have other effects on the efficiency of the counting process. The analyses generally specify a sample aliquot size that allows for maximum efficiency of the sample extraction and preparation process and increasing sample aliquot size can quickly lead to diminishing returns due to decreases in counting efficiency (for non-extractive methods such as gamma counting) or decreases in extraction efficiency (for methods that involve extraction and chemical

purification). PASI has examined all its procedures and evaluated the effects of increased counting times and sample aliquot size and the proposed best MDCs represent the values that PASI believes can be reliably achieved under laboratory conditions.

Table B.1
Risk Associated with Radioisotopes with MDCs Greater than Agricultural PRGs

Isotope	Ag PRG (pCi/g)	Best MDC (pCi/g)	Associated Risk
Americium-241	0.0132	0.05	3.8×10^{-6}
Americium-243 (+D)	0.0111	0.05	4.5×10^{-6}
Carbon-14	0.0000563	10	**1.8×10^{-1}**
Iodine-129	0.0000276	1.0	**3.6×10^{-2}**
Iron-55	0.821	10	1.2×10^{-5}
Lead-210 (+D)	0.0000642	0.2	**3.1×10^{-3}**
Neptunium-237 (+D)	0.000448	0.0111	2.5×10^{-5}
Radium-226 (+D)	0.000632	0.01	1.6×10^{-5}
Radium-228 (+D)	0.00116	0.01	8.6×10^{-6}
Silver-108m	0.00629	0.01	1.6×10^{-6}
Strontium-90 (+D)	0.00139	0.03	2.2×10^{-5}
Technetium-99	0.00557	0.1	1.8×10^{-5}
Thorium-228 (+D)	0.0338	0.04	1.2×10^{-6}
Thorium-229 (+D)	0.00171	0.05	2.9×10^{-5}
Thorium-230	0.0105	0.04	3.8×10^{-6}
Thorium-232	0.00942	0.04	4.2×10^{-6}
Uranium-232	0.00059	0.33	**5.6×10^{-4}**
Uranium-233	0.00184	0.04	2.2×10^{-5}
Uranium-234	0.00187	0.04	2.1×10^{-5}
Uranium-235	0.00181	0.04	2.2×10^{-5}
Uranium-236	0.00198	0.04	2.0×10^{-5}
Uranium-238	0.00147	0.04	2.7×10^{-5}

(+D) = The listed for this isotope plus daughters is presented.
Risk values in bold and shaded indicates a risk number outside the EPA target range of 1×10^{-4} to 1×10^{-6}.

APPENDIX C

PACE ANALYTICAL SERVICES, INC.
LABORATORY QUALITY ASSURANCE MANUAL

Pace Analytical™

QUALITY ASSURANCE MANUAL

Quality Assurance/Quality Control
Policies and Procedures
Revision 12.0

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PACE ANALYTICAL SERVICES – PITTSBURGH
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1.0 INTRODUCTION AND ORGANIZATIONAL STRUCTURE

"Working together to protect our environment and improve our health"

Pace Analytical Services Inc. - Mission Statement

Introduction to PASI

Pace Analytical Services, Inc. (PASI) is a privately held, full-service analytical testing firm operating a nationwide system of laboratories. PASI offers extensive services beyond standard analytical testing, including: bioassay for aquatic toxicity, air toxics, industrial hygiene testing, explosives, high resolution mass spectroscopy (including dioxins, furans and coplanar PCB's), radiochemical analyses, product testing, pharmaceutical testing, field services and mobile laboratory capabilities. PASI has implemented a consistent Quality System in each of its laboratories and service centers. In addition, the company utilizes an advanced data management system that is highly efficient and allows for flexible data reporting. Together, these systems ensure data reliability and superior on-time performance. This document defines the Quality System and QA/QC protocols.

Our goal is to combine our expertise in laboratory operations with customized solutions to meet the specific needs of our customers.

Statement of Purpose

To meet the business needs of our customers for high quality, cost-effective analytical measurements and services.

Quality Policy Statement and Goals of the Quality System

The PASI management is committed to maintaining the highest possible standard of service for our customers by following a documented quality system. The overall objective of this quality system is to provide reliable data through adherence to rigorous quality assurance policies and quality control procedures as documented in this Quality Assurance Manual.

All personnel within the PASI network are required to be familiar with all facets of the quality system and implement these policies and procedures in their daily work. This daily focus on quality is applied with initial project planning, continued through all field and laboratory activities, and is ultimately included in the final report generation.

PASI management demonstrates its commitment to quality by providing the resources, including facilities, equipment and personnel to ensure the adherence to these documented policies and procedures and to promote the continuous improvement of the quality system. All PASI personnel comply with all current applicable state, federal, and industry standards (such as the NELAC and ISO 17025 standards).

Pace Analytical Services Core Values

- **INTEGRITY**
- **VALUE EMPLOYEES**
- **KNOW OUR CUSTOMERS**
- **HONOR COMMITMENTS**
- **FLEXIBLE RESPONSE TO DEMAND**
- **PURSUE OPPORTUNITIES**
- **CONTINUOUSLY IMPROVE**

Code of Ethics

PASI's fundamental ethical principles are as follows:

- Each PASI employee is responsible for the propriety and consequences of his or her actions.
- Each PASI employee must conduct all aspects of Company business in an ethical and strictly legal manner, and must obey the laws of the United States and of all localities, states and nations where PASI does business or seeks to do business.
- Each PASI employee must reflect the highest standards of honesty, integrity and fairness on behalf of the Company with customers, suppliers, the public, and one another.

Strict adherence by each PASI employee to this Code of Ethics and to the Standards of Conduct is essential to the continued vitality of PASI.

Failure to comply with the Code of Ethics and Standards of Conduct will result in disciplinary action up to and including termination and referral for civil or criminal prosecution where appropriate. An employee will be notified of an infraction and given an opportunity to explain, as prescribed under current disciplinary procedures.

Standards of Conduct

1.1.1 Data Integrity

The accuracy and integrity of the analytical results produced at PASI are the cornerstones of the company. Lack of data integrity is an assault on our most basic values and puts PASI and its employees at grave financial and legal risk. Therefore, employees are to accurately prepare and maintain all technical records, scientific notebooks, calculations and databases. Employees are prohibited from making false entries or misrepresentations of data (e.g., dates, calculations, results or conclusions).

Managerial staff must make every effort to ensure that personnel are free from any undue pressures that may affect the quality or integrity of their work; including commercial, financial, over-scheduling and working condition pressures.

1.1.2 Confidentiality

PASI employees must not (directly or indirectly) use or disclose confidential or proprietary information except when in connection with their duties at PASI. This is effective over the course of employment and for a period of two years thereafter.

Confidential or proprietary information, belonging to either PASI and/or its customers, includes but is not limited to test results, trade secrets, research and development matters, procedures, methods, processes and standards, company-specific techniques and equipment, marketing and customer information, inventions, materials composition, etc.

1.1.3 Conflict of Interest

PASI employees must avoid situations that might involve a conflict of interest or appear questionable to others. The employee must be careful in two general areas:

- Participation in activities that conflict or appear to conflict with PASI responsibilities.
- Offering or accepting anything that might influence the recipient or cause another person to believe that the recipient may be influenced. This includes bribes, kickbacks or illegal payments.

Employees are not to engage in outside business or economic activity relating to a sale or purchase by the Company. Other questionable activities include service on the Board of Directors of a competing or supplier company, significant ownership in a competing or supplier company, employment for a competing or supplier company or participation in any outside business during the employee's work hours.

1.1.4 Compliance

All employees are required to read, understand and comply with the various components of the standards listed in this document. As confirmation that they understand this responsibility, each employee is required to sign an acknowledgment form (either hardcopy or in electronic database) annually (or as revisions become finalized) that becomes part of the employee's permanent record. Employees will be held accountable for complying with the Quality Systems as summarized in the Quality Assurance Manual.

Laboratory Organization

The PASI Corporate Office centralizes company-wide accounting, business development, financial management, human resources development, information systems, marketing, quality, safety, and training activities. PASI's Director of Quality, Safety & Training is responsible for assisting the development, implementation and monitoring of quality programs for the company. See Attachment IIB for the Corporate Organizational structure.

Each laboratory within the system operates with local management, but all share common systems and receive support from the Corporate Office.

A General Manager (GM) supervises each regional laboratory. Some operations may have an Assistant General Manager (AGM) in situations where the General Manager is responsible for multiple laboratory facilities and is not necessarily in the facility on a regular basis. Quality Managers (QM) at each lab report directly to their General Manager (or Assistant General Manager) but receive guidance and direction from the Director of Quality, Safety & Training.

The General Manager bears the responsibility for the laboratory operations and serves as the final, local authority in all matters. In the absence of the General Manager (and an Assistant General Manager), the Quality Manager serves as the next in command. He or she assumes the responsibilities of the GM until the GM is available to resume the duties of their position. In the absence of the GM and QM, management responsibility of the laboratory is passed to the Technical Director – provided such a position is identified – and then to the most senior department manager until the return of the GM or QM. The most senior department manager in charge may include the Client Services Manager or the Administrative Business Manager at the discretion of the General Manager.

A Technical Director who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member meeting the qualifications of the technical director to temporarily perform this function. The laboratory General Manager or Quality Manager has the authority to make this designation in the event the existing Technical Director is unable to do so. If this absence exceeds 65 consecutive calendar days, the primary accrediting authority shall be notified in writing.

The Quality Manager has the responsibility and authority to ensure the Quality System is implemented and followed at all times. In circumstances where a laboratory is not meeting the established level of quality or following the policies set for in this Quality Assurance Manual, the Quality Manager has the authority to halt laboratory operations should he or she deem such an action necessary. The QM will immediately communicate the halting of operations to the GM and keep him or her posted on the progress of corrective actions. In the event the GM and QM are not in agreement as to the need for the suspension, the Chief Operating Officer and Director of Quality, Safety and Training will be called in to mediate the situation.

Under the direction of the General Manager, the technical staff of the laboratory is generally organized into the following functional groups:

- Organic Sample Preparation
- Wet Chemistry Analysis
- Metals Analysis
- Volatiles Analysis
- Semi-volatiles Analysis
- Radiochemical Analysis
- Product Testing
- Equipment Maintenance
- Microbiology

Appropriate support groups are present in each laboratory. The actual organizational structure for PASI – Pittsburgh is listed in Attachment IIA. In the event of a change in General Manager, Quality Manager, or Technical Director(s), the laboratory will notify its accrediting authorities and revise the organizational chart in the Quality Assurance Manual (QAM) within 30 days. For changes in Department Managers or Supervisors or other laboratory personnel, no notifications will be sent to the laboratory's accrediting agencies; changes to the organizational chart will be updated during or prior to the annual review process. Changes or additions in these key personnel will also be noted by the additional signatures on the QAM Local Approval page. In any case, the QAM will remain in effect until the next scheduled revision.

Laboratory Job Descriptions

1.1.5 **Senior General Manager**

1. Oversees all functions of all the operations within their designated region.
2. Oversees the development of local General Managers within their designated region.
3. Oversees and authorizes personnel development including staffing, recruiting, training, workload scheduling, employee retention and motivation.
4. Oversees the preparation of budgets and staffing plans for all operations within their designated region.
5. Ensures compliance with all applicable state, federal and industry standards.

1.1.6 General Manager

1. Oversees all functions of the operations.
2. Authorizes personnel development including staffing, recruiting, training, workload scheduling, employee retention and motivation.
3. Prepares budgets and staffing plans.
4. Monitors the Quality Systems of the laboratory and advises the Quality Manager accordingly.
5. Ensures compliance with all applicable state, federal and industry standards.

1.8.2 Assistant General Manager / Operations Manager

1. In the absence of the GM, performs all duties as listed above for the General Manager.
2. Oversees the daily production and quality activities of the department.
3. Manages department and works with staff to ensure department objectives are met.
4. Works with other departments to ensure capacity and customer expectations are accurately understood and met.
5. Works with General Manager to prepare appropriate budget and staffing plans for the department.

6. Responsible for prioritizing personnel and production activities within the department.
7. Performs formal and informal performance reviews of departmental staff.

1.8.3 Quality Manager

1. Oversees the laboratory Quality Systems while functioning independently from laboratory operations. Reports directly to the General Manager.
2. Monitors Quality Assurance policies and Quality Control procedures to ensure that the laboratory achieves established standards of quality.
3. Maintains records of quality control data and evaluates data quality.
4. Conducts periodic internal audits and coordinates external audits performed by regulatory agencies or customer representatives.
5. Reviews and maintains records of proficiency testing results.
6. Maintains the document control system
7. Assists in development and implementation of appropriate training programs.
8. Provides technical support to laboratory operations regarding methodology and project QA/QC requirements.
9. Maintains certifications from federal and state programs.
10. Ensures compliance with all applicable state, federal and industry standards.
11. Maintains the laboratory training records, including those in the Learning Management System (LMS).

1.8.4 Technical Director

1. Monitors the standards of performance in quality assurance and quality control data
2. Monitors the validity of analyses performed and data generated.
3. Reviews tenders, contracts and QAPPs to ensure the laboratory can meet the data quality objectives for any given project
4. Serves as the general manager of the laboratory in the absence of the GM, AGM and QM.
5. Provides technical guidance in the review, development and validation of new methodologies.

1.8.5 Administrative Business Manager

1. Responsible for financial and administrative management for the entire facility.
2. Provides input relative to tactical and strategic planning activities.
3. Organizes financial information so that the facility is run as a fiscally responsible business.
4. Works with staff to confirm that appropriate processes are put in place to track revenues and expenses.
5. Provide ongoing financial information to the General Manager and the management team so they can better manage their business.
6. Utilizes historical information and trends to accurately forecast future financial positions.
7. Works with management to ensure that key measurements (mileposts) are put in place to be utilized for tread analysis—this will include personnel and supply expenses, and key revenue and expense ratios.
8. Works with General Manager to develop accurate budget and track on an ongoing basis.
9. Works with entire management team to submit complete and justified capital budget requests and to balance requests across departments.
10. Works with project management team and administrative support staff to ensure timely and accurate invoicing.

1.8.6 Client Services Manager

1. Oversees all the day to day activities of the Client Services Department which includes Project Management and, possibly, Sample Control.

2. Responsible for staffing and all personnel management related issues for Client Services.
3. Serves as the primary senior consultant to customers on all project related issues such as set up, initiation, execution and closure.
4. Performs or is capable of performing all duties listed for that of Project Manager.

1.8.7 Project Manager

1. Coordinates daily activities including taking orders, reporting data and analytical results.
2. Serves as the primary technical and administrative liaison between customers and PASI.
3. Communicates with operations staff to update and set project priorities.
4. Provides results to customers in the requested format (verbal, hardcopy, electronic, etc.).
5. Works with customers, laboratory staff, and other appropriate PASI staff to develop project statements of work or resolve problems of data quality.
3. Responsible for solicitation of work requests, assisting with proposal preparation and project initiation with customers and maintain customer records.
4. Mediation of project schedules and scope of work through communication with internal resources and management.
5. Responsible for preparing routine and non-routine quotations, reports and technical papers.
6. Interfaces between customers and management personnel to achieve customer satisfaction.
7. Manages large-scale complex projects.
8. Supervises less experienced project managers and provide guidance on management of complex projects.
6. Arranges bottle orders and shipment of sample kits to customers.
7. Verifies login information relative to project requirements and field sample Chains-of-Custody.

1.8.8 Project Coordinator

1. Responsible for preparation of project specifications and provides technical/project support.
2. Coordinates project needs with other department sections and assists with proposal preparation.
3. Prepares routine proposals and invoicing.
4. Responsible for scanning, copying, assembling and binding final reports.
5. Other duties include filing, maintaining forms, process outgoing mail, maintaining training database and data entry.

1.8.8 Department Manager/Supervisor

1. Oversees the day-to-day production and quality activities of their assign department.
2. Ensures that quality assurance and quality control criteria of analytical methods and projects are satisfied.
3. Assesses data quality and takes corrective action when necessary.
4. Approves and releases technical and data management reports.
5. Ensures compliance with all applicable state, federal and industry standards.

1.8.9 Group Leader/Supervisor

1. Trains analysts in laboratory operations and analytical procedures.
1. Organizes and schedules analyses with consideration for sample holding times.
2. Implements data verification procedures by assigning data verification duties to appropriate personnel.
3. Evaluates instrument performance and supervises instrument calibration and preventive maintenance programs.
4. Reports non-compliance situations to laboratory management including the Quality Manager.

1.8.10 Laboratory Analyst

1. Performs detailed preparation and analysis of samples according to published methods and laboratory procedures.
2. Processes and evaluates raw data obtained from preparation and analysis steps.
3. Generates final results from raw data, performing primary review against method criteria.
4. Monitors quality control data associated with analysis and preparation. This includes examination of raw data such as chromatograms as well as an inspection of reduced data, calibration curves, and laboratory notebooks.
5. Reports data in LIMS, authorizing for release pending secondary approval.
6. Conducts routine and non-routine maintenance of equipment as required.
7. Performs or is capable of performing all duties associated with that of Laboratory Technician.

1.8.11 Laboratory Technician

1. Prepares standards and reagents according to published methods or in house procedures.
2. Performs preparation and analytical steps for basic laboratory methods.
3. Works under the direction of a Laboratory Analyst on complex methodologies.
4. Assists Laboratory Analysts on preparation, analytical or data reduction steps for complex methodologies.
5. Monitors quality control data as required or directed. This includes examination of raw data such as chromatograms as well as an inspection of reduced data, calibration curves, and laboratory notebooks.

1.8.12 Field Technician

1. Prepares and samples according to published methods, PASI Quality Assurance Manual and/or customer directed sampling objectives.
2. Capable of the collection of representative environmental or process related air samples.
3. Use computer software to compile, organize, create tables, create graphics and write test reports.
4. Reviews project documentation for completeness, method compliance and contract fulfillment.
5. Train less experienced environmental technicians and provide guidance on sampling and analysis.
6. Responsible for project initiation and contact follow-up.
7. Develop sampling plans and prepare test plan documents.

1.8.13 Field Analyst

1. Analyzes field samples according to published methods, PASI Quality Assurance Manual and/or customer directed sampling objectives.
2. Capable of the collection and analysis of representative environmental or process related air samples.
3. Proficient in a variety of analytical tests; specifically on-site gas-phase organic and inorganic compounds by extractive fourier transform infrared spectroscopy (FTIR).
4. Train less experienced staff and provide guidance on FTIR sampling and analysis.
5. Assist in reporting tasks and project management responsibilities.
6. Perform back-up support for manager tasks such as reporting needs and customer concerns.

1.8.14 Sample Management Personnel

1. Signs for incoming samples and verifies the data entered on the Chain-of-Custody forms.

2. Enters the sample information into the Laboratory Information Management System (LIMS) for tracking and reporting.
3. Stages samples according to EPA requirements.
4. Assists Project Managers and Coordinators in filling bottle orders and sample shipments.

1.8.15 Systems Administrator or Systems Manager

1. Assists with the creation and maintenance of electronic data deliverables (EDDs).
2. Coordinates the installation and use of all hardware, software and operating systems.
3. Performs troubleshooting on all aforementioned systems.
4. Trains new and existing users on systems and system upgrades.
5. Maintains all system security passwords.
6. Maintains the electronic backups of all computer systems.

1.8.16 Safety/Chemical Hygiene Officer

1. Maintains the laboratory Chemical Hygiene Plan.
2. Plans and implements safety policies and procedures.
3. Maintains safety records.
4. Organizes and/or performs safety training.
5. Performs safety inspections and provides corrective/preventative actions.
6. Assists personnel with safety issues (e.g. personal protective equipment).

1.8.17 Waste Coordinator

1. Evaluates waste streams and helps to select appropriate waste transportation and disposal companies.
2. Maintains complete records of waste disposal including waste manifests and state reports.
3. Assists in training personnel on waste-related issues such as waste handling and storage, waste container labeling, proper satellite accumulation, secondary containment, etc.
4. Conducts a weekly inspection of the waste storage areas of the lab.

1.9 Training and Orientation

Each new employee receives a five part orientation: human resources, ethics and data integrity, safety, Quality Systems, and departmental.

The human resources orientation includes benefits, salary, and company policies. All records are stored with Human Resources.

The ethics and data integrity training covers the obligations of each employee to ensure the defensibility of laboratory data. Employees are provided with general policies related to ethics in the laboratory and specific examples of improper practices that are unacceptable in any PASI facility. The employee is trained to make the right decisions with regards to laboratory practices and where to go for answers in circumstances where they may be unclear as to the correct protocol.

The safety orientation includes an in-depth review of the PASI Chemical Hygiene Plan/Safety Plan, which are consistent with the requirements of OSHA's Hazard Communication Program (29 CFR 1910.1200) and other pertinent regulations.

The Quality Systems orientation provides the new employee with information through an introduction to the Quality Assurance Manual and SOPs, acceptable record keeping practices, and the individual's responsibility to data quality. Quality Systems training is reinforced with the new employee as specific topics are covered during the departmental or analytical method training. Quality Systems training will address policies and practices that ensure the quality and defensibility of the analytical data. These topics include but are not

limited to traceability of measurements, method calibration, calibration verification, accuracy, precision and uncertainty of measurements, corrective actions, documentation and root cause analysis.

The new employee's Department Supervisor provides the employee with a basic understanding of the role of the laboratory within the structure of PASI and the basic elements of that individual's position.

Supervised training uses the following techniques:

- Hands-on training
- Training checklists
- Lectures and training sessions
- Method-specific training
- Conferences and seminars
- Short courses
- Specialized training by instrument manufacturers
- Proficiency testing programs.

Group Supervisors/Leaders are responsible for providing documentation of training and proficiency for each employee under their supervision. The employee's training file indicates what procedures an analyst or a technician is capable of performing, either independently or with supervision. The files also include documentation of continuing capability (see Section 3.4 for details on Demonstration of Capability requirements). Training documentation files for each person are maintained by the Quality Office either in hardcopy format or within the Learning Management System (LMS).

All procedures and training records are maintained and available for review during laboratory audits. These procedures are reviewed/updated periodically by lab management. Additional information can be found in SOPPGH-C-002 **Training of Laboratory Personnel** or its equivalent revision or replacement.

1.10 Laboratory Safety

It is the policy of PASI to make safety and health an integral part of daily operations and to ensure that all employees are provided with safe working conditions, personal protective equipment, and requisite training to do their work without injury. Each employee is responsible for his/her own safety by complying with established company rules and procedures. These rules and procedures as well as a more detailed description of the employees' responsibilities are contained in the corporate Safety Manual and Chemical Hygiene Plan.

1.11 Security and Confidentiality

Security is maintained by controlled access to laboratory buildings. Exterior doors to laboratory buildings remain either locked or continuously monitored by PASI staff. Posted signs direct visitors to the reception office and mark all other areas as off limits to unauthorized personnel. All visitors to the facility must sign the Visitor's Logbook maintained by the receptionist. A staff member will accompany them during the duration of their stay on the premises unless the GM, QM or TD specify otherwise. In this instance, the staff member will escort the visitor back to the reception area at the end of his/her visit where he/she signs out. The last staff member to leave their department for the day should ensure that all outside access points to that area are secure.

Additional security is provided where necessary, e.g., specific secure areas for sample, data and customer report storage, as requested by customers or cases where national security is of concern. These areas are lockable within the facilities, or are in secure offsite storage. Access is limited to specific individuals or their designees. Security of sample storage areas is the responsibility of the Sample Custodian. Security of samples and data during analysis and data reduction is the responsibility of Group Supervisors. Security of customer

report archives is the responsibility of the Client Services Manager. These secure areas are locked whenever these individuals or their designees are not present in the facility.

Access to designated laboratory sample storage locations is limited to authorized personnel only. Provisions for lock and key access are provided. No samples are to be removed without proper authorization. If requested by customer or contract, samples are not to be removed from secure storage areas without filling out the associated internal Chain-of-Custody records.

Standard business practices of confidentiality are applied to all documents and information regarding customer analyses. Specific protocols for handling confidential documents are described in PASI SOPs. Additional protocols for internal identification of samples and data by number only are implemented as required under contract specific Quality Assurance Project Plans (QAPPs).

All information pertaining to a particular customer, including national security concerns will remain confidential. Data will be released to outside agencies only with written authorization from the customer or where federal or state law requires the company to do so (i.e. federal or state subpoena).

2.0 SAMPLE CUSTODY

2.1 Sampling Support

Each individual PASI laboratory provides shipping containers, sample containers (including applicable chemical preservatives), custody documents, and field quality control samples (e.g., trip blanks) to support field-sampling events. Guidelines for sample container types, preservatives, and holding times for a variety of methods are listed in Attachment VIII. Note that all analyses listed are not necessarily performed at all PASI and there may be additional laboratory analyses performed that are not included in these tables. PASI – Pittsburgh may provide pick-up and delivery services to their customers when needed.

Any sampling activities conducted by laboratory field personnel are conducted with the expectation that they will be made for routine monitoring purposes, unless specifically stated to the contrary prior to the field investigation. Therefore, the use of proper sampling procedures cannot be overemphasized. The collection of representative samples depends upon:

- Ensuring that the samples taken are representative of the material or medium being sampled;
- Using proper sampling, sample handling, preservation, and quality control techniques;
- Properly identifying the collected samples and documenting their collection in field records;
- Maintaining sample chain-of-custody; and
- Protecting the collected samples by properly packing and transporting them to the laboratory for analysis.

2.2 Field Services Division

Pace Analytical has a large Field Services Division which is based in their Minneapolis facility as well as limited field service capabilities in some of the other facilities. Field Services provides comprehensive nationwide service offerings including:

- Stack Testing
- Ambient Air
- CEM Certification Testing
- Air Quality Monitoring
- Onsite Analytical Services- FTIR and GC
- Real-time Process Diagnostic/Optimization Testing
- Wastewater, Groundwater and Drinking Water Monitoring
- Storm water and Surface Water Monitoring
- Soil and Waste Sampling
- Mobile Laboratory Services

The Field Services Division operates under the PASI Corporate Quality System, with applicable and necessary provisions to address the activities, methods, and goals specific to Field Services for a unit specific Quality Program. All procedures and methods used by Field Services are documented in Standard Operating Procedures and Procedure Manuals.

2.3 Project Initiation

Prior to accepting new work, the laboratory reviews performance capability. The laboratory establishes that sufficient resources (personnel, equipment capacity, analytical method capability, etc.) are available

to complete the required work. The customer needs and data quality objectives are defined and appropriate environmental test methods are assured to meet customer's requirements by project managers or sales representative. Project Managers review laboratory certifications. Members of the management staff review current instrument capacity, personnel availability and training, analytical procedures capability and projected sample load. Management then informs the sales and client services personnel whether or not the laboratory can accept the new project via written correspondence, email, and/or daily operations meetings.

The laboratory maintains records of all such reviews, including discussions with customers. Routine analytical project documentation of quotes, notes, dates, initials and/or recordings is maintained in a project folder by project management. Conditions for new and more complex contracts are determined by the General Managers and sales representatives. Quality Management is consulted on technical requirements and operations staff provides input on volume capacities. Evidence of these reviews is maintained in the form of awarded Request for Proposals (RFPs), signed quotes or contracts, and a Customer Relationship Management (CRM) database. If a review identifies a potential mismatch between customer requirements and laboratory capabilities and/or capacities, Pace will specify its level of commitment by listing these exceptions to the requirements within the RFP, quote or contract.

Additional information regarding specific procedures for reviewing new work requests can be found in SOP S-ALL-Q-006 ***Review of Analytical Requests*** or its equivalent revision or replacement.

2.4 Chain-Of-Custody

A chain-of-custody (COC) (see Attachment VII) document provides the legal documentation of samples from time of collection to completion of analysis. Importance is stressed on completeness of COCs. PASI has implemented Standard Operating Procedures to ensure that sample custody traceability and responsibility objectives are achieved for every project.

Field personnel or client representatives complete a chain-of-custody form for all samples. Samples are received by the laboratory accompanied by these forms.

If sample shipments are not accompanied by the correct documentation, the Sample Receiving department notifies a Project Manager. The Project Manager then obtains the correct documentation/information from the customer in order for analysis of samples to proceed.

The sampler is responsible for providing the following information on the chain-of-custody form:

- Customer project name
- Project location or number
- Field sample number/identification
- Date and time sampled
- Sample type (matrix)
- Preservative
- Requested analyses
- Sampler signature
- Relinquishing signature
- Date and time relinquished
- Sampler remarks (if applicable)
- Custody Seal Number (if applicable)
- Regulatory Program Designation
- The state where the samples were collected to ensure all applicable state requirements are met
- Turnaround time requested
- Purchase order number

The record is filled out completely and legibly with indelible ink. Errors are corrected by drawing a single line through the initial entry and initialing and dating the change. All transfers of samples are recorded on the chain-of-custody in the "relinquished" and "received by" sections. All information except signatures is printed.

Additional information can be found in SOP PGH-C-001 **Sample Management** or its equivalent revision or replacement.

2.5 Sample Acceptance Policy

In accordance with regulatory guidelines, PASI complies with the following sample acceptance policy for all samples received.

If the samples do not meet the sample receipt acceptance criteria outlined below, the laboratory is required to document all non-compliances, contact the customer, and either reject the samples or fully document any decisions to proceed with analyses of samples which do not meet the criteria. Any results reported from samples not meeting these criteria are appropriately qualified on the final report.

All samples must:

- Have unique customer identification that are clearly marked with durable waterproof labels on the sample containers and that match the chain of custody.
- Have clear documentation on the chain of custody related to the location of the sampling site with the time and date of sample collection.
- Have the sampler's name and signature
- Have the requested analyses clearly marked
- Have clear documentation of any special analysis requirements (data deliverables, etc.);
- Be in appropriate sample containers with clear documentation of the preservatives used.
- Be correctly preserved unless method allows for laboratory preservation.
- Be received within holding time. Any samples with hold times that are exceeded will not be processed without prior customer permission.
- Have sufficient sample volume to proceed with the analytical testing. If insufficient sample volume is received, analysis will not proceed without customer approval.
- Be received within appropriate temperature ranges - not frozen but =6°C (See Note 1), unless program requirements or customer contractual obligations mandate otherwise (see Note 2). The cooler temperature is recorded directly on the COC and the SCUR. Samples that are delivered to the lab immediately after collection are considered acceptable if there is evidence that the chilling process has been started, for example by the arrival of the samples on ice. If samples arrive that are not compliant with these temperature requirements, the customer will be notified. The analysis will NOT proceed unless otherwise directed by the customer. If less than 72 hours remain in the hold time for the analysis, the analysis may be started while the customer is contacted to avoid missing the hold time. Data will be appropriately qualified on the final report.

  Note 1: Temperature will be read and recorded based on the precision of the measuring device. For example, temperatures obtained from a thermometer graduated to 0.1°C will be read and recorded to ±0.1°C. Measurements obtained from a thermometer graduated to 0.5°C will be read to ±0.5°C. Measurements read at the specified precision are not to be rounded down to meet the =6°C limit (i.e. 6.2°C rounded and recorded as 6°C).

  Note 2: Some microbiology methods allow sample receipt temperatures of up to 10°C. Consult the specific method for microbiology samples received above 6°C prior to initiating corrective action for out of temperature preservation conditions.

Upon sample receipt, the following items are also checked and recorded:

- Presence of custody seals or tapes on the shipping containers
- Sample condition: Intact, broken/leaking
- Sample holding time
- Sample pH when required
- Appropriate containers

Samples for drinking water analysis that are improperly preserved, or are received past holding time, are rejected at the time of receipt, with the exception of VOA samples that are tested for pH at the time of analysis.

Additional information can be found in SOPPGH-C-001 **Sample Management** or its equivalent revision or replacement.

2.6 Sample Log-in

After sample inspection, all sample information on the chain-of-custody is entered into the Laboratory Information Management System (LIMS).

This permanent record documents receipt of all sample containers including:

- Customer name and contact
- Customer number
- Pace Analytical project number
- Pace Analytical Project Manager
- Sample descriptions
- Due dates
- List of analyses requested
- Date and time of lab receipt
- Field ID code
- Date and time of collection
- Any comments resulting from inspection for sample rejection

All samples received are logged into the LIMS system within one working day of receipt. Sample login may be delayed due to customer clarification of analysis needed, corrective actions for sample receipt non-conformance, or other unusual circumstances. If the time collected for any sample is unspecified and Pace is unable to obtain this information from the customer, the laboratory will use 08:00 as the time sampled. All hold times will be based on this sampling time and qualified accordingly if exceeded.

The Laboratory Information Management System (EPIC Pro) automatically generates a unique identification number for each sample created in the system. The LIMS sample number follows the general convention of BB-XXXXX-YYY. The BB represents the laboratory identification within Pace's laboratory network. The 5 digit "X" number represents the project number followed by a 3 digit sample number. The project number is a sequential number that is assigned as a new project is created. The sample number corresponds to the number of samples submitted by the client. In addition to the unique sample ID, there is a sample container ID that consists of the sample number, the container type (ex. BP1U), and bottle 1 of Y, where Y represent the total number of containers of that particular type. Together the sample LIMs number and sample container ID number create a unique barcode encryption that can be linked to the sample analysis requested by the client. This unique identification number is placed on the sample container as a durable label and becomes the link between the laboratory's sample management system and the client's field identification; it will be a permanent reference number for all future interactions.

Sample labels are printed from the LIMS system and affixed to each sample container.

Samples with hold times that are near expiration date/time may be sent directly to the laboratory for analysis at the discretion of the Project Manager and/or General Manager.

Additional information can be found in SOP PGH-C-001 **Sample Management** or its equivalent revision or replacement.

2.7 Sample Storage

2.7.1 Storage Conditions

Samples are stored away from all standards, reagents, or other potential sources of contamination. Samples are stored in a manner that prevents cross-contamination (e.g. volatile samples are stored separate from other samples). All sample fractions, extracts, leachates and other sample preparation products are stored in the same manner as actual samples or as specified by the analytical method.

2.7.2 Temperature Monitoring

Samples are taken to the appropriate storage location (ambient, refrigerator, freezer) immediately after sample receipt and check-in procedures are completed. All sample storage areas are located in limited access areas and are monitored to ensure sample integrity.

The temperature of each refrigerated storage area is maintained at =6°C unless state or program requirements differ. The temperature of each freezer storage area is maintained at < - 10°C unless state or program requirements differ. The temperature of each storage area is monitored and recorded each workday. If the temperature falls outside the acceptable limits, the following corrective actions are taken and appropriately documented:

- The temperature is rechecked after two hours to verify temperature exceedance. Corrective action is initiated if necessary.
- The Quality Manager and/or laboratory management are notified if the problem persists.
- The samples are relocated to a proper environment if the temperature cannot be maintained after corrective actions are implemented.
- The affected customers are notified.
- Documentation is provided on analytical report.

2.7.3 Hazardous Materials

Pure product or potentially heavily contaminated samples are tagged as "hazardous" or "lab pack" and are stored separately from other samples.

2.7.4 Foreign/Quarantined Soils

Depending on the soil disposal practices of the laboratory, foreign soils and soils from USDA regulated areas are segregated. The USDA requires these samples to be incinerated or sterilized by an approved treatment procedure.

Additional information can be found in SOP PGH-C-001 **Sample Management** or its equivalent revision or replacement.

2.8 Sample Protection

PASI laboratory facilities are operated under controlled access to ensure sample and data integrity. Visitors must register at the front desk and be properly escorted.

Samples are removed from storage areas by designated personnel and returned to the storage areas, if necessary, immediately after the required sample quantity has been taken.

Upon customer request, additional and more rigorous chain of custody protocols for samples and data can be implemented. For example, some projects may require complete documentation of sample custody within the secure laboratory.

Additional information can be found in SOPPGH-C-001 **Sample Management** or its equivalent revision or replacement.

2.9 Subcontracting Analytical Services

Every effort is made to perform chemical analyses for PASI customers within the laboratory that receives the samples. When subcontracting to a laboratory other than the receiving laboratory (inside or outside the PASI network) becomes necessary, a preliminary verbal communication with an appropriate laboratory is undertaken. Customers are notified in writing of the lab's intention to subcontract any portion of the testing to another laboratory. Work performed under specific protocols may involve special considerations.

Prior to subcontracting samples to a laboratory outside Pace Analytical, the potential sub-contract laboratory will be pre-qualified by verifying that the subcontractor meets the following criteria:

- All certifications required for the proposed subcontract are in effect,
- Sufficient professional liability and other required insurance coverage is in effect, and
- Is not involved in legal action by any federal, state, or local government agency for data integrity issues and has not been convicted in such investigation at any time during the past 5 years.

Additional information can be found in SOP S-ALL-Q-027 **Evaluation & Qualification of Vendors** or its equivalent revision or replacement. The contact and preliminary arrangements are made between the PASI Project Manager and the appropriate subcontract laboratory personnel. The specific terms of the subcontract laboratory agreement include:

- Method of analysis
- Number and type of samples expected
- Project specific QA/QC requirements
- Deliverables required
- Laboratory certification requirement
- Price per analysis
- Turnaround time requirements

Chain-of-custody forms are generated for samples requiring subcontracting to other laboratories. Sample receiving personnel re-package the samples for shipment, create a transfer chain-of-custody form and record the following information:

- Pace Analytical Laboratory Number
- Matrix
- Requested analysis
- Special instructions (quick turn-around, required detection or reporting limits, unusual information known about the samples or analytical procedure).
- Signature in "Relinquished By"

All subcontracted sample data reports are sent to the PASI Project Manager.

Any Pace Analytical work sent to other labs within the PASI network is handled as subcontracted work (also known as inter-regional) and all final reports are labeled clearly with the name of the laboratory performing the work. Any non-NELAC work is clearly identified. PASI will not be responsible for analytical data if the subcontract laboratory was designated by the customer.

Additional information can be found in SOP S-ALL-Q-017 **Subcontracting Samples** or its equivalent revision or replacement.

2.10 Sample Retention and Disposal

Samples (and sample by-products) must be retained by the laboratory for a period of time necessary to protect the integrity of the sample or sample by-product (e.g. method holding time) and to protect the interests of the laboratory and the customer.

Unused portions of samples are retained by each laboratory based on program or customer requirements for sample retention and storage. The sample retention time is a minimum of 45 days from receipt of the samples. Samples requiring storage beyond this time due to special requests or contractual obligations will not be stored under temperature controlled conditions unless the laboratory has sufficient capacity and their presence does not compromise the integrity of other samples.

After this period expires, non-hazardous samples are properly disposed of as non-hazardous waste. The preferred method for disposition of hazardous samples is to return the excess sample to the customer. If it is not feasible to return samples, or the customer requires PASI to dispose of excess samples, PASI will arrange for proper disposal by an approved contractor.

Additional information can be found in PGH-C-017 **Waste Management and Disposal** and PGH-C-001 **Sample Management** or their equivalent revisions or replacements.

3.0 ANALYTICAL CAPABILITIES

3.1 Analytical Method Sources

PASI laboratories are capable of analyzing a full range of environmental samples from a variety of matrices, including air, surface water, wastewater, groundwater, soil, sediment, biota, and other waste products. The latest valid editions of methodologies are applied from regulatory and professional sources including EPA, ASTM, USGS, NIOSH, and State Agencies. Section 11 of this manual is a representative listing of general analytical protocol references. PASI discloses in writing to its customers and regulatory agencies any instances in which modified methods are being used in the analysis of samples.

In the event of a customer-specific need, instrumentation constraint or regulatory requirement, PASI laboratories reserve the right to use valid versions of methods that may not be the most recent edition available.

3.2 Analytical Method Documentation

The primary form of documentation of analytical methods is the Standard Operating Procedure (SOP). SOPs contain pertinent information as to what steps are required by an analyst to successfully perform a procedure. The required contents for the SOPs are specified in the company-wide SOP for Preparation of SOPs (S-ALL-Q-001).

The SOPs may be supplemented by other training materials that further detail how methods are specifically performed. This training material will undergo periodic, documented review along with the other Quality System documentation.

3.3 Analytical Method Validation

In some situations, PASI develops and validates methodologies that may be more applicable to a specific problem or objective. When non-standard methods (e.g. methods other than EPA, NIOSH, ASTM, AOAC, etc.) are required for specific projects or analytes of interest, or when the laboratory develops a method, or modifies a standard method, the laboratory validates the method prior to applying it to customer samples. Method validity is established by meeting criteria for precision and accuracy as established by the data quality objectives specified by the end user of the data. The laboratory records the validation procedure, the results obtained and a statement as to the usability of the method. The minimum requirements for method validation include determination of the limit of detection and limit of quantitation, evaluation of precision and bias, and evaluation of selectivity of each analyte of interest.

3.4 Demonstration of Capability (DOC)

Analysts complete an initial demonstration of capability (IDOC) study prior to performing a method or when there is a change in instrument type, personnel or test method (when a defined 'work cell' is in operation, the entire work cell must meet the criteria). The mean recovery and standard deviation of each analyte, taken from 4 replicates of a quality control standard is calculated and compared to method criteria (if available) or established lab criteria for evaluation of acceptance. Each laboratory maintains copies of all demonstrations of capability and corresponding raw data for future reference and must document the acceptance criteria prior to the analysis of the DOC. Demonstrations of capability are verified on an annual basis.

Alternative demonstration of capability procedures may be used for IDOC for methods that don't lend themselves to the "4 replicate" approach. For methods that only measure precision, the precision of four laboratory duplicate pairs will be assessed. The relative percent differences must be within the method acceptance limits. For procedures like TCLP or SPLP, the analyst will demonstrate making the buffered solution and performing the tumbling process. The trainer or supervisor will sign-off on demonstration of

capability of the tumbling process. Additional demonstration of capability options will be specified in Section 14 – Method Performance of the applicable method SOP.

For Continuing Demonstrations of Capability, the laboratories may use Performance Testing (PT) samples or any of the approaches utilized for IDOCs. For methods or procedures that do not lend themselves to the "4 replicate" approach, the demonstration of capability requirements will be specified in Section 14 – Method Performance of the applicable SOP.

3.5 Regulatory and Method Compliance

PASI understands that expectations of our customers commonly include the assumption that laboratory data will satisfy specific regulatory requirements. Therefore PASI attempts to ascertain, prior to beginning a project, what applicable regulatory jurisdiction, agency, or protocols apply to that project. This information is also required on the Chain-of-Custody submitted with samples.

PASI makes every effort to detect regulatory or project plan inconsistencies, based upon information from the customer, and communicate them immediately to the customer in order to aid in the decision-making process. PASI will not be liable if the customer chooses not to follow PASI recommendations.

It is PASI policy to disclose in a forthright manner any detected noncompliance affecting the usability of data produced by our laboratories. The laboratory will notify customers within 30 days of fully characterizing the nature of the nonconformance, the scope of the nonconformance and the impact it may have on data usability.

4.0 QUALITY CONTROL PROCEDURES

4.1 Data Integrity System

The data integrity system at PASI provides assurances to management that a highly ethical approach is being applied to all planning, training and implementation of methods. Data integrity is crucial to the success of our company and Pace Analytical is committed to providing a culture of quality throughout the organization. To accomplish this goal, PASI has implemented a data integrity system that encompasses the following four requirements:

1. A data integrity training program: Standardized training is given to each new employee and a yearly refresher is presented to all employees. Key topics within this training include:
   - Need for honesty in analytical reporting
   - Process for reporting data integrity issues
   - Specific examples of unethical behavior and improper practices
   - Documentation of non-conforming data that is still useful to the data user
   - Consequences and punishments for unethical behavior
   - Examples of monitoring devices used by management to review data and systems
2. Signed data integrity documentation for all employees: This includes a quiz following the Ethics training session and written agreement to abide by the Code of Ethics and Standards of Conduct explained in the employee manual The quiz along with the employee's electronic signature of agreement are maintained within the Learning Management System.
3. In-depth, periodic monitoring of data integrity: Including peer data review and validation, internal data audits, proficiency testing studies, etc.
4. Documentation of any review or investigation into possible data integrity infractions. This documentation, including any disciplinary actions involved, corrective actions taken, and notifications to customers must be available for review for lab assessors and must be retained for a minimum of five years.

PASI management makes every effort to ensure that personnel are free from any undue pressures that affect the quality of their work including commercial, financial, over-scheduling, and working condition pressures.

Corporate management also provides all PASI facilities a mechanism for confidential reporting of data integrity issues that ensures confidentiality and a receptive environment in which all employees are comfortable discussing items of ethical concern. The anonymous message line is monitored by the Corporate Director of Quality, Safety and Training who will ensure that all concerns are evaluated and, where necessary, brought to the attention of executive management and investigated. **The message line voice mail box is available at 612-607-6427.**

4.2 Method Blank

A method blank is used to evaluate contamination in the preparation/analysis system. The method blank is processed through all preparation and analytical steps with its associated samples.

A method blank is processed at a minimum frequency of 1 per preparation batch. In the case of a method that has no separate preparation step (e.g. volatiles), a method blank is processed with no more than 20 samples of a specific matrix performed by the same analyst, in the same method, using the same standards or reagents.

The method blank consists of a matrix similar to the associated samples that is known to be free of the analytes of interest. Laboratories will characterize a representative matrix as "clean" if the matrix contains contaminants at less than ½ the laboratory's reporting limit.

Each method blank is evaluated for contamination. The source of any contamination is investigated and documented corrective action is taken when the concentration of any target analyte is detected above the

reporting limit and is greater than 1/10 of the amount of that analyte found in any associated sample. Corrective actions include the re-preparation and re-analysis of all the samples (where possible) along with the full set of required quality control samples. Data qualifiers must be applied to any result reported that is associated with a contaminated method blank.

Deviations made from this policy must be approved by the Quality Manager prior to release of the data.

4.3 Laboratory Control Sample

The Laboratory Control Sample (LCS) is used to evaluate the performance of the entire analytical system including preparation and analysis.

An LCS is processed at a minimum frequency of 1 per preparation batch. In the case of a method that has no separate preparation step (e.g. volatiles), an LCS will be processed with no more than 20 samples of a specific matrix performed by the same analyst, in the same method, using the same standards or reagents.

The LCS consists of a matrix similar to the associated samples that is known to be free of the analytes of interest that is then spiked with known concentrations of target analytes.

The LCS contains **all** analytes specified by a specific method or by the customer or regulatory agency (which may include full list of target compounds, with certain exceptions. These exceptions may include analyzing only specific Aroclors when PCB analysis is requested or not spiking with all EPA Appendix compounds when a full Appendix list of compounds is requested). In the absence of specified components, the lab will spike with the following compounds:

- For multi-peak analytes (e.g. PCBs, technical chlordane, toxaphene), a representative standard will be processed.
- For methods with long lists of analytes, a representative number of target analytes may be chosen. The following criteria is used to determine the number of LCS compounds used:
    - For methods with 1-10 target compounds, the lab will spike with all compounds
    - For methods with 11-20 target compounds, the lab will spike with at least 10 compounds or 80%, whichever is greater
    - For methods with greater than 20 compounds, the lab will spike with at least 16 compounds.

The LCS is evaluated against the method default or laboratory-derived acceptance criteria. Method default control limits will be used until the laboratory has a minimum of 20 (preferably greater than 30) data points from which to derive internal criteria. Any compound that is outside of these limits is considered to be 'out of control' and must be qualified appropriately. Any associated sample containing an 'out-of-control' compound must either be re-analyzed with a successful LCS or reported with the appropriate data qualifier.

For LCSs containing a large number of analytes, it is statistically likely that a few recoveries will be outside of control limits. This does not necessarily mean that the system is out of control, and therefore no corrective action would be necessary (except for proper documentation). NELAC has allowed for a minimum number of marginal exceedances, defined as recoveries that are beyond the LCS control limits (3X the standard deviation) but less than the marginal exceedance limits (4X the standard deviation). The number of allowable exceedances depends on the number of compounds in the LCS. If more analyte recoveries exceed the LCS control limits than is allowed (see below) or if any one analyte exceeds the marginal exceedance limits, then the LCS is considered non-compliant and corrective actions are necessary. The number of allowable exceedances is as follows:

- >90 analytes in the LCS- 5 analytes
- 71-90 analytes in the LCS- 4 analytes
- 51-70 analytes in the LCS- 3 analytes

- 31-50 analytes in the LCS- 2 analytes
- 11-30 analytes in the LCS- 1 analyte
- <11 analytes in the LCS- no analytes allowed out)

A matrix spike (MS) can be used in place of a non-compliant LCS in a batch as long as the MS passes the LCS acceptance criteria (this is a NELAC allowance). When this happens, full documentation must be made available to the data user. If this is not allowed by a customer or regulatory body, the associated samples must be rerun with a compliant LCS (if possible) or reported with appropriate data qualifiers.

Deviations made from this policy must be approved by the Quality Manager prior to release of the data.

4.4 Matrix Spike/Matrix Spike Duplicate (MS/MSD)

A matrix spike (MS) is used to determine the effect of the sample matrix on compound recovery for a particular method. The information from these spikes is sample or matrix specific and is not used to determine the acceptance of an entire batch (see LCS).

A **Matrix Spike/Matrix Spike Duplicate** (MS/MSD) set is processed at a frequency specified in a particular method or as determined by a specific customer. This frequency will be specified in the applicable method SOP or customer QAPP. In the absence of such requirements, an MS/MSD set is routinely analyzed once per every 20 samples per general matrix (i.e. soil, water, biota, etc.) per method.

The MS and MSD consist of the sample matrix that is then spiked with known concentrations of target analytes. Lab personnel spike customer samples that are specifically designated as MS/MSD samples or, when no designated samples are present in a batch, randomly select samples to spike that have adequate sample volume or weight. Spiked samples are prepared and analyzed in the same manner as the original samples and are selected from different customers if possible.

The MS and MSD contain all analytes specified by a specific method or by the customer or regulatory agency. In the absence of specified components, the lab will spike with the same number of compounds as previously discussed in the LCS section.

The MS and MSD are evaluated against the method or laboratory-derived criteria. Any compound that is outside of these limits is considered to be 'out of control' and must be qualified appropriately. Batch acceptance, however, is based on method blank and LCS performance, not on MS/MSD recoveries. The spike recoveries give the data user a better understanding of the final results based on their site-specific information.

A matrix spike and sample duplicate will be performed instead of a matrix spike and matrix spike duplicate when specified by the customer or method.

Deviations made from this policy must be approved by the Quality Manager prior to release of the data.

4.5 Surrogates

Surrogates are compounds that reflect the chemistry of target analytes and are typically added to samples for organic analyses to monitor the effect of the sample matrix on compound recovery.

Surrogates are added to each customer sample (for organics), method blank, LCS and MS prior to extraction or analysis. The surrogates are evaluated against the method or laboratory-derived acceptance criteria. Any surrogate compound that is outside of these limits is considered to be 'out of control' and must be qualified appropriately. Samples with surrogate failures are typically re-extracted and/or re-analyzed to confirm that the out-of-control value was caused by the matrix of the sample and not by some other systematic error. An exception to this would be samples that have high surrogate values but no

reportable hits for target compounds. These samples would be reported, with a qualifier, because the implied high bias would not affect the final results.

Deviations made from this policy must be approved by the Quality Manager prior to release of the data.

4.6 Sample Duplicate

A sample duplicate is a second portion of sample that is prepared and analyzed in the laboratory along with the first portion. It is used to measure the precision associated with preparation and analysis. A sample duplicate is processed at a frequency specified by the particular method or as determined by a specific customer.

The sample and duplicate are evaluated against the method or laboratory-derived criteria for relative percent difference (RPD). Any duplicate that is outside of these limits is considered to be 'out of control' and must be qualified appropriately.

Deviations made from this policy must be approved by the Quality Manager prior to release of the data.

4.7 Internal Standards

Internal Standards are method-specific analytes added to every standard, method blank, laboratory control sample, matrix spike, matrix spike duplicate, and sample at a known concentration, prior to analysis for the purpose of adjusting the response factor used in quantifying target analytes. At a minimum, the laboratory will follow method specific guidelines for the treatment of internal standard recoveries as they are related to the reporting of data.

Deviations made from this policy must be approved by the Quality Manager prior to release of the data.

4.8 Field Blanks

Field blanks are blanks prepared at the sampling site in order to monitor for contamination that may be present in the environment where samples are collected. These field quality control samples are often referenced as field blanks, rinseate blanks, or equipment blanks. The lab analyzes these field blanks as normal samples and informs the customer if there are any target compounds detected above the reporting limit.

4.9 Trip Blanks

Trip blanks are blanks that originate from the laboratory as part of the sampling event and are used to monitor for contamination of samples during transport. These blanks accompany the empty sample containers to the field and then accompany the collected samples back to the lab. These blanks are routinely analyzed for volatile methods where ambient background contamination is likely to occur.

4.10 Limit of Detection (LOD)

PASI laboratories are required to use a documented procedure to determine a limit of detection (LOD) for each analyte of concern in each matrix reported. All sample-processing steps of the preparation and analytical methods are included in this determination. For any test that does not have a valid LOD, sample results below the limit of quantitation (LOQ) cannot be reported.

The LOD is initially established for the compounds of interest for each method in a clean matrix with no target analytes present and no interferences at a concentration that would impact the results. The LOD is then determined every time there is a change in the test method that affects how the test is performed or when there has been a change in the instrument that affects the sensitivity. If required by customer, method or accreditation body, the LOD will be re-established annually for all applicable methods.

Unless otherwise noted, the method used by PASI laboratories to determine LODs is based on the Method Detection Limit (MDL) procedure outlined in 40 CFR Part 136, Appendix B. Where required by regulatory program or customer, the above referenced procedure will be followed.

Where specifically stated in the published method, LODs (or MDLs) will be performed at the listed frequency.

The validity of the LOD must be verified by detection (a value greater than zero) of the analytes in a QC sample in each quality system matrix. The QC sample must contain the analyte at no more than 3X the LOD for a single analyte test and 4X the LOD for multiple analyte tests. This verification must be performed on each instrument used for sample analysis and reporting of data. The validity of the LOD must be verified as part of the LOD determination process. This verification must be done prior to the use of the LOD for sample analysis.

An LOD study is not required for any analyte for which spiking solutions or quality control samples are not available (e.g. temperature).

The LOD, if required, shall be verified annually for each quality system matrix, technology and analyte. In lieu of performing full LOD (MDL) studies annually, the lab can verify the LOD (MDL) on an annual basis, providing this verification is fully documented and does not contradict other customer or program requirements that the lab must follow. The requirements of this verification are:

- The spike concentration of the verification must be no more than 3X times the LOD for single analyte tests and 4X the LOD for multiple analyte tests.
- The lab must verify the LOD on each instrument used for the reporting of sample data.
- The lab must be able to qualitatively identify all target analytes in the verification standard (distinguishable from noise).

Additional information can be found in SOP S-ALL-Q-004 **Method Detection Limit Studies** or its equivalent revision or replacement.

4.11 Limit of Quantitation (LOQ)

A limit of quantitation (LOQ) for every analyte of concern must be determined. For PASI laboratories, this LOQ is referred to as the RL, or Reporting Limit. This RL is based on the lowest calibration standard concentration that is used in each initial calibration. Results below this level are not allowed to be reported without qualification since the results would not be substantiated by a calibration standard. For methods with a determined LOD, results can be reported out below the LOQ but above the LOD if they are properly qualified (e.g. J flag).

There must be a sufficient buffer between the LOD and the limit of quantitation (LOQ). The LOQ must be higher than the LOD.

To verify the LOQ, the laboratory will prepare a sample in the same matrix used for the LCS. The sample will be spiked with target analytes at the concentration(s) equivalent to or less than the RL(s). This sample must undergo the routine sample preparation procedure including any routine sample cleanup steps. The sample is then analyzed and the recovery of each target analyte determined. The recovery for each target analyte must meet the laboratories current control limits.

Additional information can be found in SOP S-ALL-Q-004 **Method Detection Limit Studies** or its equivalent revision or replacement.

4.12 Estimate of Uncertainty

PASI laboratories can provide an estimation of uncertainty for results generated by the laboratory. The estimate quantifies the error associated with any given result at a 95% confidence interval. This estimate does not include bias that may be associated with sampling. The laboratory has a procedure in place for making this estimation. In the absence of a regulatory or customer-specific procedure, PASI laboratories base this estimation on the recovery data obtained from the Laboratory Control Spikes. The uncertainty is a function of the standard deviation of the recoveries multiplied by the appropriate Student's t Factor at 95% confidence. Additional information pertaining to the estimation of uncertainty and the exact manner in which it is derived are contained in the SOP PGH-C-021**Measurement of Uncertainty** or its equivalent revision or replacement.

The measurement of uncertainty is provided only on request by the customer, as required by specification or regulation and when the result is used to determine conformance within a specification limit.

4.13 Proficiency Testing (PT) Studies

PASI laboratories participate in the NELAC-defined proficiency testing program. PT samples are obtained from approved providers and analyzed and reported at a minimum of two times per year for the relevant fields of testing per matrix.

The lab initiates an investigation whenever PT results are deemed 'unacceptable' by the PT provider. All findings and corrective actions taken are reported to the Quality Manager. A corrective action plan (including re-analysis of similar samples) is initiated and this report is sent to the appropriate state accreditation agencies for their review.

PT samples are treated as typical customer samples, utilizing the same staff, methods, equipment, facilities, and frequency of analysis. PT samples are included in the laboratory's normal analytical processes and do not receive extraordinary attention due to their nature.

Comparison of analytical results with anyone participating in the same PT study is prohibited prior to the close of the study.

Additional information can be found in SOP S-ALL-Q-010 **PE/PT Program** or its equivalent revision or replacement.

4.14 Rounding and Significant Figures

In general, the PASI laboratories report data to no more than three significant digits. Therefore, all measurements made in the analytical process must reflect this level of precision. In the event that a parameter that contributes to the final result has less than three significant figures of precision, the final result must be reported with no more significant figures than that of the parameter in question. The rounding rules listed below are descriptive of the LIMS and not necessarily of any supporting program (Excel, etc.).

Rounding

PASI-Pittsburgh follows the odd / even guidelines for rounding numbers:

- If the figure following the one to be retained is less than five, that figure is dropped and the retained ones are not changed (with three significant figures, 2.544 is rounded to 2.54).
- If the figure following the ones to be retained is greater than five, that figure is dropped and the last retained one is rounded up (with three significant figures, 2.546 is rounded to 2.55).

- If the figure following the ones to be retained is five and if there are no figures other than zeros beyond that five, then the five is dropped and the last figure retained is unchanged if it is even and rounded up if it is odd (with three significant figures, 2.525 is rounded to 2.52 and 2.535 is rounded to 2.54).

Significant Digits

PASI-Pittsburgh follows the following convention for reporting to a specified number of significant figures. Unless specified by federal, state or local requirements or on specific request by a customer, the laboratory reports:

- Values > 10 – Reported to 3 significant digits
- Values = 10 – Reported to 2 significant digits

5.0 DOCUMENT MANAGEMENT AND CHANGE CONTROL

5.1 Document Management

Additional information can be found in SOP S-ALL-Q-002 **Document Management** or its equivalent revision or replacement.

Pace Analytical Services, Inc. has an established procedure for managing documents that are part of the quality system. The list of managed documents includes, but is not limited to, Standard Operating Procedures, Quality Assurance Manuals, quality policy statements, training documents, work-processing documents, charts, posters, memoranda, notices, forms, software, and any other procedures, tables, plans, etc. that have a direct bearing on the quality system.

A master list of all managed documents is maintained at each facility identifying the current revision status and distribution of the controlled documents. This establishes that there are no invalid or obsolete documents in use in the facility. All documents are reviewed periodically and revised if necessary. Obsolete documents are systematically discarded or archived for audit or knowledge preservation purposes.

Each managed document is uniquely identified to include the date of issue, the revision identification, page numbers, the total number of pages and the issuing authorities. For complete information on document numbering, refer to SOP S-ALL-Q-003 **Document Numbering**.

As an alternative to the hard copy system of controlled documents, secured electronic copies of controlled documents may be maintained on the local or wide-area network (LAN or WAN). These document files must be read-only for all personnel except the Quality Department and system administrator. Other requirements for this system are as follows:

- Electronic documents must be readily accessible to all facility employees.
- Electronic documents (i.e. pdf's) must be locked from printing. All hardcopy SOPs must be obtained from the Quality Department.

5.1.1 Quality Assurance Manual (QAM)

The Quality Assurance Manual is the company-wide document that describes all aspects of the quality system for PASI. The base QAM template is distributed by the Corporate Quality Department to each of the regional Quality Managers. The regional management personnel modify the necessary and permissible sections of the base template and submit those modifications to the Corporate Director of Quality for review. Once approved and signed by both the CEO and the Director of Quality, the General Manager, Quality Manager and Technical Director(s) sign the Quality Assurance Manual. Each regional Quality Manager is then in charge of distribution to employees, external customers or regulatory agencies and maintaining a distribution list of controlled document copies. The Quality Assurance Manual template is reviewed on an annual basis by all of the PASI Quality Managers and revised accordingly by the Director of Quality, Safety and Training.

5.1.2 Standard Operating Procedures (SOPs)

SOPs fall into two categories: company-wide documents (starting with the prefix S-ALL-) and facility-specific documents (starting with the individual facility prefix).

The purpose of the company-wide SOPs is to establish policies and procedure that are common and applicable to all PASI facilities. Company-wide SOPs are document-controlled by the corporate quality office and signed copies are distributed to all of the regional Quality Managers. The regional management personnel sign the company-wide SOPs. The regional Quality

Manager is then in charge of distribution to employees, external customers or regulatory agencies and maintaining a distribution list of controlled document copies.

Regional PASI facilities are responsible for developing facility-specific SOPs applicable to their respective facility. The regional facility develops these facility-specific SOPs based on the corporate-wide SOP template. This template is written to incorporate a set of minimum method requirements and PASI best practice requirements. The regional facilities may add to or modify the corporate-wide SOP template provided there are no contradictions to the minimum method or best practice requirements. Facility-specific SOPs are controlled by the regional Quality Manager according to the corporate document management policies.

SOPs are reviewed every two years at a minimum (a more frequent review may be required by state or federal agencies or customers). A review of the document does not necessarily constitute a re-issue of a new revision. Documentation of this review and any applicable revisions are made in the last section of each SOP. This provides a historical record of all revisions.

All copies of superseded SOPs are removed from general use and the original copy of each SOP is archived for audit or knowledge preservation purposes. This ensures that all PASI employees use the most current version of each SOP and provides the Quality Manager with a historical record of each SOP.

Additional information can be found in SOP S-ALL-Q-001 **Preparation of SOPs** or its equivalent revision or replacement.

5.2 Document Change Control

Changes to managed documents are reviewed and approved in the same manner as the original review. Any revision to a document requires the approval of the applicable signatories. After revisions are approved, a revision number is assigned and the previous version of the document is officially retired. Copies may be kept for audit or knowledge preservation purposes.

All controlled copies of the previous document are replaced with controlled copies of the revised document and the superseded copies are destroyed or archived. All affected personnel are advised that there has been a revision and any necessary training is scheduled.

6.0 EQUIPMENT AND MEASUREMENT TRACEABILITY

Each PASI facility is equipped with sufficient instrumentation and support equipment to perform the relevant analytical testing or field procedures performed by each facility. Support equipment includes chemical standards, thermometers, balances, disposable and mechanical pipettes, etc. This section details some of the procedures necessary to maintain traceability and perform proper calibration of instrumentation and support equipment. See Attachment III for a list of equipment currently used at the PASI-Pittsburgh facility.

6.1 Standards and Traceability

Each PASI facility retains all pertinent information for standards, reagents and chemicals to assure traceability to a national standard. This includes documentation of purchase, receipt, preparation and use.

Upon receipt, all purchased standard reference materials are recorded into a standard logbook or database and assigned a unique identification number. The entries include the facility's unique identification number, the chemical name, manufacturer name, manufacturer's identification numbers, receipt date and expiration date. Vendor's certificates of analysis for all standards, reagents, or chemicals are retained for future reference.

Subsequent preparations of intermediate or working solutions are also documented in a standard logbook or database. These entries include the stock standard name and lot number, the manufacturer name, the solvents used for preparation, the solvent lot number and manufacturer, the preparation steps, preparation date, expiration dates, preparer's initials, and a unique PASI identification number. This number is used in any applicable sample preparation or analysis logbook so the standard can be traced back to the standard preparation record. This process ensures traceability back to the national standard.

All prepared standard or reagent containers include the PASI identification number, the standard or chemical name, the date of preparation, the date of expiration, the concentration with units, and the preparer's initials. This ensures traceability back to the standard preparation logbook.

If a second source standard is required to verify an existing calibration or spiking standard, this standard is purchased from a different supplier. If no second source is available, a second standard from a different lot may be purchased from the same supplier if the lot can be demonstrated as prepared independently from other lots.

Additional information concerning standards and reagent traceability can be found in the SOP S-ALL-Q-025 **Standard and Reagent Preparation and Traceability** or its equivalent revision or replacement.

6.2 General Analytical Instrument Calibration Procedures

All types of support equipment and instrumentation are calibrated or checked before use to ensure proper functioning and verify that the laboratory's requirements are met. All calibrations are performed by, or under the supervision of, an experienced analyst at scheduled intervals against either certified standards traceable to recognized national standards or reference standards whose values have been statistically validated.

Calibration standards for each parameter are chosen to establish the linear range of the instrument and must bracket the concentrations of those parameters measured in the samples. The lowest calibration standard is the lowest concentration for which quantitative data may be reported. Data reported below this level is considered to have less certainty and must be reported using appropriate data qualifiers (e.g. J flag) or explained in a narrative. The highest calibration standard is the highest concentration for which quantitative data may be reported. Data reported above this level is considered to have less certainty and must be reported using appropriate data qualifiers (e.g. E flag) or explained in the narrative. Any specific method requirement for number and type of calibration standards supersedes the general requirement. Instrument and method specific calibration criteria are explained within the specific analytical standard operating procedures for each facility.

Instrumentation or support equipment that cannot be calibrated to specification or is otherwise defective is clearly labeled as out-of-service until it has been repaired and tested to demonstrate it meets the laboratory's specifications. All repair and maintenance activities including service calls are documented in the maintenance log. Equipment sent off-site for calibration testing is packed and transported to prevent breakage and is in accordance with the calibration laboratory's recommendations.

In the event that recalibration of a piece of test equipment indicates the equipment may have been malfunctioning during the course of sample analysis, an investigation is performed. The results of the investigation along with a summary of the information reviewed are documented and maintained by the Quality Manager. If the investigation indicates sample results have been impacted, the customer is notified within 30 days. This allows for sufficient investigation and review of documentation to determine the impact on the analytical results. Instrumentation found to be consistently out of calibration is either repaired and positively verified or replaced.

Raw data records are retained to document equipment performance. Sufficient raw data is retained to reconstruct the instrument calibration and explicitly connect the continuing calibration verification to the initial calibration.

6.2.1 General Organic Calibration Procedures

Calibration standards are prepared at a minimum of five concentrations for organic analyses. Results from all calibration standards must be included in constructing the calibration curve with the following exceptions:

- The lowest level calibration standard may be removed from the calibration as long as the remaining number of concentration levels meets the minimum established by the method and standard operating procedure. For multi-parameter methods, this may be done on an individual analyte basis. The reporting limit must be adjusted to the lowest concentration included in the calibration curve.
- The highest level calibration standard may be removed from the calibration as long as the remaining number of concentration levels meets the minimum established by the method and standard operating procedure. For multi-parameter methods, this may be done an individual analyte basis. The upper limit of quantitation must be adjusted to the highest concentration included in the calibration curve.
- Multiple points from either the high end or the low end of the calibration curve may be excluded as long as the remaining points are contiguous in nature and the minimum number of levels remain as established by method or standard operating procedure. The reporting limit or quantitation range, which is appropriate, must be adjusted accordingly.
- Results from a concentration level between the lowest and highest calibration levels can be excluded from the calibration curve for an acceptable cause with approval from the responsible department supervisor if the results for all analytes are excluded and the point is replaced by re-analysis. Re-analysis must occur within the same 12 hour tune time period for GC/MS methodologies and within 8 hours of the initial analysis for non-GC/MS methodologies. All samples analyzed prior to the re-analyzed calibration curve point must be re-analyzed after the calibration curve is completed.

Initial calibration curves are evaluated against appropriate statistical models as required by the analytical methods. Curves that do not meet the appropriate criteria require corrective action that may include re-running the initial calibration curve. All initial calibrations are verified with a standard obtained from a second manufacturer or second lot from the same manufacturer if the lot can be demonstrated as prepared independently from other lots prior to the analysis of samples. Sample results are quantitated from the initial calibration unless otherwise required by regulation, method, or program.

The calibration curve is periodically verified by the analysis of a mid-level continuing calibration verification (CCV) standard during the course of sample analysis. Calibration verification is performed at the beginning and end of each analytical batch (except if an internal standard is used only one verification at the beginning of the batch is needed), whenever it is expected that the analytical system may be out of calibration, if the time period for calibration has expired, or for analytical systems that contain a calibration verification requirement. This verification standard must meet acceptance criteria in order for sample analysis to proceed.

In the event that the CCV does not meet the acceptance criteria, a second CCV may be injected as part of the diagnostic evaluation and corrective action investigation. If the second CCV is acceptable, the analytical sequence is continued. If both CCVs fail, the analytical sequence is terminated. All samples analyzed since the last compliant CCV are re-analyzed for methodologies utilizing external calibration.

When instruments are operating unattended, the autosamplers may be programmed to inject consecutive CCVs as a preventative measure against CCV failure with no corrective action. In this case, both CCVs must be evaluated to determine potential impact to the results. A summary of the decision tree and necessary documentation are listed below:

- If both CCVs meet the acceptance criteria, the analytical sequence is allowed to continue without corrective action. (The 12 hour clock begins with the injection of the second CCV.)
- If the first CCV does not meet the acceptance criteria and the second CCV is acceptable, the analytical sequence is continued and the results are reported.
- If the first CCV meets the acceptance criteria and the second CCV is out of control, the samples preceded by the out of control CCV must be re-analyzed in a compliant analytical sequence.
- If both CCVs are out of control, all samples since the last acceptable CCV must be re-analyzed in a compliant analytical sequence.

Some analytical methods require that samples be bracketed by passing CCVs analyzed both before and after the samples. This is specific to each method but, as a general rule, all external calibration methods require bracketing CCVs. Most internal standard calibrations do not require bracketing CCVs.

Some analytical methods require verification based on a time interval; some methods require a frequency based on an injection interval. The type and frequency of the calibration verifications is dependent on both the analytical method and possibly on the quality program associated with the samples. The type and frequency of calibration verification will be documented in the method specific SOP employed by each laboratory.

6.2.2 General Inorganic Calibration Procedures

The instrument is initially calibrated with standards at multiple concentrations to establish the linearity of the instrument's response. A calibration blank is also included. Initial calibration curves are evaluated against appropriate statistical models as required by the analytical methods. The number of calibration standards used depends on the specific method criteria or customer project requirements, although normally a minimum of three standards is used.

The ICP and ICP/MS can be standardized with a zero point and a single point calibration if:

- Prior to analysis, the zero point and the single point calibration are analyzed and a linear range is established,
- Zero point and single point calibration standards are analyzed with each batch
- A standard corresponding to the LOQ is analyzed with the batch and meets the established acceptance criteria
- The linearity is verified at the frequency established by the method or manufacturer.

All initial calibrations are verified with a standard obtained from a second manufacturer or second lot from the same manufacturer if the lot can be demonstrated as prepared independently from other lots prior to the analysis of samples. Sample results are quantitated from the initial calibration unless otherwise required by regulation, method, or program.

During the course of analysis, the calibration curve is periodically verified by the analysis of calibration verification standards. A calibration verification standard is analyzed within each analytical batch at method/program specific intervals to verify that the initial calibration is still valid. The CCV is also analyzed at the end of the analytical batch.

A calibration blank is also run with each calibration verification standard to verify the cleanliness of the system. All reported results must be bracketed by acceptable CCVs. Instrument and method specific calibration acceptance criteria are explained within the specific analytical standard operating procedures for each facility.

Interference check standards are also analyzed per method requirements and must meet acceptance criteria for metals analyses.

6.3 Support Equipment Calibration Procedures

All support equipment is calibrated or verified at least annually using NIST traceable references over the entire range of use. The results of calibrations or verifications must be within the specifications required or the equipment will be removed from service until repaired. The laboratory maintains records to demonstrate the correction factors applied to working thermometers.

Prior to use on each working day, balances, ovens, refrigerators, freezers, and water baths are checked in the expected use range with NIST traceable references in order to ensure the equipment meets laboratory specifications.

6.3.1 Analytical Balances

Each analytical balance is checked and (if necessary) calibrated annually by a qualified service technician. The calibration of each balance is checked each day of use with weights traceable to NIST. Calibration weights are ASTM Class 1 (or other class weights that have been calibrated against a NIST standard weight) and are re-certified annually against a NIST traceable reference. Some accrediting agencies may require more frequent checks. If balances are calibrated by an external agency, verification of their weights must be provided. All information pertaining to balance maintenance and calibration is recorded in the individual balance logbook and/or is maintained on file in the Quality department.

6.3.2 Thermometers

Certified, or reference, thermometers are maintained for checking calibration of working thermometers. Reference thermometers are provided with NIST traceability for initial calibration and are re-certified, at a minimum, yearly with equipment directly traceable to NIST.

Working thermometers are compared with the reference thermometers annually according to corporate metrology procedures. Each thermometer is individually numbered and assigned a correction factor based on the NIST reference source. In addition, working thermometers are visually inspected by laboratory personnel prior to use and temperatures are documented.

Laboratory thermometer inventory and calibration data are maintained in the Quality department.

6.3.3 pH/Electrometers

The meter is calibrated before use each day, using fresh buffer solutions.

6.3.4 Spectrophotometers

During use, spectrophotometer performance is checked at established frequencies in analysis sequences against initial calibration verification (ICV) and continuing calibration verification (CCV) standards.

6.3.5 Mechanical Volumetric Dispensing Devices

Mechanical volumetric dispensing devices including bottle top dispensers, pipettes, and burettes, excluding Class A volumetric glassware, are checked for accuracy on a quarterly basis. The accuracy of glass microliter syringes is verified and documented prior to use.

Additional information regarding calibration and maintenance of laboratory support equipment can be found in SOP S-ALL-Q-013 **Support Equipment** or its equivalent revision or replacement.

6.4 Instrument/ Equipment Maintenance

The objectives of the Pace Analytical maintenance program are twofold: to establish a system of instrument care that maintains instrumentation and equipment at required levels of calibration and sensitivity, and to minimize loss of productivity due to repairs.

The Laboratory Operations Manager and department manager/supervisors are responsible for providing technical leadership to evaluate new equipment, solve equipment problems and coordinate instrument repair and maintenance. The analysts have a primary responsibility to perform routine maintenance.

To minimize downtime and interruption of analytical work, preventative maintenance is routinely performed on each analytical instrument. Up-to-date instructions on the use and maintenance of equipment are available to staff in the department where the equipment is used.

Department manager/supervisors are responsible for maintaining an adequate inventory of spare parts required to minimize equipment downtime. This inventory includes parts and supplies that are subject to frequent failure, have limited lifetimes, or cannot be obtained in a timely manner should a failure occur.

All major equipment and instrumentation items are uniquely identified to allow for traceability. Equipment/instrumentation are, unless otherwise stated, identified as a system and not as individual pieces. The laboratory maintains equipment records that include the following:

- The name of the equipment and its software
- The manufacturer's name, type, and serial number
- Approximate date received and date placed into service
- Current location in the laboratory
- Condition when received (new, used, etc.)
- Copy of any manufacturer's manuals or instructions
- Dates and results of calibrations and next scheduled calibration (if known)
- Details of past maintenance activities, both routine and non-routine
- Details of any damage, modification or major repairs

All instrument maintenance is documented in maintenance logbooks that are assigned to each particular instrument or system.

When maintenance is performed to repair an instrument problem, depending on the initial problem, demonstration of return to control may be satisfied by the successful analysis of a reagent blank or continuing calibration standard. The entry must include a summary of the results of that analysis and verification by the analyst that the instrument has been returned to an in-control status. In addition, each entry must include the initials of the analyst making the entry, the dates the maintenance actions were performed, and the date the entry was made in the maintenance logbook, if different from the date(s) of the maintenance.

Any equipment that has been subjected to overloading or mishandling, or that gives suspect results, or has been shown to be defective, is taken out of service and clearly identified. The equipment shall not be used to analyze customer samples until it has been repaired and shown to perform satisfactorily.

7.0 CONTROL OF DATA

Analytical results processing, verification and reporting are procedures employed that result in the delivery of defensible data. These processes include, but are not limited to, calculation of raw data into final concentration values, review of results for accuracy, evaluation of quality control criteria and assembly of technical reports for delivery to the data user.

All analytical data undergo a well-defined, well-documented multi-tier review process prior to being reported to the customer. This section describes procedures used by PASI for translating raw analytical data into accurate, final sample reports and PASI data storage policies.

7.1 Analytical Results Processing

When analytical, field, or product testing data is generated, it is either recorded in a bound laboratory logbook (e.g. Run log or Instrument log) or copies of computer-generated printouts are appropriately labeled and filed. These logbooks and other laboratory records are kept in accordance with each facility's Standard Operating Procedure for documentation storage and archival. If the lab chooses to minimize paper usage, these records can be kept as electronic records. In this case, the laboratory must ensure that there are sufficient redundant electronic copies so no data is lost due to unforeseen computer issues.

The primary analyst is responsible for initial data reduction and review. This includes confirming compliance with required methodology, verifying calculations, evaluating quality control data, noting discrepancies in logbooks and as footnotes or narratives, and uploading analytical results into the LIMS.

The primary analyst then compiles the initial data package for verification. This compilation must include sufficient documentation for data review. It may include standard calibrations, chromatograms, manual integration documentation, electronic printouts, chain-of-custody forms, and logbook copies.

Some agencies or customers require different levels of data reporting. For these special levels, the primary analyst may need to compile additional project information, such as initial calibration data or extensive spectral data, before the data package proceeds to the verification step.

7.2 Data Verification

Data verification is the process of examining data and accepting or rejecting it based on pre-defined criteria. This review step is designed to ensure that reported data are free from calculation and transcription errors, that quality control parameters are evaluated and that any discrepancies are properly documented.

Analysts performing the analysis and subsequent data reduction have primary responsibility for quality of the data produced. The primary analyst initiates the data verification process by reviewing and accepting the data, provided QC criteria have been met for the samples being reported. Data review checklists, either hardcopy or electronic, are used to document the data review process. The primary analyst is responsible for the initial input of the data into the LIMS.

The completed data package is then sent to a designated qualified reviewer (this cannot be the primary analyst). The following criteria have been established to qualify someone as a data reviewer. To perform secondary data reviewer, the reviewer must:

1. Have a current Demonstration of Capability (DOC) study on file and have an SOP acknowledgement form on file for the method/procedure being reviewed; or, See Note
2. Have a DOC on file for a similar method/technology (i.e. GC/MS) and have an SOP acknowledgment form on file for the method/procedure being reviewed; or, See Note
3. Supervise or manage a Department and have an SOP acknowledgment form on file for the method/procedure being reviewed; or,

4. Have significant background in the department/methods being reviewed through education or experience and have an SOP acknowledgment form on file for the method/procedure being reviewed.

Note: Secondary reviewer status must be approved personally by the Quality Manager or General Manager in the event that this person has no prior experience on the specific method or general technology (i.e. GC/MS).

This reviewer provides an independent technical assessment of the data package and technical review for accuracy according to methods employed and laboratory protocols. This assessment involves a quality control review for use of the proper methodology and detection limits, compliance to quality control protocol and criteria, presence and completeness of required deliverables, and accuracy of calculations and data quantitation. The reviewer also validates the data entered into the LIMS.

Once the data have been technically reviewed and approved, authorization for release of the data from the analytical section is indicated by initialing and dating the data review checklist or otherwise initialing and dating the data (or designating the review of data electronically). The Operations or Project Manager examines the report for method appropriateness, detection limits and QC acceptability. Any deviations from the referenced methods are checked for documentation and validity, and QC corrective actions are reviewed for successful resolution.

7.3 Data Reporting

All data segments pertaining to a particular PASI project number are delivered to the Client Services Department (Project Manager) for assembly into the final report. All points mentioned during technical and QC reviews are included in a case narrative if there is potential for data to be impacted.

Final reports are prepared according to the level of reporting required by the customer and can be transmitted to the customer via hardcopy or electronic deliverable. A standard PASI final report consists of the following components:

1. A title which designates the report as "Final Report", "Laboratory Results", "Certificate of Results", etc.
2. Name and address of laboratory (or subcontracted laboratories, if used).
3. Phone number and name of laboratory contact where questions can be referred.
4. A unique number for the report (project number). The pages of the report shall be numbered and a total number of pages shall be indicated (usually in the cover letter).
5. Name and address of customer and name of project (if applicable).
6. Unique identification of samples analyzed (including customer sample numbers).
7. Identification of any sample that did not meet acceptable sampling requirements (from NELAC or other governing agency), such as improper sample containers, holding times missed, sample temperature, etc.
8. Date and time of collection of samples, date of sample receipt by the laboratory, dates of sample preparation and analysis, and times of sample preparation and analysis when the holding time for either is 72 hours or less.
9. Identification of the test methods used.
10. Identification of sampling procedures if sampling was conducted by the laboratory.
11. Deviations from, additions to, or exclusions from the test methods. These can include failed quality control parameters, deviations caused by the matrix of the sample, etc., and can be shown as a case narrative or as defined footnotes to the analytical data.
12. Identification of whether calculations were performed on a dry or wet-weight basis.
13. Reporting limits used.
14. Final results or measurements, supported by appropriate chromatograms, charts, tables, spectra, etc.
15. A signature and title of person accepting responsibility for the content of the report (can be an equivalent electronic identification) and date report was issued.
16. A statement clarifying that the results of the report relate only to the samples tested or to the samples as they were received by the laboratory.
17. If necessary, a statement indicating that the report must not be reproduced except in full, without the written approval of the laboratory.
18. Identification of all test results provided by a subcontracted laboratory or other outside source.

19. Identification of results obtained outside of quantitation levels.

Any changes made to a final report shall be designated as "Revised" or equivalent wording. The laboratory must keep sufficient archived records of all lab reports and revisions. For higher levels of data deliverables, a copy of all applicable raw data is sent to the customer along with a final report of results. When possible, the PASI facility will provide electronic data deliverables (EDD) as required by contracts or upon customer request.

Customer data that requires transmission by telephone, telex, facsimile or other electronic means undergoes appropriate steps to preserve confidentiality.

The following positions are the only approved signatories for PASI final reports:

- Senior General Manager
- General Manager
- Quality Manager
- Client Services Manager
- Project Manager
- Project Coordinator

7.4 Data Security

All data including electronic files, logbooks, extraction/digestion/distillation worksheets, calculations, project files and reports, and other information used to produce the technical report are maintained secured and retrievable by the PASI facility.

7.5 Data Archiving

All records compiled by PASI are maintained legible and retrievable and stored secured in a suitable environment to prevent loss, damage, or deterioration by fire, flood, vermin, theft, and/or environmental deterioration. Records are retained for a minimum of five years unless superseded by federal, state, contractual, and/or accreditation requirements. These records may include, but are not limited to, customer data reports, calibration and maintenance of equipment, raw data from instrumentation, quality control documents, observations, calculations and logbooks. These records are retained in order to provide for possible historical reconstruction including sampling, receipt, preparation, analysis and personnel involved. NELAP-related records will be made readily available to accrediting authorities. Access to archived data is documented and controlled by the Quality Manager or a designated Data Archivist.

Records that are computer-generated have either a hard copy or electronic write-protected backup copy. Hardware and software necessary for the retrieval of electronic data is maintained with the applicable records. Archived electronic records are stored protected against electronic and/or magnetic sources.

In the event of a change in ownership, accountability or liability, reports of analyses performed pertaining to accreditation will be maintained by the acquiring entity for a minimum of five years. In the event of bankruptcy, laboratory reports and/or records will be transferred to the customer and/or the appropriate regulatory entity upon request.

7.6 Data Disposal

Data that has been archived for the facility's required storage time may be disposed of in a secure manner by shredding, returning to customer, or utilizing some other means that does not jeopardize data confidentiality. Records of data disposal will be archived for a minimum of five years unless superseded by federal, contractual, and/or accreditation requirements.

8.0 QUALITY SYSTEM AUDITS AND REVIEWS

8.1 Internal Audits

8.1.1 Responsibilities

The Quality Manager is responsible for designing and/or conducting internal audits in accordance with a predetermined schedule and procedure. Since internal audits represent an independent assessment of laboratory functions, the auditor must be functionally independent from laboratory operations to ensure objectivity. The auditor must be trained, qualified and familiar enough with the objectives, principles, and procedures of laboratory operations to be able to perform a thorough and effective evaluation. The Quality Manger evaluates audit observations and verifies the completion of corrective actions. In addition, a periodic corporate audit will be conducted by the Director of Quality, Safety and Training and/or designee. The corporate audits will focus on the execution of the Quality System as outlined in this manual but may also include other quality programs applicable to each laboratory.

8.1.2 Scope and Frequency of Internal Audits

Internal systems audits are conducted yearly at a minimum. The scope of these audits includes evaluation of specific analytical departments or a specific quality-related system as applied throughout the laboratory.

Examples of system-wide elements that can be audited include:

- Quality Systems documents, such as Standard Operating Procedures, training documents, Quality Assurance Manual and all applicable addenda
- Personnel and training files.
- General laboratory safety protocols.
- Chemical handling practices, such as labeling of reagents, solutions, standards, and associated documentation.
- Documentation concerning equipment and instrumentation, calibration/maintenance records, operating manuals.
- Sample receipt and management practices.
- Analytical documentation, including any discrepancies and corrective actions.
- General procedures for data security, review, documentation, reporting and archiving.
- Data integrity issues such as proper manual integrations.

When the operations of a specific department are evaluated, a number of additional functions are reviewed including:

- Detection limit studies
- Internal chain-of-custody documentation
- Documentation of standard preparations
- Quality Control limits and Control charts

Certain projects may require an internal audit to ensure laboratory conformance to site work plans, sampling and analysis plans, QAPPs, etc.

A representative number of data audits are completed annually. The report format of any discrepancy is similar to that of other internal audits.

The laboratory, as part of their overall internal audit program, ensures that a review is conducted with respect to any evidence of inappropriate actions or vulnerabilities related to data integrity. Discovery and reporting of potential data integrity issues are handled in a confidential manner until

such time as a follow up evaluation, full investigation, or other appropriate actions are completed and the issues clarified. All investigations that result in findings of inappropriate activity are fully documented, including the source of the problem, the samples and customers affected, the impact on the data, the corrective actions taken by the lab and which final reports had to be re-issued. Customers are notified within 30 days when the investigation indicates analytical results are affected.

8.1.3 Internal Audit Reports and Corrective Action Plans

Additional information can be found in SOP S-ALL-Q-011 **Audits and Inspections** or its equivalent revision or replacement.

A full description of the audit, including the identification of the operation audited, the date(s) on which the audit was conducted, the specific systems examined, and the observations noted are summarized in an internal audit report. Although other personnel may assist with the performance of the audit, the Quality Manager writes and issues the internal audit report identifying which audit observations are deficiencies that require corrective action.

When audit findings cast doubt on the effectiveness of the operations or on the correctness of validity of the laboratory's environmental test results, the laboratory will take timely corrective action and notify the customer in writing within 3 business days, if investigations show that the laboratory results may have been affected.

Once completed, the internal audit report is issued jointly to the Laboratory General Manager and the manager(s)/supervisor(s) of the audited operation at a minimum. The responsible manager(s)/supervisor(s) responds within 14 days with a proposed plan to correct all of the deficiencies cited in the audit report. The Quality Manager may grant additional time for responses to large or complex deficiencies (not to exceed 30 days). Each response must include timetables for completion of all proposed corrective actions.

The Quality Manager reviews the audit responses. If the response is accepted, the Quality Manager uses the action plan and timetable as a guideline for verifying completion of the corrective action(s). If the Quality Manager determines that the audit response does not adequately address the correction of cited deficiencies, the response will be returned for modification.

To complete the audit process, the Quality Manager performs a re-examination of the areas where deficiencies were found to verify that all proposed corrective actions have been implemented. An audit deficiency is considered closed once implementation of the necessary corrective action has been verified. If corrective action cannot be verified, the associated deficiency remains open until that action is completed.

8.2 External Audits

PASI laboratories are audited regularly by regulatory agencies to maintain laboratory certifications, and by customers to maintain appropriate specific protocols.

Audit teams external to the company review the laboratory to assess the existence of systems and degree of technical expertise. The Quality Manager and other QA staff host the audit team and assist in facilitation of the audit process. Generally, the auditors will prepare a formalized audit report listing deficiencies observed and follow-up requirements for the laboratory. In some cases, items of concern are discussed during a debriefing convened at the end of the on-site review process.

The laboratory staff and supervisors develop corrective action plans to address any deficiencies with the guidance of the Quality Manager. The Laboratory General Manager provides the necessary resources for staff to develop and implement the corrective action plans. The Quality Manager collates this information

and provides a written report to the audit team. The report contains the corrective action plan and expected completion dates for each element of the plan. The Quality Manager follows-up with the laboratory staff to ensure corrective actions are implemented.

8.3 Quarterly Quality Reports

The Quality Manager is responsible for preparing a quarterly report to management summarizing the effectiveness of the laboratory Quality Systems. This status report will include:

- Results of internal systems or performance audits
- Corrective action activities
- Discussion of QA issues raised by customers
- Results of third party or external audits
- Status of laboratory certifications
- Proficiency Testing Study Results
- Results of internal laboratory review activities
- Summary of holding time violations
- Method detection limit study status
- Training activity summary
- SOP revision summary
- 3P Implementation summary (internal program)
- Other significant Quality System items

The Corporate Director of Quality, Safety & Technology utilizes the information from each laboratory to make decisions impacting the Quality Systems of the company as a whole. Each General Manager utilizes the quarterly report information to make decisions impacting Quality Systems and operational systems at a local level.

Additional information can be found in SOP S-ALL-Q-014 **Quality System Review** or its equivalent revision or replacement.

8.4 Annual Managerial Review

A managerial review of Quality Systems is performed on an annual basis at a minimum. This allows for assessing program effectiveness and introducing changes and/or improvements.

The managerial review must include the following topics of discussion:

- Policy and procedure suitability
- Manager/Supervisor reports
- Internal audit results
- Corrective and preventative actions
- External assessment results
- Proficiency testing studies
- Sample capacity and scope of work changes
- Customer feedback, including complaints

This managerial review must be documented for future reference by the Quality Manager and copies of the report are distributed to laboratory staff. The laboratory shall ensure that any actions identified during the review are carried out within an appropriate and agreed timescale.

8.5 Customer Service Reviews

As part of the annual managerial review listed previously, the sales staff is responsible for reporting on customer feedback, including complaints. The acquisition of this information is completed by performing surveys.

The sales staff continually receives customer feedback, both positive and negative, and reports this feedback to the lab management in order for them to evaluate and improve their management system, testing activities and customer service.

In addition, the labs must be willing to cooperate with customers or their representatives to clarify customer requests and to monitor the lab's performance in relation to the work being performed for the customers.

9.0 CORRECTIVE ACTION

Additional information can be found in SOP PGH-C-011 **Corrective Actions** or its equivalent revision or replacement.

During the process of sample handling, preparation and analysis, certain occurrences may warrant the necessity of corrective actions. These occurrences may take the form of analyst errors, deficiencies in quality control, method deviations, or other unusual circumstances. The Quality System of PASI provides systematic procedures for documentation, monitoring and completion of corrective actions. This can be done using PASI's LabTrack system or other system that lists among other things, the deficiency by issue number, the deficiency source, responsible party, root cause, resolution, due date, and date resolved.

9.1 Corrective Action Documentation

The following items are examples of laboratory deviations or non-conformances that warrant some form of documented corrective action:

- Quality Control data outside of acceptance criteria
- Sample Acceptance Policy deviations
- Missed holding times
- Instrument failures (including calibration failure)
- Sample preparation or analysis errors
- Sample contamination
- Errors in customer reports
- Audit findings (internal and external)
- Proficiency Testing (PT) sample failures
- Customer complaints or inquiries

Documentation of corrective actions may be in the form of a comment or footnote on the final report that explains the deficiency (e.g. matrix spike recoveries outside of acceptance criteria) or it may be a more formal documentation (either paper system or computerized spreadsheet). This depends on the extent of the deficiency, the impact on the data, and the method or customer requirements for documentation.

The person who discovers the deficiency or non-conformance initiates the corrective action documentation on the Non-Conformance Corrective/ Preventative Action report and/or LabTrack. The documentation must include the affected projects and sample numbers, the name of the applicable Project Manager, the customer name and the sample matrix involved. The person initiating the corrective action documentation must also list the known causes of the deficiency or non-conformance as well as any corrective/preventative actions that they have taken. Preventive actions must be taken in order to prevent or minimize the occurrence of the situation.

In the event that the laboratory is unable to determine the cause, laboratory personnel and management staff will start a root cause analysis by going through an investigative process. During this process, the following general steps must be taken into account: defining the non-conformance problem, assigning responsibilities, determining if the condition is significant, and investigating the root cause of the nonconformance problem. General non-conformance investigative techniques follow the path of the sample through the process looking at each individual step in detail. The root cause must be documented on the Corrective/Preventative Action Report.

After all the documentation is completed, the routing of the Corrective/Preventative Action Report will continue from the person initiating the corrective action, to their immediate supervisor or the Project Manager and finally to the Quality Manager, who is responsible for final review and signoff of all formal corrective/preventative actions.

9.2 Corrective Action Completion

9.2.1 Quality Control outside of acceptance criteria

The analyst that is generating or validating Analytical data is responsible for checking the results against established acceptance criteria (quality control limits). The analyst must immediately address any deficiencies discovered. Method blank, LCS or matrix spike failures are evaluated against method, program, and customer requirements and appropriate footnotes are entered into the LIMS system. Some deficiencies may be caused by matrix interferences. Where possible, matrix interferences are confirmed by re-analysis.

Quality control deficiencies must be made known to the customer on the final report for their review of the data for usability. If appropriate, the supervisor is alerted to the QC failure and if necessary a formal corrective action can be initiated. This may involve the input of the Quality Manager or the General Manager.

The department supervisor and/or Operations Manager are responsible for evaluating the source of the deficiency and for returning the analytical system to control. This may involve instrument maintenance, analytical standard or reagent evaluation, or an internal audit of the analytical procedure.

9.2.2 Sample Acceptance Policy deviations

Any deviation from the Sample Acceptance Policy listed in this Manual must be documented on the Chain-of-Custody or other applicable form by the sample receiving personnel or by the Project Manager. Analysts or supervisors that discover such deviations must contact the sample receiving personnel or appropriate Project Manager so they can initiate the proper documentation and customer contact. If a more formalized corrective action must be documented, the Quality Manager is made aware of the situation.

The customer is notified of these deviations as soon as possible so they can make decisions on whether to continue with the sample analysis or re-sample. Copies of this documentation are included in the project file.

9.2.3 Missed holding times

In the event that a holding time requirement has been missed, the analyst or supervisor must complete a formal corrective action form. The Project Manager and the Quality Manager must be made aware of these hold time exceedances.

The Project Manager must contact the customer for appropriate decisions to be made with the resolution documented and included in the customer project file. The Quality Manager includes a list of all missed holding times in their Quarterly Report to the corporate office.

9.2.4 Instrument Failures

In the event of an instrument failure that either causes the necessity for re-analysis or questions the validity of generated results, a formal corrective action must be initiated. The analyst and supervisor evaluate any completed data for validity and usability. They are also responsible for returning the instrument to valid operating condition and for documenting that the system is in control (e.g. acceptable calibration verification).

9.2.5 Sample Preparation or Analysis errors

When there is an error in the preparation or analysis of samples, the analyst evaluates the impact on the usability of the analytical data with the assistance of the supervisor or manager. The affected samples will be re-processed or re-analyzed under acceptable conditions. In the event that no additional sample is available for re-analysis, the customer must be contacted for their decision on how to proceed. Documentation may take the form of footnotes or a formal corrective action form.

9.2.6 Errors in customer reports

When an error on the customer report is discovered, the Project Manager is responsible for initiating a formal corrective action form that describes the failure (e.g. incorrect analysis reported, reporting units are incorrect, reporting limits do not meet objectives). The Project Manager is also responsible for revising the final report if necessary and submitting it to the customer.

9.2.7 Audit findings

The Quality Manager is responsible for documenting all audit findings and their corrective actions. This documentation must include the initial finding, the persons responsible for the corrective action, the due date for reporting back to the auditing body, the root cause of the issue, and the corrective action taken to resolve the findings. The Quality Manager is also responsible for providing any back-up documentation used to prove that a corrective action has been completed.

9.2.8 Proficiency Testing failures

Any PT result returned to the Quality Manager as "not acceptable" requires an investigation and applicable corrective actions. The operational staff is made aware of the PT failures and they are responsible for reviewing the applicable raw data and calibrations and list possible causes for error. The Quality Manager reviews their findings and initiates another external PT sample or an internal PT sample to try and correct the previous failure. Replacement PT results must be monitored by the Quality Manager and reported to the applicable regulatory authorities.

9.2.9 Customer Complaints

Project Managers are responsible for issuing corrective action forms for customer complaints. As with other corrective actions, the possible causes of the problem are listed and the form is passed to the appropriate analyst or supervisor. After the corrective actions have been listed, the Project Manager reviews the corrective action to determine if the customer needs or concerns are being addressed.

9.3. Preventive Action Documentation

Pace laboratories can take advantage of several available information sources in order to identify needed improvements in all of their systems (technical, managerial, quality, etc.). These sources may include:

- Management Continuous Improvement Plan (CIP) metrics which are used by all production departments within Pace. When groups compare performance across the company, ways to improve systems are discovered. These improvements can be made within a department or lab-wide.
- Annual managerial reviews- part of this NELAC-required review is to look at all processes and procedures used by the lab over the past year and to determine ways to improve these processes in the future.
- Quality systems reviews- any frequent checks of quality systems (monthly logbook reviews, etc.) can uncover issues that can be corrected or adjusted before they become a larger issue.

When improvement opportunities are identified or if preventive action is required, the lab can develop, implement, and monitor preventive action plans.

10.0 GLOSSARY

3P Program	The Pace Analytical continuous improvement program that focuses on Process, Productivity and Performance. Best Practices are identified that can be used by all PASI labs.
Accuracy	The agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; a data quality indicator.
Aliquot	A portion of a sample taken for analysis.
Analyte	The specific chemical species or parameter an analysis seeks to determine.
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 NELAC-defined matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch is composed of prepared environmental samples (extracts, digestates or concentrates) that are analyzed together as a group. An analytical batch can include prepared samples originating from various environmental matrices and can exceed 20 samples.
Blank	A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results.
Blind Sample	A sample for submitted for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test analyst or laboratory proficiency in the execution of the measurement process.
Calibration	To determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument, or other device. The levels of the applied calibration standard must bracket the range of planned or expected sample measurements.
Calibration Curve	The graphic representation of known values, such as concentrations for a series of calibration standards and their instrument response.
Chain-of-Custody (COC)	A record that documents the possession of samples from the time of collection to receipt in the laboratory. This record generally includes the number and type of containers, mode of collection, collector, time of collection, preservation, and requested analyses.
Confirmation	Verification of the identity of a component through the use of an alternate scientific approach from the original method. These may include, but are not limited to: • second-column confirmation • alternate wavelength • derivatization derivative • mass spectral interpretation • additional cleanup procedures
Contract Required Detection Limit (CRDL)	Detection limit that is required for EPA Contract Laboratory Program (CLP) contracts.
Contract Required Quantitation Limit (CRQL)	Quantitation limit (reporting limit) that is required for EPA Contract Laboratory Program (CLP) contracts.
Comparability	An assessment of the confidence with which one data set can be compared to another. Comparable data are produced through the use of standardized procedures and techniques.

Completeness	The percent of valid data obtained from a measurement system compared to the amount of valid data expected under normal conditions. The equation for completeness is: % Completeness = (Valid Data Points/Expected Data Points)*100
Calibration Verification	The process of verifying a calibration by analysis of standards and comparing the results with the known amount.
Control Chart	A graphic representation of a series of test results, together with limits within which results are expected when the system is in a state of statistical control (see definition for Control Limit)
Control Limit	A range within which specified measurement results must fall to verify that the analytical system is in control. Control limit exceedances may require corrective action or require investigation and flagging of nonconforming data.
Corrective Action	The action taken to eliminate the causes of a nonconformity, defect, or other undesirable situation in order to prevent recurrence.
Corrective and Preventative Action (CAPA)	The primary management tools for bringing improvements to the quality system, to the management of the quality system's collective processes, and to the products or services delivered which are an output of established systems and processes.
Data Quality Objective (DOQ)	Systematic strategic planning tool based on the scientific method that identifies and defines the type, quality, and quantity of data needed to satisfy a specified use or end user.
Data Reduction	The process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more usable form.
Demonstration of Capability	A procedure to establish the ability of the analyst to generate acceptable accuracy.
Detection Limit (DL)	General term for the lowest concentration or amount of the target analyte that can be identified, measured and reported with confidence that the analyte concentration is not a false positive value. See definitions for Method Detection Limit and Limit of Detection.
Document Control (Management)	Procedures to ensure that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled (managed) to ensure use of the correct version at the location where the prescribed activity is performed.
Dry Weight	The weight after drying in an oven at a specified temperature.
Duplicate or Replicate Analysis	The identically performed measurement on two or more sub-samples of the same sample within a short interval of time
Environmental Sample	A representative sample of any material (aqueous, non-aqueous, or multimedia) collected from any source for which determination of composition or contamination is requested or required. Environmental samples can generally be classified as follows: • Non Potable Water (Includes surface water, ground water, effluents, water treatment chemicals, and TCLP leachates or other extracts) • Drinking Water - Delivered (treated or untreated) water designated as potable water • Water/Wastewater - Raw source waters for public drinking water supplies, ground waters, municipal influents/effluents, and industrial influents/effluents • Sludge - Municipal sludges and industrial sludges. • Soil - Predominately inorganic matter ranging in classification from sands to clays. • Waste - Aqueous and non-aqueous liquid wastes, chemical solids, and industrial liquid and solid wastes
Equipment Blank	A sample of analyte-free media used to rinse common sampling equipment to check effectiveness of decontamination procedures.
Field Blank	A blank sample prepared in the field by filling a clean container with reagent water and appropriate preservative, if any, for the specific sampling activity being undertaken.

Field Measurement	Determination of physical, biological, or radiological properties, or chemical constituents that are measured on-site, close in time and space to the matrices being sampled/measured, following accepted test methods. This testing is performed in the field outside of a fixed-laboratory or outside of an enclosed structure that meets the requirements of a mobile laboratory.
Holding Time	The maximum time that samples may be held prior to preparation and/or analysis as defined by the method.
Homogeneity	The degree to which a property or substance is uniformly distributed throughout a sample.
Initial Calibration (ICAL)	The process of analyzing standards, prepared at specified concentrations, to define the quantitative response relationship of the instrument to the analytes of interest. Initial calibration is performed whenever the results of a calibration verification standard do not conform to the requirements of the method in use or at a frequency specified in the method.
Internal Standards	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.
Intermediate Standard Solution	Reference solutions prepared by dilution of the stock solutions with an appropriate solvent.
Laboratory Control Sample (LCS)	A blank sample matrix, free from the analytes of interest, spiked with known amounts of analytes or a material containing known 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. Sometimes referred to as Laboratory Fortified Blank, Spiked Blank or QC Check Sample.
Limit of Detection (LOD)	An estimate of the minimum amount of a substance that an analytical process can reliably detect. An LOD is analyte and matrix specific and may be laboratory-dependent.
Limit of Quantitation (LOQ) .	The minimum levels, concentrations or quantities of a target variable (e.g. target analyte) that can be reported with a specified degree of confidence
Laboratory Information Management System (LIMS)	A computer system that is used to maintain all sample information from sample receipt, through preparation and analysis and including sample report generation.
Learning Management System (LMS)	A web-based database used by the laboratories to track and document training activities. The system is administered by the corporate training department and each lab's learn centers are maintained by a local administrator.
Lot	A quantity of bulk material of similar composition processed or manufactured at the same time.

Matrix	The component or substrate that contains the analyte of interest. For purposes of batch and QC requirement determinations, the following matrix distinctions are used: • **Aqueous or Non-Potable Water**: any aqueous sample excluded from the definition of Drinking Water matrix or Saline/Estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts. • **Drinking Water**: any aqueous sample that has been designated a potable or potentially potable water source. • **Saline/Estuarine**: any aqueous sample from an ocean or estuary, or other saltwater source. • **Non-aqueous liquid**: any organic liquid with <15% settleable solids. • **Biological Tissue**: any sample of a biological origin such as fish tissue, shellfish or plant material. Such sample can be grouped according to origin. • **Solid**: includes soils, sediments, sludges, and other matrices with >15% settleable solids. • **Chemical Waste**: a product or by-product or an industrial process that results in a matrix not previously defined • **Air and Emissions**: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas vapor that are collected with a sorbent tube, impinger solution, filter, or other device.
Matrix Spike (MS)	A sample prepared by adding a known quantity of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used to determine the effect of the matrix on a method's recovery efficiency. (sometimes referred to as Spiked Sample or Fortified Sample)
Matrix Spike Duplicate (MSD)	A second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of precision of the recovery of each analyte. (sometimes referred to as Spiked Sample Duplicate or Fortified Sample Duplicate)
Method Blank	A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures: and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.
Method Detection Limit (MDL)	One way to establish a Limit of Detection (LOD); defined as the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte.
Performance Based Measurement System (PBMS)	An analytical system wherein the data quality needs, mandates or limitations of a program or project are specified and serve as criteria for selecting appropriate test methods to meet those needs in a cost-effective manner.
Precision	The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms.
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.
Proficiency Testing	A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.
Protocol	A detailed written procedure for field and/or laboratory operation that must be strictly followed.
Quality Assurance Project Plan (QAPP)	A formal document describing the detailed quality control procedures required by a specific project.
Quality Assurance (QA)	An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

Quality Control (QC)	The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users.
Quality Control Sample	A sample used to assess the performance of all or a portion of the measurement system. QC samples may be Certified Reference Materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking.
Quality Assurance Manual	A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.
Quality System	A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.
Random Error	The EPA has established that there is a 5% probability that the results obtained for any one analyte will exceed the control limits established for the test due to random error. As the number of compounds measured increases in a given sample, the probability for statistical error also increases.
Raw Data	Any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g. tapes which have been transcribed verbatim, dated and verified accurate by signature), the exact copy or exact transcript may be submitted.
Reagent Grade	Analytical reagent (AR) grade, ACS reagent grade, and reagent grade are synonymous terms for reagents that conform to the current specifications of the Committee on Analytical Reagents of the American Chemical Society.
Reference Standard	A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.
Reporting Limit (RL)	The level at which method, permit, regulatory and customer-specific objectives are met. The reporting limit may never be lower than the Limit of Detection (i.e. statistically determined MDL). Reporting limits are corrected for sample amounts, including the dry weight of solids, unless otherwise specified. There must be a sufficient buffer between the Reporting Limit and the MDL.
Representativeness	A quality element related to the ability to collect a sample reflecting the characteristics of the part of the environment to be assessed. Sample representativeness is dependent on the sampling techniques specified in the project work plan.
Sample Delivery Group (SDG)	A unit within a single project that is used to identify a group of samples for delivery. An SDG is a group of 20 or fewer field samples within a project, received over a period of up to 14 calendar days. Data from all samples in an SDG are reported concurrently.
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 (concentrations) of a variable of interest.
Standard	A substance or material with properties known with sufficient accuracy to permit its use to evaluate the same property in a sample.

Standard Blank	A calibration standard consisting of the same solvent/reagent matrix used to prepare the calibration standards without the analytes. It is used to construct the calibration curve by establishing instrument background.
Standard Operating Procedure (SOP)	A written document which details the method of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks
Stock Standard	A concentrated reference solution containing one or more analytes prepared in the laboratory using an assayed reference compound or purchased from a reputable commercial source.
Surrogate	A substance with properties that mimic the analyte of interest. It is unlikely to be found in environmental samples and is added to them for quality control purposes.
Systems Audit	An on-site inspection or assessment of a laboratory's quality system.
Traceability	The property of a material or measurement result defining its relationship to recognized international or national standards through an unbroken chain of comparisons.
Training Document	A training resource that provides detailed instructions to execute a specific method or job function.
Trip Blank	This blank sample is used to detect sample contamination from the container and preservative during transport and storage of the sample. A cleaned sample container is filled with laboratory reagent water and the blank is stored, shipped, and analyzed with its associated samples.
Uncertainty Measurement	The parameter associated with the result of a measurement that characterized the dispersion of the values that could be reasonably attributed to the measurand (i.e. the concentration of an analyte).

11.0 REFERENCES

- "Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act." Federal Register, 40 CFR Part 136.
- "Test Methods for Evaluating Solid Wastes: Physical/Chemical Methods." SW-846.
- "Methods for Chemical Analysis of Water and Wastes", EPA 600-4-79-020, 1979 Revised 1983, U.S. EPA.
- U.S. EPA Contract Laboratory Program Statement of Work for Organic Analysis
- U.S. EPA Contract Laboratory Program Statement of Work for Inorganic Analysis
- "Standard Methods for the Examination of Water and Wastewater." Current Edition APHA-AWWA-WPCF
- "Annual Book of ASTM Standards", Section 4: Construction, Volume 04.04: Soil and Rock; Building Stones, American Society of Testing and Materials.
- "Annual Book of ASTM Standards", Section 11: Water and Environmental Technology, American Society of Testing and Materials.
- "NIOSH Manual of Analytical Methods", Third Edition, 1984, U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health.
- "Methods for the Determination of Organic Compounds in Finished Drinking Water and Raw Source Water", U.S. EPA, Environmental Monitoring and Support Laboratory – Cincinnati (September 1986).
- Quality Assurance of Chemical Measurements, Taylor, John K.; Lewis Publishers, Inc. 1987
- Methods for Non-conventional Pesticides Chemicals Analysis of Industrial and Municipal Wastewater, Test Methods, EPA-440/1-83/079C
- Environmental Measurements Laboratory (EML) Procedures Manual, HASL-300, US DOE, February, 1992.
- Requirements for Quality Control of Analytical Data, HAZWRAP, DOE/HWP-65/R1, July, 1990.
- Requirements for Quality Control of Analytical Data for the Environmental Restoration Program, Martin Marietta, ES/ER/TM-16, December, 1992.
- Quality Assurance Manual for Industrial Hygiene Chemistry, AIHA, 1988
- National Environmental Laboratory Accreditation Conference, Constitution, Bylaws, and Standards. Most recent
- ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories.

12.0 REVISIONS

The PASI Corporate Quality and Safety Manager files both a paper copy and electronic version of a Microsoft Word document with tracked changes detailing all revisions made to the previous version of the Quality Assurance Manual. This document is available upon request. All revisions are summarized in the table below.

Document Number	Reason for Change	Date
Quality Assurance Manual Revision 11.0	Overall conversion to template format. Removed all references to Addenda. Changes required based on conversion are not explicitly noted unless change represents a significant policy change. SECTION 1: • Add comment to address continuous improvement to quality system. • Changed statement of purpose in Section header to "Mission Statement". • Added requirements for appointment when Technical Director absent. • Added requirements for notification to AA's and updates to organizational charts when management changes. • Added Client Services Manager job description. SECTION 2: • Changed temperature requirements to "Not Frozen but =6°C". • Added flexible section concerning default sampling time in absence of customer-specified time. • Added flexible section to address sample and container identification by the LIMS. • Changed sample retention requirement to 45 days from receipt of samples. Added comment allowing for storage outside of temperature controlled conditions. SECTION 3: • Inserted allowance for use of older methods. • Changed references to work processing and training documents to allow for use of LMS and other types of training media. • Inserted allowance for alternative DOCs where spiking not possible. SECTION 4: • Inserted reference to Anonymous Message line. • Inserted reference to the use of default control limits. • Inserted allowance for release of data without corrective action for obvious matrix interferences. • Inserted reference to the treatment of internal standards. • Inserted allowance for use of MDL annual MDL verification in lieu of full 40 CFR Part 136 annual MDL studies. • Inserted general procedure for LOQ verification SECTION 5: • Added general process for approval and use of QAM template. • Removed specific reference of Work Process Manuals. Left flexible section to include all other controlled documentation. SECTION 6: • No changes noted. SECTION 7: • Added qualifications for secondary reviewers. SECTION 8: • Changed frequency listing for Corporate Audits. SECTION 9: • Changed references from QA Track to Lab Track – left flexible to	17Sep2007

Document Number	Reason for Change	Date
	accommodate information still in QA Track. SECTION 10: • No changes noted. SECTION 11: • No changes noted. ATTACHMENTS: • Standardized format for Attachments.	
Quality Assurance Manual Revision 12.0	General: replaced the word 'client' with 'customer', where applicable. SECTION 1: • Section 1.6.4: added language for clarity • Added new section 1.8.1; responsibilities of Senior General Managers. • Section 1.8.3: added reference to LMS. • Added new section 1.8.17: responsibilities of Waste Coordinators. • Section 1.9, last paragraph: changed 'annually' to 'periodically'. Next to last paragraph- added reference to LMS. SECTION 2: • Incorporated optional language into section 2.1 for laboratories with field services staff supervised by the laboratory • Added new section 2.2 entitled Field Services. • Section 2.3: added reference to the new Review of Analytical Requests SOP. • Changed optional text in 2.6 to explain how EpicPro assigns unique ID # to projects and samples including the unique container ID • Section 2.7.2: changed freezer temp requirement to match SOP. SECTION 3: • Section 3.4: Included optional language for performing IDOCs for tests not amenable to spiking using the "4 replicate" approach. SECTION 4: • Section 4.1: expanded language to allow electronic signature and storing of integrity training documentation within the LMS • Section 4.10: revised and added language regarding LOD studies, initial verification and annual verification, where applicable. • Section 4.11: changed PRL to RL. • Section 4.13: added editable line regarding PT study information. Changed wording to say approved PT providers are utilized • Section 4.14: added sentence regarding rounding rules listed applying only to LIMS. SECTION 5: • Section 5.1, last bullet point: changed language to reflect that SOPs must be locked from printing if controlled electronically. SECTION 6: • Section 6.3.1: adjusted language about classes of weights potentially used. • Section 6.3.3: removed customer-specific requirement to re-calibrate every four hours but added space for this to be added back in where applicable. • Added reference to Attachment III in the introductory paragraph to this section. SECTION 7: • Sections 7.1-7.3: added language for those labs that are minimizing or	13Nov2008

Document Number	Reason for Change	Date
	eliminating the need for paper copies. • Section 7.2: clarified language in numbered items so that it does not appear that all 4 criteria must be applicable at one time. • Section 7.3: added list of approved signatories for final reports. SECTION 8: • Section 8.1.2, last paragraph: revised language regarding data integrity issues and added a timeframe to notify customers of affected data. • Added section 8.5 "Customer Service Reviews"- ISO requirement SECTION 9: • Added new section 9.3 regarding Preventive Action. SECTION 10: • No revisions. SECTION 11: • No revisions. Attachments: • *Attachment IIb: updated corporate org chart* • Attachment VIII: revised to match the current Analytical Guides.	

ATTACHMENT I

Quality Control Calculations

PERCENT RECOVERY (%REC)

$$\%REC = \frac{(MSConc - SampleConc)}{TrueValue} * 100$$

NOTE: The SampleConc is zero (0) for theLCS and Surrogate Calculations

PERCENT DIFFERENCE (%D)

$$\%D = \frac{MeasuredValue - TrueValue}{TrueValue} * 100$$

where:
TrueValue = Amount spiked (can also be the $\overline{CF}$ or $\overline{RF}$ of the ICAL Standards)
Measured Value = Amount measured (can also be the CF or RF of the CCV)

PERCENT DRIFT

$$\%Drift = \frac{CalculatedConcentration - TheoreticalConcentration}{TheoreticalConcentrtion} * 100$$

RELATIVE PERCENT DIFFERENCE (RPD)

$$RPD = \frac{|(R1 - R2)|}{(R1 + R2)/2} * 100$$

where:
R1 = Result Sample 1
R2 = Result Sample 2

CORRELATION COEFFICIENT (R)

$$CorrCoeff = \frac{\sum_{i=1}^{N} W_i * (X_i - \overline{X}) * (Y_i - \overline{Y})}{\sqrt{\left(\sum_{i=1}^{N} W_i * (X_i - \overline{X})^2\right) * \left(\sum_{i=1}^{N} W_i * (Y_i - \overline{Y})^2\right)}}$$

With:	N	Number of standard samples involved in the calibration
	i	Index for standard samples
	Wi	Weight factor of the standard sample no. i
	Xi	X-value of the standard sample no. i
	X(bar)	Average value of all x-values
	Yi	Y-value of the standard sample no. i
	Y(bar)	Average value of all y-values

ATTACHMENT I (CONTINUED)

Quality Control Calculations (continued)

STANDARD DEVIATION (S)

$$S = \sqrt{\sum_{i=1}^{n} \frac{(X_i - \overline{X})^2}{(n-1)}}$$

where:
n = number of data points
X_i = individual data point
$\overline{X}$ = average of all data points

AVERAGE ($\overline{X}$)

$$\overline{X} = \frac{\sum_{n=1}^{i} X_i}{n}$$

where:
n = number of data points
X_i = individual data point

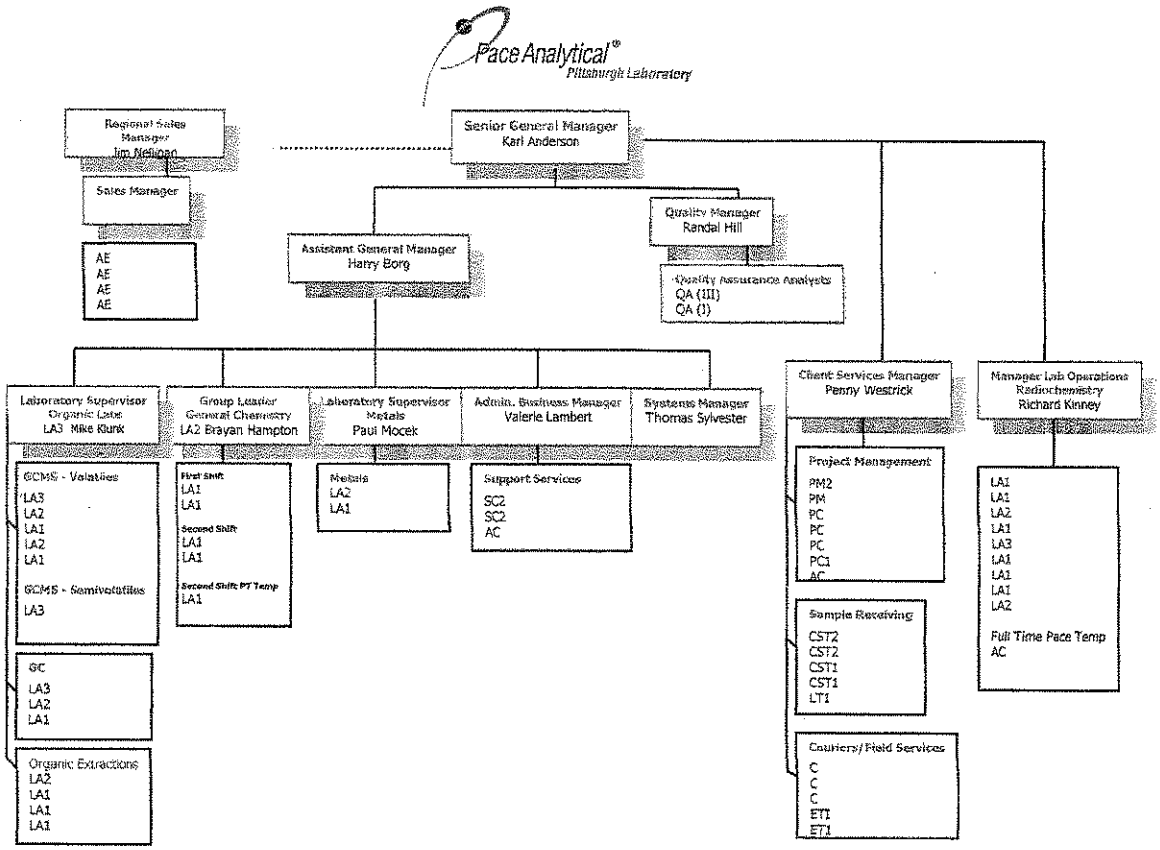
RELATIVE STANDARD DEVIATION (RSD)

$$RSD = \frac{S}{\overline{X}} * 100$$

where:
S = Standard Deviation of the data points
$\overline{X}$ = average of all data points

ATTACHMENT IIA

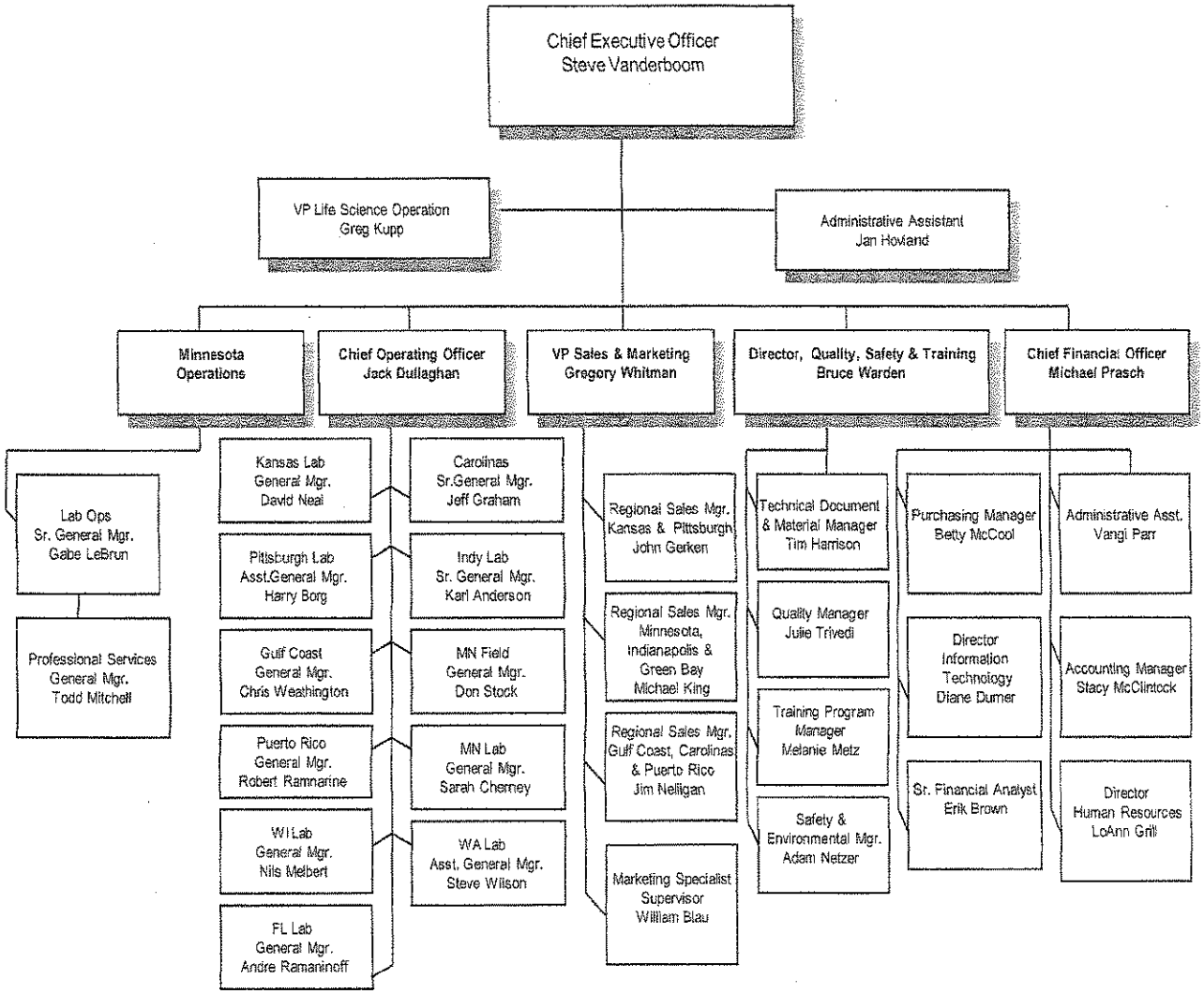
PASI – PITTSBURGH ORGANIZATIONAL CHART



ATTACHMENT IIB

PASI – CORPORATE ORGANIZATIONAL CHART

CORPORATE/MANAGEMENT STRUCTURE



_____ Date: _____
Steve Vanderboom, Chief Executive Officer Dec. 2008

ATTACHMENT III

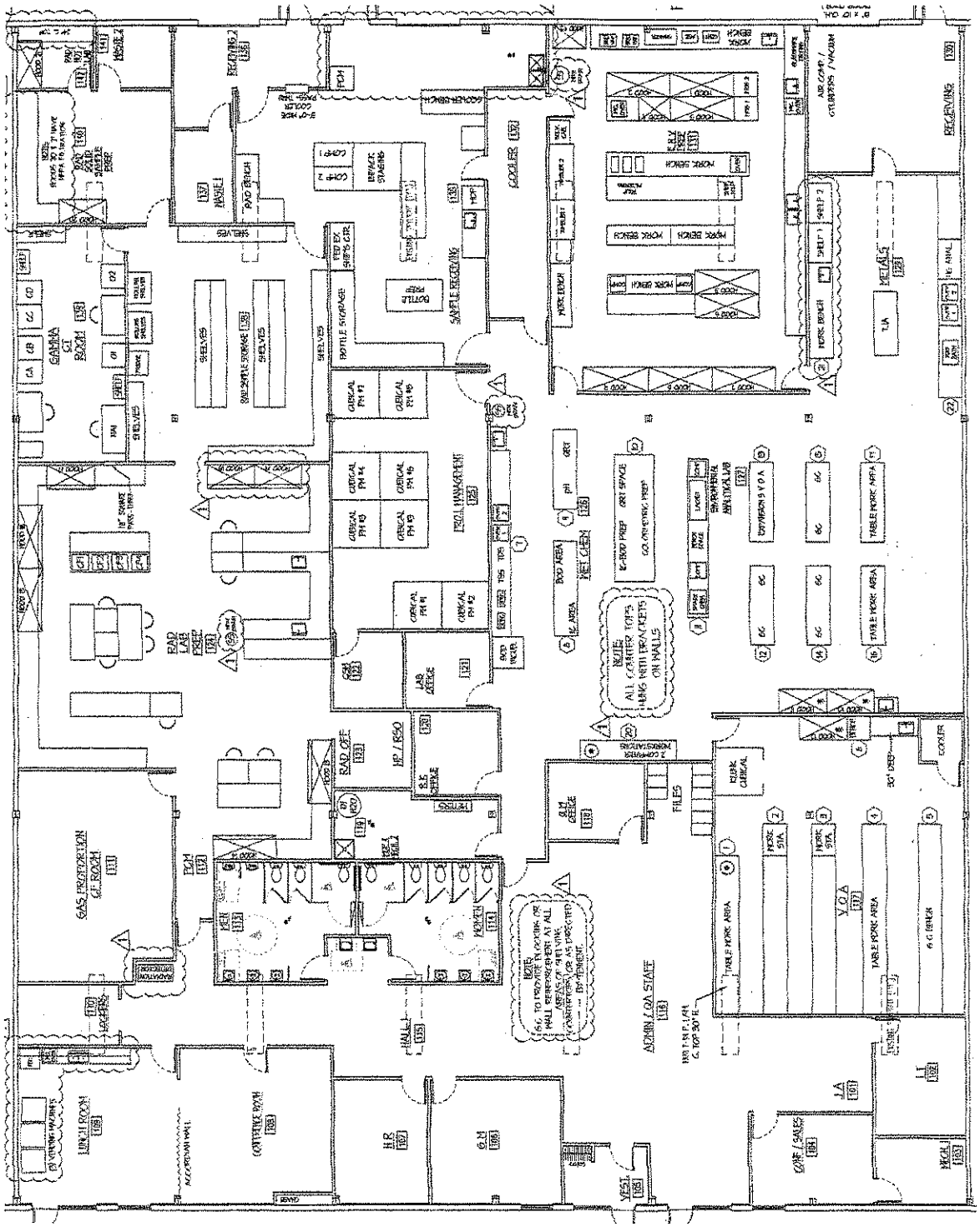
PASI – PITTSBURGH EQUIPMENT LIST

Environmental Lab				
Instrument	Manufacturer	Model No.	Instrument ID	Dept./Test
GC/MS				
	Hewlett-Packard	5973	M5	Semivoa
	Hewlett-Packard	5973	M6	Semivoa
	Hewlett-Packard	5973	M7	Semivoa
	Hewlett-Packard	5973	HP1	Volatiles
	Hewlett-Packard	5973	HP2	Volatiles
	Hewlett-Packard	5973	HP3	Volatiles
	Hewlett-Packard	5973	HP4	Volatiles
GC				
	Hewlett-Packard	5890A	GC A	Pest/PCB
	Hewlett-Packard	5890A	GC D	PCB
	Hewlett-Packard	5890 Series II	GC G	Herbicides
	Hewlett-Packard	5890A	GC C	TPH/DRO
	Hewlett-Packard	5890 Series II	GC P	Glycols/Alcohols
	Hewlett-Packard	5890 Series II	GC K	GRO
ICP				
	Thermo Jerrell Ash	ICAP-61E	ICP 1	Trace Metals
Mercury				
	Leeman	PS-200 II	Hg 1	Mercury
	Cetak	M-6100	Hg-2	Mercury
Automated Spectrophotometers				
	Lachat	QuickChem 8000		Wet Chem
	SmartChem	Discreet Analyzer		Wet Chem
Total Organic Carbon				
	OI Analytical	1030	TOC	Wet Chem
Spectrophotometers				
	Sequoia Turner	SP-850		Wet Chem
	Hach	DR5000		Wet Chem
Infrared Spectrophotometer				
	Perkin Elmer	1310		TPH
Solvent Extractor				
	Dionex	ASE-200		Soil Extraction
Solid Phase Extractor				
	Horizon	SPE-Dex 3000XL		1664A
Microwave Extractor				
	Mars	230/60		Soil Extraction
Ion Chromatograph				
	Dionex	LC20		Anions

Radiochemistry Lab				
Instrument	Instrument	Model No.	Instrument ID	Dept./Test
Carbon/Sulfur Analyzer				
	LECO	EC12 755-10D		Carbon - Sulfur
Moisture Analysis				
	Panametrics	Image Series 2		% Mositure
Gamma Spectrometer				
Canberra	HP Ge Detector 10%	IGC-4019	A (15647)	Gamma Spec
Canberra	HP Ge Detector 40%	GX5019	B (15648)	Gamma Spec
Canberra	HP Ge Detector 60%	GC-6022	C (OOS)	Gamma Spec
Canberra	HP Ge Detector 20%	GR-3521	D	Gamma Spec
Ortec	HP Ge Detector 100%	GEM100P4ST	1 (19623)	Gamma Spec
Ortec	HP Ge Detector 150%	GEM100S	2 (19625)	Gamma Spec
Canberra	NaI	Unispec	1-4	Gamma Spec
Gas Flow Proportional Counter				
	Berthold (10 Detectors)	LB770	1-10 (15641)	Radiochem
	Protean (28 Detectors)	MPC-9604	11-38	Radiochem
Liquid Scintillation Counter				
Parckard	Benchtop LSC	Tri-Carb 2900TR		Radiochem
Alpha Spectrometer				
Canberra	Canberra	Alpha Analyst	1-24 (15645)	Radiochem
Oxford-Tennelec	Tennelec	Alpha Oasis	25-40 (15679)	Radiochem
Alpha Scintillation Counters				
Ludlum	Ludlum	Model 2000 Scaler	A-C	Ra-226
Kinetic Phosphorescence Analyzer				
Chemchek	KPA	KPA-11		Uranium

ATTACHMENT IV

PASI –PITTSBURGH FLOOR PLAN



ATTACHMENT V

PASI – PITTSBURGH SOP LIST

PACE SOP No.	Revision	Document Name
PGH-C-003	2	Review and Verification of Data
PGH-C-001	0	Sample Management
S-ALL-C-002	0	Bottle Order Database
PGH-C-006	3	Assignment of Project Numbers and Sample Identifications
PGH-C-008	1	Subcontracting Analytical Services
PGH-C-009	1	Glassware Washing
PGH-C-012	0	Customer Complaints
PGH-C-016	1	Data Packages
PGH-C-017	1	Waste Management & Disposal
PGH-C-019	A	Hood Face Velocity Measurements
PGH-C-024	0	Cooler Tracking
PGH-C-025	0	PADEP MCL Violation Reporting
PGH-L-001	3	Error Correction Policy
PGH-L-003	0	Incoming Work Policy
PGH-L-004	2	Signature Stamp Policy
PGH-L-005	0	Commercial Dedication of Services and Supplies for Safety Projects
PGH-C-002	1	Training of Laboratory Personnel
S-ALL-Q-001	7	Preparation of Standard Operating Procedures
PGH-C-023	3	Archiving Laboratory Documents
S-ALL-Q-002	2	Document Management
S-ALL-Q-003	2	Document Numbering Procedure
S-ALL-Q-004	4	Method Detection Limit Studies
ALL-PGH-Q-004	0	MDL Addendum
ALL-Q-005	2	Purchase of Laboratory Supplies (& Addendum)
ALL-Q-006	1	Receipt and Storage of Laboratory Supplies (& Addendum)
PGH-C-011	3	Corrective Actions
PGH-C-020	1	Logbook of Logbooks
PGH-C-022	1	Spreadsheet Validation
PGH-C-021	1	Measurement of Uncertainty
S-ALL-Q-009	2	Laboratory Documentation
S-ALL-Q-010	2	PE/PT Program
S-ALL-Q-011	1	Audits and Inspections
S-ALL-Q-013	1	Support Equipment
S-ALL-Q-014	1	Quality System Review
S-ALL-Q-016	3	Manual Integration
S-ALL-Q-018	2	Monitoring Storage Units
S-ALL-Q-021	3	Subsampling (Sample Homogenization)
ALL-Q-022	1	Continuous Process Improvement
S-ALL-Q-025	2	Standard & Reagent Prep & Traceability
ALL-PGH-Q-025	0	Standard & Reagent Prep & Traceability - Addendum
S-ALL-Q-027	0	Evaluation and Qualification of Vendors
S-ALL-Q-028	0	Use and Operations of Lab Track System
S-ALL-Q-029	0	MintMiner Data File Review