Laboratory Quality Assurance Plan

(LQAP)

ALS ENVIRONMENTAL

Fort Collins, CO

Laboratory Quality Assurance Plan (LQAP)

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Appendices use in conjunction with the LQAP are documents routinely revised and do not constitute a revision to the LQAP. If you require an appendix referenced in this document please contact your project manager or quality assurance department for the most current version.

1. INTRODUCTION

This Laboratory Quality Assurance Plan (LQAP) describes the policies, procedures and accountabilities established by the ALS Environmental (ALS) to ensure that the environmental test results reported from the analysis of air, water, soil, waste, and other matrices are reliable and of known and documented quality. This document describes the quality assurance and quality control procedures followed to generate reliable analytical data.

This LQAP is designed to be an overview of ALS operations. Detailed methodologies and practices are written in ALS Standard Operating Procedures (SOPs). Where appropriate, ALS SOPs are referenced in this document to direct the reader to more complete information. A list of current SOPs is found in Appendix H.

ALS maintains certifications pertaining to various commercial and government entities. Each certification requires that the laboratory continue to perform at levels specified by the programs issuing certification. Program requirements can be rigorous; they include semiannual performance evaluations as well as annual audits of the laboratory to verify compliance.

The State of Utah has primacy in administering certification of this laboratory to perform EPA methods. Thus, the Utah State Health Department certifies ALS to perform EPA methods under Utah Rule R444-14. For that reason, reference is made to Utah Rule R444-14 in this LQAP.

ALS is a full service environmental and radiochemistry laboratory, performing analyses for organic, inorganic, and radiological constituents in a variety of matrices. ALS specializes in serving the Department of Energy (DOE), Department of Defense (DoD), and architect-engineering firms. ALS routinely provides hardcopy data packages and electronic data deliverables that are easily validated by external validators.

The management team at ALS applies an integrated approach to quality assurance, client service, and efficient operations, that enables ALS to produce compliant data that meet or exceed all technical and service requirements as prescribed by our clients. This Laboratory Quality Assurance Plan (LQAP) defines ALS's quality assurance (QA) program, and communicates ALS's goals, values and policies regarding quality, ethical conduct, data integrity, and optimized operations . ALS management is committed to continual improvement by implementing the management systems set forth in this LQAP and the following documents ISO 17025;2005, TNI 2009, DoD QSM and DOE QSAS.

Documents and forms used in the laboratory may still have previous ownership names like ATI, PAI, Paragon Analytical, DataChem or DCL. These former names can be used until revision to specific documents is needed.

1.1 MISSION STATEMENT

To provide analytical services to help our customers make informed decisions.

1.2 VISION STATEMENT

To be recognized as a global market leader.

1.3 QUALITY POLICY

ALS is committed to producing legally defensible analytical data of known and documented quality acceptable for its intended use and in compliance with the Safe Drinking Water Act, the Clean Water Act, and the Resource Conservation and Recovery Act. This LQAP is designed to satisfy the applicable requirements of the State of Utah and other state certification programs. ALS complies with the National Environmental Laboratory Accreditation Conference (TNI) standards.

ALS corporate management has committed its full support to provide the personnel, facilities, equipment, and procedures required by this LQAP.

ALS management is committed to improvements of the management systems through compliance with TNI 2009 and ISO 17025:2005 ALS management is also committed to compliance with project related requirements including DOECAP QSAS and DoD QSM 4.2 Gray Boxes.

ALS management reviews its operations on an ongoing basis and seeks input from staff and clients to make improvements. See section 12.1.5 of this plan for details.

It is the policy of ALS that all employees shall be familiar with all Quality documentation.

Within this framework, ALS performs analyses in strict accordance with promulgated methodologies, including:

- USEPA, SW-846, Test Methods for Evaluating Solid Waste, Physical/Chemical Methods;
- USEPA, Methods for Chemical Analysis of Waters and Wastes (MCAWW);
- USEPA, Methods for Determination of Metals in Environmental Samples;
- American Public Health Association (APHA), Standard Methods for the Examination of Water and Wastewater (SM);
- USEPA, Methods for Determination of Organic Compounds in Drinking Water;
- American Society for Testing and Materials (ASTM), Annual Book of ASTM Standards, Volume 11 – Water and Environmental Technology;

- American Society for Testing and Materials (ASTM), Annual Book of ASTM Standards, Volume 12 – Nuclear Energy;
- USDOE, Environmental Measurements Laboratory (EML), Procedures Manual (HASL-300);
- USEPA, Eastern Environmental Radiation Facility (EERF), Radiochemistry Procedures Manual;
- USDOE, Radiological and Environmental Sciences (RESL), Procedures Manual;
- USEPA, Prescribed Procedures for Measurement of Radioactivity in Drinking Water; and
- US, Code of Federal Regulations (40 CFR).

1.4 STATEMENT ON WASTE, ABUSE AND FRAUD

ALS is committed to achieving our goals in the most efficient and effective manner possible, thus avoiding wasteful use of resources. This is accomplished by assuring the proper utilization of ALS's purchased materials and equipment, and time and ability of our personnel. *Any ALS employee who has any suggestion or concern regarding ALS's practices, is encouraged to discuss his/her idea or question with their Department Manager, the Quality Assurance Manager, and/or the Laboratory Director*. A means of confidentially reporting concerns anonymously is also available. Grievances and allegations of unethical conduct will be fully investigated, and appropriate actions taken.

Training regarding ALS's Waste, Abuse and Fraud policies is provided to every new staff member, and to all employees lab-wide as an annual refresher. ALS's policies regarding waste, abuse and fraud are included in ALS SOP 143 and CE-GEN-001**.**

1.5 CODE OF ETHICS AND DATA INTEGRITY STATEMENTS

ALS is responsible for creating a work environment that enables all employees to perform their duties in an ethical manner. *It is ALS's expectation that all employees exhibit professionalism and respect for clients and each other in all interactions and tasks.* ALS requires that each employee abide by the following guidelines:

- Every ALS employee is responsible for the propriety and consequences of his or her actions. Each employee shall conduct him or herself in a professional manner towards all clients, regulators, auditors, vendors, and other employees. Professional conduct relates to honesty, integrity, respect, and tolerance for cultural diversity.

- Every ALS employee shall perform all assigned duties in accordance with ALS's established quality assurance policies and quality control procedures that have been developed to ensure conformance with contractual and regulatory requirements.

- ALS expects all employees to use professional judgment and to document all situations thoroughly. It is the responsibility of each ALS employee to consult the Department Manager or Quality Assurance Manager when atypical or unusual situations occur and to disclose and document the decision-making process. Every employee must disclose any instance of noncompliance. ALS reports all noncompliance issues affecting data to the client.

- It is the responsibility of each ALS employee to report any suspicion of unethical conduct to the Quality Assurance Manager or the Laboratory Director.

Data integrity procedures provide assurance that a highly ethical approach to testing is a key component of all laboratory planning, training and implementation of methods. The following list provides examples of improper, unethical, or illegal practices that ALS ***does not*** tolerate:

- Falsification of records to meet method requirements (e.g., sample records, logbooks, sample results, electronic records). This includes intentional misrepresentation of the date or time of analysis (e.g., intentionally resetting a computer system's or instrument's date and/or time to make it appear that a date/time requirement has been achieved); and unwarranted manipulation of computer software (e.g., improper background subtraction to meet ion abundance criteria for GC/MS tuning compounds).

- Improper use of manual integrations performed to meet calibration or method quality control criteria (e.g., peak shaving or peak enhancement performed solely to meet quality control requirements).

- Selective exclusion of data to meet quality control criteria (e.g., eliminating initial calibration points without technical justification).

- Misrepresentation of quality control samples (e.g., adding surrogates or tracers after sample extraction, omitting preparation steps for quality control samples; over- or under- spiking).

- Reporting results without analyses to support the results (i.e., dry-labbing).

- Notation of matrix interference as basis for exceeding acceptance limits in interference-free matrices.

- Intentional plagiarism or willful misrepresentation of another employee's work as one's own (e.g., Initial or Continuing Demonstration of Capability study (IDOC, CDOC) or Proficiency Testing (PT) study.

Strict adherence to ALS's Code of Ethics and Data Integrity is essential to the reputation and continued health of our business. All ALS employees are required to acknowledge their responsibility and intent to behave in an ethical manner by attesting to the requirements described above upon joining the ALS staff, and annually thereafter.

1.6 REVIEW, REVISION, DISTRIBUTION AND HIERARCHY OF QA DOCUMENTS

Current copies of pertinent quality assurance guidance documents, such as ALS's LQAP, the TNI Standards, ISO 17025:2005, the US DOE Quality Systems for Analytical Services (QSAS), the US DoD Quality Systems Manual (QSM) and others, are posted to the ALS network so that they are accessible to every employee. Laboratory Standard Operating Procedures (SOPs) and other method references are also posted to the network for lab-wide employee access. Project-specific requirements are disseminated to the laboratory via Laboratory Information Management Systems (LIMS) program specifications (discussed further below).

ALS Laboratory Group - Fort Collins recognizes a hierarchy of guidance that provides for comprehensive definition, yet flexible coverage, thus enabling both overall program and site-specific needs to be met. An overview explaining this hierarchy is given below and in ALS SOP 143. **SOP 926** provides detailed guidance on the review, revision, and distribution of laboratory-generated controlled documents.

1.6.1 LABORATORY QUALITY ASSURANCE PLAN

The LQAP is an encompassing controlled-document that describes ALS's quality assurance program and policies. All systems, policies, and procedures have been developed and implemented in accordance with applicable USEPA requirements, regulations, and guidance; the current TNI standards; and requirements set forth in various client quality assurance documents and contractual specifications. This document has been prepared in accordance with these referenced documents, as well as others, cited in the attached **Bibliography**. The LQAP is intended to provide a 'quality requirements framework', including quality control (QC) procedures to be followed in the absence of project-specific requirements (note that project-specific requirements are communicated to laboratory staff via LIMS program specifications, which are discussed subsequently).

The Quality Assurance Manager (QAM) bears primary responsibility for ensuring that the LQAP meets industry standards. Proposed revisions to the LQAP are approved by key laboratory personnel . Following approval, the QAM posts the revised LQAP to the ALS network, revised to LQAP document in LIMS. The LIMS notifies personnel of all revised documents. It is the requirement of all employee to read and update reading records for all assigned controlled documents. Archival records of all LQAP iterations are maintained by the Quality Assurance Department.

1.6.2 STANDARD OPERATING PROCEDURES

The second kind of controlled-document in the hierarchy of quality assurance guidance are the Standard Operating Procedures (SOPs). An SOP defines the QA/QC requirements for each method and describes in detail how personnel perform procedures and evaluate data. SOPs pertaining to general practices (e.g., standards, temperature monitoring, etc.), administrative procedures (e.g., procurement of supplies and materials, etc.) and health & safety requirements (e.g., ALS Safety Modules and the Chemical Hygiene Plan), are also maintained by ALS. It is ALS's intent that the information contained in our SOPs are both method-compliant, and accurately reflect actual practice. *Suggestions for SOP content clarification or revision are encouraged.* SOPS are published to the network when approved.

The LIMS notifies personnel of all revised documents. It is the requirement of all employees to read and update reading records for all assigned controlled documents

This process of revision, approval and distribution is established in the ALS SOP 926. A list of current SOPs is provided in **Appendix H**. The Quality Assurance Department manages the review, revision and controlled distribution of documents and maintains associated records.

1.6.3 LABORATORY MANAGEMENT INFORMATION SYSTEMS (LIMS) PROGRAM SPECIFICATION

The last and most specific controlled-document in this hierarchy is the LIMS program specification. The LIMS program specification is a distillation of client Quality Assurance Project Plan (QAPjP) or contractual requirements, prepared electronically by the ALS Project Manager (PM), in collaboration with the QAM and applicable Department Managers. This custom program specification, along with the associated LIMS test code nicknames, contain directives and controls that govern testing and reporting data. The program specification is often limited in scope and addresses only those QA/QC criteria required for a specific project. *When the client's requirements differ from those stated in the SOPs and/or LQAP, the project-specific*

LIMS program specification requirements supersede the others. ***It is the responsibility of all personnel who work with samples or data to consult the applicable LIMS program specification for client-specific requirements prior to initiating handling of the samples or data.***

2. LABORATORY ORGANIZATION AND RESPONSIBILITIES

This section provides an overview of ALS organization and defines key personnel, their responsibilities, and the lines of communication between these employees. An organization chart that illustrates reporting relationships is provided in **Appendix B**.

ALS policy is to perform work for clients in the most efficient manner possible, avoiding waste of resources and undue pressure on employees. It is the role of both ALS management and employees to ensure that work for clients is performed most efficiently and effectively by properly utilizing ALS purchased materials, equipment, and the time and ability of personnel..

2.1 GENERAL REQUIREMENTS FOR LABORATORY PERSONNEL

ALS maintains sufficient personnel to perform analytical services for our clients. Each employee must have a combination of experience and education that enables him or her to demonstrate a specific knowledge of his or her job function, and a general knowledge of laboratory operations, test methods, QA/QC procedures, and records management. *All personnel are responsible for complying with the requirements that pertain to his/her assigned duties.*

2.2 KEY PERSONNEL

Education, experience and skill requirements for these positions are addressed in job descriptions (Title). Functional responsibilities are further discussed below.

In the event of a temporary absence, key personnel must notify other key staff of their absence and reassign their duties to another employee (deputy) who will perform the assigned duties. For example, a PM may assign another PM to cover his or her duties; a Department Manager may assign a senior chemist to cover his or her duties within the Department; and the Laboratory Director may assign a Manager to cover his or her duties.

2.1.1 LABORATORY DIRECTOR

The Laboratory Director (Laboratory Director) is responsible for:

- All laboratory operations, including: business functions such as marketing, sales and financial issues; technical functions such as sample control, preparation, analysis, data management; and quality assurance;

- Providing input and support to proposal processes, including interacting with the Sales, Technical and Quality Assurance staff, to ensure that the laboratory is capable of complying with client and regulatory requirements;

- Supervising all personnel through Management staff, who ensure that QA/QC procedures are being performed and that any nonconformances or discrepancies are documented and remedied properly and promptly;

- Ensuring that corrective actions relating to Findings from internal and external audits are completed in a timely fashion;

- Ensuring that the laboratory has the appropriate resources and facilities to perform analytical services;

- Ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory;

- Defining the minimum level of education, experience, and skills necessary for all positions in the laboratory;

- Ensuring that only those vendors and supplies that are of adequate quality are used; and

- Directing the performance of the annual Managerial Review.

2.1.2 QUALITY ASSURANCE MANAGER

The Quality Assurance Manager (Manager) reports to the Laboratory Director and is independent of daily operation and production requirements. Therefore, the QAM is able to evaluate data objectively and perform assessments without production influence. *The QAM has authority to stop work if systems are sufficiently out of control to compromise the integrity of the data generated.*

The QAM shall have documented training and/or experience in QA/QC procedures; knowledge of quality systems as defined by TNI and other management systems standards; and a general knowledge of the analytical test methods for which data review is performed.

The QAM (and/or designee) is responsible for:

- Defining and implementing the quality system;

- Developing and maintaining a pro-active program for prevention and detection of improper, unethical, or illegal

practices (e.g., single- or double-blind proficiency testing studies, electronic data audits, maintaining documents that identify appropriate and inappropriate laboratory and data manipulation practices);

- Ensuring continuous improvement of laboratory procedures via training, control charts, proficiency testing studies, internal audits, and external audits;
- Coordinating the laboratory's participation in state and Federal certification programs;
- Scheduling the review and distribution and maintaining distribution records of controlled documents, including plans (e.g., LQAP, etc.) and SOPs;
- Reviewing, when requested, Requests For Proposal (RFPs) to ensure ALS compliance with required QA/QC practices;
- Facilitating external audits;
- Overseeing or conducting internal audits of the entire operation annually (technical, management system, data, electronic);
- Coordinating, preparing and approving external and internal audit responses and corrective actions;
- Managing the laboratory's participation in proficiency testing (PT) studies;
- Reviewing nonconformances and approving corrective actions;
- Reviewing QC limits per established procedures;
- Ensuring that Detection Limit studies are performed and documented per requirements;
- Managing the reference standards used in the calibration and/or verification of support equipment (e.g., weights, thermometers, balances);
- Revising the LQAP annually in accordance with industry standards;
- Maintaining an archival system for quality records; and

- Maintaining technical and quality assurance training records, including employee competency to perform testing.

2.1.3 HEALTH & SAFETY MANAGER/RADIATION SAFTETY OFFICER (RSO)

The Health & Safety Manager/Radiation Safety Officer (RSO) (Safety Officer)reports to the Laboratory Director. This Manager is responsible for establishing and monitoring adequate systems, procedures and training to ensure that the laboratory staff, facilities and operational activities conducted, function in a manner that minimizes employee risk of illness and injury, is compliant with all applicable regulations pertaining to matters of safety and health, and that limits the financial liability of the corporation as it relates to these matters. As RSO, this Manager is also responsible for discharging the duties and requirements prescribed by ALS's Radioactive Materials License.

Key responsibilities of the Health & Safety Manager/RSO (and/or designee) include:

- Ensuring that all employees have sufficient training to perform their job without unnecessary risk of illness or injury, providing health and safety, including radiation safety, training for new employees, and maintaining health and safety-related training records;

- Providing procedural guidance in the form of the Chemical Hygiene Plan (CHP), Radiation Protection Plan (RPP), Respiratory Protection Plan (ResPP), Emergency and Contingency Plan (ECP) and Health and Safety SOPs, and ensuring that these guidances are reviewed by laboratory staff;

- Ensuring that the laboratory facilities are maintained and operated in a safe manner, including:

    (a) Performing routine safety inspections of all operational areas;

    (b) Performing routine radiation surveys and managing the radiation dosimetry program; and

    (c) Performing personal monitoring, as indicated, for chemical and other exposures.

- Maintaining the laboratory's Colorado Radioactive Materials License and ensuring compliance with the terms of the license. Included in this responsibility are:

(a) Procuring and managing radioactive sources and standards;

(b) Maintaining the laboratory's radioactive materials inventory, which also includes directing prescreen analyses that provide initial characterization of potential sample radioactivity;

(c) Overseeing permitted low level radioactive materials releases to the sanitary sewer; and

(d) Ensuring that radioactive materials waste are transported in accordance with all Federal and state regulations, and are transferred only to facilities that possess a radioactive materials license.

2.1.4 FACILITIES/WASTE COMPLIANCE MANAGER (SAFETY OFFICER)

The Facilities/Waste Compliance Manager (Safety Officer), reports to the Laboratory Director. This Manager is responsible for day-to-day management of the building and serves as the primary point of contact for all matters related to waste collection and disposal.

The Facilities/Waste Compliance Manager (and/or designee) is responsible for:

- Coordinating heating, ventilation, and air-conditioning (HVAC) systems operation and maintenance;
- Maintaining the uninterruptible power supply (UPS) and coordinating maintenance and repairs to the electrical system;
- Maintaining the in-house vacuum system;
- Coordinating repairs to the building (e.g., doors, locks, windows, cabinetry);
- Maintaining the building's security and fire alarm system;
- Interfacing with fire inspectors; and responding to security and fire alarms on a 24-hour basis;
- Implementing waste reduction procedures;
- Managing the accumulation of radioactive waste in the laboratory;

- Developing and maintaining Satellite Accumulation Areas (SAAs) and 90-Day Storage Areas;

- Overseeing all waste disposal operations performed by ALS, including (1) ensuring compliance with Federal, state, and local regulations for waste handling and disposal in accordance with RCRA, TSCA, and radioactive waste disposal regulations; (2) managing hazardous waste shipments to Temporary Storage and Disposal Facilities (TSDFs); (3) managing sanitary sewer releases; and (4) managing sample archives and the return of samples and sample residues to clients;

- Training personnel on proper techniques for sample handling and waste disposal, according to standards implemented by Federal, state, and local authorities and maintaining associated training records; and

- Supervising the Sample Receiving Department.

2.1.5 INFORMATION SYSTEMS MANAGER

The Information Systems (IS) Manager (Manager) reports to the Laboratory Director. This Manager is responsible for administering the network, maintaining data recovery systems, and for managing personal computing (PC) equipment and peripherals, thus supporting instrumentation and LIMS. The IS Manager (and/or designee) is responsible for:

- Managing and maintaining the laboratory computer system. This function includes determining and purchasing appropriate hardware and verifying that its function meets intended objectives, establishing network server structure, and developing and implementing proper maintenance and backup procedures;

- Procuring, configuring and maintaining all printers and copiers;

- Serving as a technical resource on computer-related issues;

- Documenting related operating procedures through SOPs, manuals or other proprietary documentation;

- Supervising recovery of all systems in the event of a disaster;

- Along with the Laboratory Information Systems Manager, analyzing information flow in the laboratory and suggesting the most effective hardware, applications software, and/or programming changes as solutions to meet long-term customer requirements; also, implementing those changes in data acquisition and management by purchasing hardware or software, where software is not developed internally; and

- Maintaining and implementing existing and future communications systems, including all internet and telephone systems.

2.1.6 LABORATORY INFORMATION MANAGEMENT SYSTEMS MANAGER

The Laboratory Information Management Systems (LIMS) Manager reports to the Laboratory Director, and bears the primary responsibility for the LIMS, which serves the needs of the technical, business, and management functions of the laboratory.

Key responsibilities of the LIMS Manager (and/or designee) include:

- Designing and developing information systems that relate to data capture and reporting;

- Maintaining and supporting applications that access LIMS and maintaining and supporting database back-end applications used for LIMS;

- Documenting changes and procedures through SOPs, manuals or other proprietary documentation;

- Developing software, as needed, using the appropriate tools, and per industry standard methodologies and validations;

- Overseeing and assisting with the implementation, testing and verification of upgrades made to instrument software;

- Coordinating all efforts to automate and improve electronic systems and processes throughout the laboratory;

- Developing interfaces necessary to achieve the requirements for client-specified electronic data deliverables (EDDs), and managing all deliverable formats provided to clients (hardcopy, electronic); and

- Providing training, as applicable, for all LIMS-related applications.

2.1.7 PROJECT MANAGER

- Project Managers report to the Client Services Manager . *The Project Manager serves as the primary point of contact between clients and ALS.* Each PM (and/or designee) is responsible for:

- Managing and coordinating the laboratory's performance after contract award, by defining technical and service requirements for personnel via LIMS, and interacting with clients and laboratory personnel to ensure that technical criteria and client service needs are met, including monitoring holding times (if appropriate) and deliverable deadlines, for all project sample analyses;

- Reviewing and approving any nonconformances reported by the laboratory and notifying the client, if appropriate, and communicating with clients pro-actively to ensure that all client service and technical concerns are resolved promptly;

- Reviewing all final reports for completeness, compliance with project requirements, clerical accuracy, and reasonableness;

- Generating, as directed by prompts provided in ALS's proprietary EDD generator, and transmitting EDDs to their clients as required;

- Ensure communications with the clients are in compliance with ALS SOP 997 "Client Communication"; and

- Communicating to the Laboratory Director any potential need for new or improved capabilities based on clients' feedback.

2.1.8 TECHNICAL OR DEPARTMENT MANAGER

Technical and Department Managers report to the Laboratory Director. These Managers exercise day-to-day supervision of laboratory personnel, procedures, and reporting of results. They maintain technical expertise in their area of specialization (e.g., organics, inorganics, radiochemistry.

Technical Managers and Department Managers (and/or their designee) are responsible for:

- Providing technical education and training to personnel, authorizing personnel with appropriate educational and/or technical background perform all tests for which the laboratory is accredited, and providing documentation of employee capability and training., and ensuring that training and documentation are up to date;

- Assigning job tasks and prioritizing analyses;

- Developing and implementing a preventive maintenance program for instrumentation in their laboratory, and ensuring that all equipment is maintained, serviced, and properly calibrated;

- Monitoring QA/QC standards of performance, including ensuring that corrective actions are developed, documented, and implemented for all external and internal audit Findings, PT study failures, and other corrective actions;

- Monitoring the validity of the analyses performed and data generated in the laboratory to ensure the production of compliant data, including, contributing to and/or overseeing data review processes;

- Ensure that SOPs are compliant with promulgated methodologies and reflect current practice;

- Maintaining current, compliant MDL studies for all methods, matrices, analytes, columns, and instruments;

- Coordinating and approving the purchase of reagents, standards, glassware, and equipment that meet requirements;

- Providing input to the Laboratory Director regarding methodologies, personnel resources, software, and instrumentation; and assisting in the evaluation and/or development of new methods and technologies that improve ALS's ability to meet clients' needs;

- Reviewing RFPs and assisting in the preparation and submission of proposals; and

- Interacting with the Quality Assurance, Information Systems, and Health and Safety Departments to ensure that the laboratory is capable of complying with client and regulatory requirements.

2.2 GENERAL TECHNICAL PERSONNEL

A chemist (analyst) or technician reports to a Technical or Department Manager. This employee performs work in accordance with ALS's controlled documents (e.g., SOPs, LQAP, etc.) and project-specific requirements as defined by the applicable LIMS specification. *ALS believes that quality begins at the bench.* Accordingly, these employees are key contributors to ALS's success.

A chemist or technician is responsible for:

- Demonstrating proficiency in the analyses for which they are responsible ***before*** analyzing samples (e.g., performing acceptable Initial Demonstration of Capability), and documenting this demonstration of proficiency in accordance with ALS Procedure 150;
- Performing analyses, recording all data accurately, directly, and promptly, and interpreting and reviewing data according to established procedures;
- Read and understand all assigned SOPs and plan documents;
- Complying with all QA/QC requirements that pertain to their job function;
- Complying with all health, safety, and waste disposal requirements, as applicable;
- Maintaining and repairing instrumentation;
- Demonstrating good house-keeping practices;
- Disclosing all instances of nonconformances promptly and in writing using the NCR process (**SOP 928**); and
- Participating in training sessions.

3. QUALITY ASSURANCE INDICATORS AND OTHER MEASUREMENT PARAMETERS

ALS' objective is the development and implementation of policies and procedures that provide results of known, documented, and appropriate quality. This LQAP defines general policies for the analysis, documentation, evaluation, validation, and reporting of data. Specific, detailed procedures for chain-of-custody, calibration of instruments, analysis, reporting, quality control, audits, preventative maintenance, and corrective actions, are provided in SOPs as listed in **Appendix H**.

In order to produce data of known, documented, and appropriate quality, ALS:

- maintains an effective quality assurance program that measures and verifies laboratory performance;

- provides for a Quality Assurance Department that is independent of the operational groups and that has stop-work authority, and that has the responsibility and authority to audit the laboratory and develop and enforce corrective actions;

- evaluates technical and service requirements of all analytical services requests before accepting samples from a client/project. This evaluation includes a review of facilities, instrumentation, staffing, turnaround times, and any project-specific quality control or reporting requirements;

- provides sufficient flexibility to allow controlled changes in routine methodology in order to achieve client-specific data requirements as prescribed in client documents and contracts;

- documents initial demonstration of capability (IDOC) and continuing demonstration of capability (CDOC) for all methods according to Appendix C of the TNI standards;

- performs all analyses according to promulgated methods or methods developed and validated by ALS and documented in SOPs;

- recognizes as soon as possible and discloses and corrects any factors that adversely affect data quality; and

- maintains complete records of sample submittal, raw data, laboratory performance, and completed analyses to support reported data.

3.1 DATA QUALITY INDICATORS

Data Quality Indicators (DQIs) are qualitative and quantitative statements developed by data users that specify the quality of data from field and laboratory data collection activities in order to support specific decisions or regulatory actions. The DQIs describe *what* data are needed, *why* the data are needed, and *how* the data will be used to address the problem being investigated. DQIs also establish qualitative and quantitative goals that allow the data user to determine whether the data are of sufficient quality for the intended application.

The principal DQIs are **precision**, **accuracy** (bias), **representativeness**, **completeness**, and **comparability** (i.e., the PARCC parameters). The following sections define and describe the application of these parameters. The QA/QC protocols used for the majority of analyses are adopted from SW-846 and 40 CFR methodologies, the USEPA Organics and Inorganics CLP SOWs, and various radiochemistry guidances, which contain detailed descriptions of the quality control measures routinely employed.

3.1.1 PRECISION

Precision is an expression of the reproducibility or degree of mutual agreement among independent measurements as the result of repeated application of the same process under similar conditions. Precision refers to the distribution of a set of reported values about the mean, or the closeness of agreement between individual test results obtained under prescribed conditions. Precision reflects random error and may be affected by systematic error. Precision characterizes the natural variation of the matrix and the contamination that may vary within that matrix. For chemical parameters that do not allow homogenization prior to analysis (e.g., volatile organics analysis), one must review precision values carefully.

Analytical precision is a measurement of the variability associated with duplicate or replicate analyses of the same sample in the laboratory. Analytical precision is determined by the analysis of matrix spike/matrix spike duplicates (MS/MSD), laboratory control sample pairs (LCS/LCSD), or by unspiked duplicate samples (DUPs). Total precision is a measurement of the variability associated with the entire sampling and analysis process, and is determined by analysis of duplicate or replicate *field* samples, thus incorporating the variability introduced by both the field and laboratory operations.

Precision is independent of bias or accuracy, and reflects only the degree to which the measurements agree *with one another*, not the degree to which they agree with the true or accepted value of the parameter measured. Precision for stable chemistry analyses is typically expressed as relative percent difference (RPD), as defined below:

$$RPD(\%) = \frac{X_1 - X_2}{(X_1 + X_2)/2} \quad (100)$$

where:

RPD = Relative Percent Difference

X_1, X_2 = analyte value of sample 1 and sample 2

Precision, for radiochemical analyses, is typically measured in terms of Duplicate Error Ratio (DER), calculated as follows:

$$DER = \frac{|S - D|}{2 * \sqrt{\sigma^2{}_S + \sigma^2{}_D}}$$

where:

DER = Duplicate Error Ratio

S, D = analyte values of (S)ample and (D)uplicate

σ = One Sigma error value associated with sample result

RPDs or DERs are compared to the control limits established for the analysis method, or other quality control criteria as prescribed in the applicable LIMS program specification. Precision objectives vary per analytical method. Sample homogeneity/non-homogeneity is an important factor that influences the precision of duplicate sample results.

3.1.2 ACCURACY

Accuracy is an expression of agreement between the measured and known or accepted reference values. Accuracy is the measure of the closeness of an observed value to the "true" value (e.g., theoretical or reference value or population mean). Accuracy is influenced by random error and systematic error (bias) that occur during sampling and analytical procedures; therefore, accuracy reflects the total error associated with a measurement. A measurement is accurate when the value reported does not differ significantly from the known concentration of the spike or standard.

Accuracy is typically measured by determining the percent recovery of known target analytes (i.e., a surrogate or matrix spike) that are spiked into a field sample or reagent water or simulated solid matrix (laboratory control sample). Surrogate recovery is reported and is used to assess method performance for each sample analyzed for volatile and semivolatile organic compounds. For organic and inorganic parameters, the stated accuracy objectives apply to spiking levels at or near the midpoint of the calibration curve. For radiochemical analyses, the spiking levels for the control spikes may vary from five to fifty times the method reporting limit.

Percent recovery is calculated as:

$$R(\%) = \frac{(C_1 - C_2)(100)}{C_3}$$

where:

R% = Spike amount recovered
C_1 = Concentration of analyte in spiked sample
C_2 = Concentration of analyte in unspiked sample
C_3 = Concentration of spike added

Acceptance limits are usually based upon established laboratory performance for similar samples. Other quality control criteria may be prescribed in the applicable LIMS program specification. Recoveries outside the established limits may indicate some assignable cause other

than normal measurement error, and the need for corrective action. This corrective action may include reanalysis of the quality control sample, recalibration of the instrument, reanalysis of the affected samples in the batch, re-preparation of samples in the batch, or flagging and qualifying the data as suspect if the problem cannot be resolved. For contaminated samples, recovery of matrix spikes may depend on homogeneity, matrix interference, and dilution requirements for quantitation.

Both accuracy and precision are calculated for each batch and the associated sample results must be interpreted by considering theses specific measures. The quality assurance objectives for precision and accuracy are to achieve the quality control acceptance criteria specified in the appropriate analytical procedure.

For organic analyses, precision and accuracy are determined by using matrix spike and matrix spike duplicate samples and/or surrogate spike compounds and laboratory control samples. For inorganic analyses, precision and accuracy are determined by using duplicate samples or matrix spike duplicate samples (precision) and matrix spike and laboratory control samples (accuracy). For radiological analyses, precision and accuracy are determined from the results of duplicate samples or matrix spike duplicate samples (precision), laboratory control sample duplicates (precision) and laboratory control samples (accuracy).

Samples identified as field blanks cannot be used for duplicate or matrix spike sample analyses.

QC limits for accuracy and precision may be developed from intra-laboratory historical data or adopted from prescribed limits required by the client. If quality control acceptance criteria do not exist for a given method, then the laboratory may establish advisory control limits derived from a minimum of four data points. Until verified by a statistically significant data population, the control limits will be considered as advisory limits only, and the laboratory will not automatically initiate reanalysis if these limits are not achieved. See Section 9.3 for further discussion of control limits and control charts.

Bias describes the systematic error of a measurement process that causes errors in one direction from the true value. Sources of bias include incomplete homogenization before subsampling and incomplete extraction of target analytes. Calibration drift, which is the nonrandom change in a measurement system over time, is another example of systematic error, and is detectable by the periodic

measurement of calibration check standards. *Bias is **not** equivalent to accuracy.*

3.1.3 REPRESENTATIVENESS

Representativeness is a qualitative element. It expresses the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition within a defined spatial and/or temporal boundary.

Sample handling protocols (e.g., holding times, storage, preservation and transportation) have been developed to preserve the representativeness of the samples. Proper documentation establishes that quality control protocols have been followed, and sample identification and integrity are ensured. *ALS makes every attempt to ensure that the aliquots taken for analysis are homogenous and representative of the samples received.*

3.1.4 COMPARABILITY

Comparability is a qualitative expression of the confidence with which one data set can be compared to another. Comparability is achieved by:

- following established, standardized, and approved sample collection techniques and analytical methods;
- achieving holding times;
- reporting results in common units;
- using consistent detection levels; and
- reporting data according to consistent rules.

See Chapter 10 of this LQAP for further discussion of standard units typically used to report various analytical parameters.

3.1.5 COMPLETENESS

Completeness is an expression of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under normal conditions. Completeness is the percentage of measurements that are judged to be usable (i.e., that meet project-specific requirements). Completeness goals are defined in the site sampling and analysis plan, QAPjP or contract, and vary with the size and complexity of the project. Completeness goals of 80-95% are traditionally accepted as realistic. ALS's objective is 100% completeness for samples unaffected by matrix interferences.

It is recognized that some samples are highly contaminated with target and/or non-target compounds, which necessitate cleanups, multiple analyses, and/or extensive dilutions. In these instances, the internal QC results for a sample help to demonstrate the impact upon recoveries and detection limits due to these atypical situations.

Factors that adversely affect completeness include:

- receipt of samples in which chain-of-custody or sample integrity is compromised in some manner (e.g., broken containers, improperly preserved);
- receipt of insufficient volume to perform initial analyses or repeat analysis if initial efforts do not meet QC acceptance criteria;
- receipt of samples for which more than 50% of the holding time has expired; and
- receipt of samples that contain high levels of contamination that can cause persistent effects on instrumentation designed for trace-level analyses.

The equation used to calculate completeness is:

$$C\% = \frac{S}{R} (100)$$

where:

C = completeness
S = number of successful analyses
R = number of requested analyses

The USEPA 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 as a result of random error, assuming the confidence interval is established at 95% (preamble to 40 CFR Part 136, Vol. 49, No. 209, October 26, 1984). As the number of compounds measured increases in a given sample, the probability for realizing statistical error also increases. The number of compounds present in various methods (e.g., GC/MS Methods SW8260B and SW8270C, ICAP Method SW6010B and Gamma Spectroscopy Method EPA 901.1), increases the probability that one or more analytes will not meet acceptance criteria, to significantly more than the 5% per analyte frequency. The number of target analytes included in these methods can be used to show that a minimum of four to seven target

analytes will exceed the control limits established for these methods as a result of the statistical probability for random error. *Establishing quality control criteria that are not consistent with the measurement of the quality objectives for which they are intended is discouraged.*

3.2 TRACEABILITY

Traceability is the extent to which results can be substantiated by hard-copy documentation, electronic or computer-generated data calculations, computer software, and data generation. Traceability documentation exists in two forms: (1) that which links final numerical results to authoritative measurement standards, and (2) that which explicitly describes the history of each sample from collection to analysis. Measurement traceability is further discussed in Chapter 7 of this LQAP.

3.3 SENSITIVITY (STABLE CHEMISTRY)

The term sensitivity is used in a broad sense to describe the various limits that enable a laboratory to meet project-specific data quality objectives (DQOs). These limit types include: instrument detection limit (IDL), method detection limit (MDL), method quantitation limit (MQL) or method reporting limit (RL), contract-required detection limit (CRDL), and contract-required quantitation limit (CRQL).

3.3.1 IDL AND LOD

The IDL is a minimum value that addresses the detection capability of the ICP instrument *only*, hence IDL studies are performed on a per analyte per instrument basis. IDL studies are particularly important to metals analyses. These IDL studies must be conducted on an whenever there is a significant change in instrument components or reagents.

The LOD (Detection Limit or MDL) is a minimum value that addresses the detection capability for the sample preparation procedures and the instrument. Hence, ALS performs LOD studies for each preparatory and determinative method combination, matrix, instrument, and analytical column. LOD studies are ongoing in each batch of samples tested LOD studies are also required for method validation, and whenever the basic chemistry of a procedure changes.

LOD (MDL) is defined as the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero. LODs are determined using ALS SOP 329.

An MDL study is not performed for radiological analyses, or any components for which spiking solutions are not available or relevant (e.g., pH, ignitability, etc.). Reporting limits for these kinds of

parameters, where applicable, are established based on the laboratory's knowledge of extraction efficiency, instrument sensitivity, and experience with the procedure. **SOP 329** provides additional information about LOD studies.

Results calculated between the MDL and the MQL (RL) contain a significant amount of error . Therefore, values reported between the LOD and LOQ(RL) are qualified as estimated – 'J' flagged for organic parameters, 'B' flagged for inorganic parameters. Also, LOD values are based on an interference-free matrix, and cannot evaluate the effects of sample matrix. Therefore, established LODsMDLs may not be achievable in some environmental matrices.

3.3.2 LOQ (MQL, RL)

ALS defines LOQ as the analyte concentration at or above which the laboratory's precision and accuracy requirements can be routinely demonstrated and achieved. The statistical error associated with this region of a calibration curve is significantly smaller than that associated with the region near the MDL. The LOQ values for most analytes reported by ALS are numbers that are approximately 3 to 5 times the values of the LOD for those analytes. It is ALS's policy to analyze a calibration standard at or below the LOQ when performing an initial calibration.

The LOQ is the lowest level that can be reliably measured by a laboratory with defined limits of precision and bias. The precision and bias at the LOQ is associated with Reporting Limits verification samples analyzed. The USEPA CLP SOW uses the terms CRDL and CRQL to describe *contractually-required* levels of reporting. These reporting terms do not describe instrument sensitivity.

3.4 MINIMUM DETECTABLE CONCENTRATION (RADIOCHEMISTRY)

The minimum detectable concentration (MDC) is used for radiochemical procedures and is defined as the concentration at which there is a 95% confidence that an analyte signal will be distinguishable from an analyte-free sample.

The general formula for calculating the MDC is based on calculations derived by Curie (Curie, L.A., "Limits for Qualitative Detection and Quantitative Determination," Analytical Chemistry 40(3); pp. 586-693; 1968) and is calculated as follows:

$$MDC = \frac{(4.65\ X\ \sigma_b) + 2.71}{T * K}$$

where:

MDC = Minimum Detectable Concentration

σb = Standard deviation of the measurement background

T = Sample count time

K = Factor for incorporating efficiency, abundance, aliquot yield, ingrowth and decay, and activity conversion factors

3.5 MEASUREMENT UNCERTAINTY

3.5.1 ANALYTICAL UNCERTAINTY FOR STABLE CHEMISTRY

Uncertainty is associated with most of the results obtained in the laboratory testing conducted by ALS. It is meaningful to estimate the extent of the uncertainty associated with each result generated by the laboratory. It is also useful to recognize that this measurement uncertainty is likely to be much less than that associated with sample collection activities. In practice, the uncertainty of a result may arise from many possible sources. ALS has considered the relative contribution of major sources of error. The approach adopted by the laboratory to estimate uncertainty resulted in the conclusion that many sources of error are insignificant compared to the processes of sample preparation, calibration, and instrumental measurement. The uncertainty associated with these processes can be estimated from quality control data. Accordingly, ALS estimates uncertainty from data derived from quality control samples carried through the entire analytical process. Each estimate of uncertainty is associated with a specific combination of analytical method and sample matrix.

The ALS Standard Operating Procedure 998 gives details of how uncertainty in the analytical process is estimated, calculated and reported if required.

3.5.2 TOTAL PROPAGATED UNCERTAINTY FOR RADIOCHEMISRY

Total propagated uncertainty (TPU), is a summation of the various uncertainties present in a measurement process, and is an integral part of every reported radiochemical value. TPU, reported as ±TPU, is the expressed estimated measure of the total uncertainty inherent in that reported radiochemical result.

The components of the TPU are classified as either random or systematic. Random uncertainties, also called counting uncertainties (CU), derive from the statistically random (normally distributed) nature of radioactive decay, and are estimated as the square root of the total number of counts acquired during analysis. In cases where the chemical yield is determined by the analysis of a radioactive tracer, the yield uncertainty (YU) is also a random uncertainty, and is estimated as the square root of the total number of tracer counts acquired. CU and YU are calculated in activity units to afford comparability to the sample result.

Systematic uncertainties are attributable to actual errors in the measurement of a physical quantity. For example, if a balance has an accuracy of $\pm$0.1%, the results of those gravimetric measurements are not normally distributed, but rather are assumed to be biased by that amount. Estimates of systematic uncertainties in

laboratory processes are somewhat subjective, but should be supported by empirical data whenever possible. Systematic uncertainties associated with the preparation of a sample are called preparation uncertainties (PU), and are defined based on the number of volumetric and gravimetric measurements, quantitative transfers, etc. Systematic uncertainties associated with the analysis, called instrument uncertainties (IU), include biases associated with sample positioning, standard values, calibration coefficients, etc. PU and IU are typically provided as a percentage of the final result. To afford comparability to sample results, PU and IU are expressed in activity units by multiplying the percentage by the sample activity (A).

All contributions to TPU are considered to be independent of each other, and the individual contributions are combined as the square root of the sum of the squares (see equation below). The final TPU result is expressed in activity units, such as

pCi/g or pCi/L.

$$TPU = \sqrt{CU^2 + YU^2 + (A * PU)^2 + (A * IU)^2}$$

TPU is expressed as a value at a specific confidence interval. The default convention at ALS is to provide the TPU at the 2-sigma confidence interval. This asserts approximately a 96% confidence level that the actual sample value is within the reported uncertainty range of the calculated result. **SOP 708** provides more information about the calculation and use of TPU.

3.6 QUALITY ASSURANCE PROJECT PLAN (QAPjP) EXCEPTIONS

As a result of the unknown nature of environmental samples prior to analysis, ALS has minimal control over analytical and quality control complications that result from sample matrix conditions. These conditions may include highly concentrated samples that contain target compounds of interest and/or non-target components; high organic content (both natural and synthetic); and extremes in pH, viscosity, solubility, etc. Each of these conditions may require a different approach.

Analysis for some samples may be achieved through the use of reduced aliquot sizes. Some sample matrices may require the laboratory to use cleanup and/or dilution techniques in order to analyze the sample by the desired protocol. Unfortunately, reduction of analysis aliquot or diluting a sample necessitates raising reporting limits (RLs) or MDCs, and often adversely impacts the calculation of surrogate, tracer, and matrix spike compound recoveries.

ALS has the responsibility to identify matrix interferences that preclude the generation of ‘compliant’ data. This determination may be made by demonstrating reproducibility (i.e., reanalysis of the affected sample) to show that the quality control measurement failure resulted from sample matrix conditions

beyond the laboratory's control and not as a result of analytical error. For example, if the surrogate or tracer recoveries are outside of control limits, then samples may be re-extracted and/or reanalyzed. Repeated non-compliant results indicate that sample matrix probably prevented the laboratory from reporting results deemed compliant.

Analytical projects containing particularly "dirty" samples (i.e., highly contaminated with target compounds and/or matrix co-extractives) will often fail to meet pre-established completeness goals (set forth in the QAPjP), when prior site history does not reveal the matrix constituents issues. Although the laboratory performs all analytical testing and cleanup procedures by the prescribed protocols, the results obtained may not meet validation criteria as a result of elevated reporting limits or the frequency at which surrogate, internal, tracer, or matrix spike recoveries fail to meet acceptance limits. In cases where the laboratory is unable to meet quality control criteria as a result of sample matrix complications, results that are qualified by data validation guidelines may still be useful to the end user of the data.

ALS is committed to adhering to the method requirements and quality control procedures prescribed by our clients. ALS strives to produce compliant data, however, uncertainties associated with environmental samples may preclude the laboratory's ability to generate fully compliant data. ALS will not assume responsibility for conditions beyond our reasonable control, that directly impact the "validity" versus the usability of the associated analytical data generated by the laboratory.

4. SAMPLE CONTAINERS, PRESERVATION, HANDLING, HOLDING TIMES

Defining the magnitude and nature of an environmental problem, and developing an appropriate solution, requires the collection of representative samples for laboratory analysis and data evaluation. The objective of field sampling is to remove a small portion of an environment that is representative of the entire body. *Analytical methods have been standardized, but the results of analyses are only as good as the sampling protocol and the sample preservation and handling methods.* Defining sampling procedures and the quality elements applicable to environmental testing is beyond the scope of this document, and beyond the responsibility of the laboratory.

Although the laboratory is not responsible for sample collection, it is responsible for maintaining the integrity of the sample after receipt. After the sample has been collected, the constituents of the sample must remain as close as possible to the field condition (i.e., degradation must be prevented). The length of time that these constituents will remain stable is related to their character and the preservation method used. Preservation is accomplished by the addition of chemical preservatives and/or storage at a controlled temperature, and by the strict observation of prescribed maximum holding time allowances. **Appendix C** lists sample container types, preservation requirements, and holding times.

4.1 FIELD SUPPORT

Unless not required by the client, sample kits are prepared at the laboratory to provide the client with all of the sample containers, preservatives and documentation needed for the analyses needed for a project. ALS provides shipping containers, custody documents, custody seals, clean sample bottles, labels, applicable high-purity chemical preservatives for water samples, trip blanks, and, upon request, "blue ice" packs to support field-sampling events. Hard-sided, insulated, "picnic" coolers are typically used to transport samples from the field to the laboratory. These coolers meet or exceed all protocol requirements (i.e., USDOT, USEPA, ASTM) for shipping. ALS **SOP 205** provides further information on sample kits.

4.2 SAMPLE CONTAINERS

ALS provides certified clean (I-Chem 300™,
Eagle Pitcher Level 1, or equivalent) sample bottles for sample collection. Used sample bottles are never used by the laboratory. The Sample Receiving Department maintains certificates of cleanliness that are provided by the vendor for all sample bottles. These certificates are provided to the client upon request. Containers are stored in clean areas, away from laboratory processes, to prevent exposure to fuels, solvents, and other contaminants.

4.3 SAMPLE PRESERVATION AND HOLDING TIMES

ALS provides the required chemical preservatives for water samples and, upon request, "blue ice" packs, for thermal preservation during transport. Typically, high quality reagent grade chemical preservatives (i.e., acids, solutions, etc.) are added to individual sample bottles, as appropriate per method and US Department of Transportation (DOT) requirements. Only trace metals grade nitric acid is used for preservation of metals or radiochemical samples, as applicable. It is the responsibility of those collecting the samples to properly use these materials (e.g., don't rinse or overfill container such that the preservative is washed out), and to ensure that chemical preservation requirements are met, and proper preservation techniques (chilling) are performed. Holding times begin with the collection of samples and continue until analysis is complete. See **Appendix C** for a summary of container, preservation and holding time requirements specific to various analyses and matrices.

4.4 SAMPLE RECEIPT SCHEDULE

ALS receives samples six days of the week, Monday through Saturday. ALS requests that clients ship samples for delivery within one day of collection, and give advance notice to the laboratory regarding shipment of RUSH samples or samples with short hold time requirements. Shipping containers received at the laboratory on holidays or after business hours are placed in a walk-in refrigerator and opened on the next business day, unless other arrangements are made in advance.

4.5 CHAIN-OF-CUSTODY

Chain-of-custody (COC) documentation begins with field sampling and continues through laboratory analysis and disposal. A chain-of-custody record that identifies all individuals who handle the sample is used to establish an intact, continuous record of the physical possession, storage, and disposal of collected samples, including their aliquots, extracts or digestates. The chain-of-custody record is initiated in the field by field personnel who complete a COC form listing all samples. This form contains the following information and remains with the samples during transport:

- client project name and project location;
- field sample number/identification;
- date and time of sample collection;
- matrix;
- container type and number of containers for each sample;
- preservative;
- analysis requested;
- sampler's remarks and signature;
- signature of person relinquishing samples and date and time relinquished;
- custody seal number (if applicable); and
- designation of matrix spike/matrix spike duplicate (MS/MSD) samples (optional).

  Note that contingent upon the sample matrix and analysis to be performed, additional sample volume may need to be submitted to accommodate MS/MSD analyses.

All transfers of samples, except directly between commercial couriers, must be recorded on the chain-of-custody form via the "relinquished" and "received by" sections. All information, except signatures, should be clearly printed.

The USEPA National Enforcement Investigations Center (NEIC) defines evidence of custody as:

- in one's actual possession, or
- in one's view, after being in one's physical possession, or
- having been in one's possession and then locked or sealed to prevent tampering, or
- kept in a secure area, restricted to authorized personnel only.

To ensure that sample custody objectives of traceability are achieved for every project, the chain-of-custody initiated in the field, is continued and maintained internally throughout the laboratory per the requirements specified in **SOP 318.** Internal chain-of-custody begins with sample acceptance and login (**SOP 202**), is maintained as samples are distributed for use throughout the laboratory (further discussed in LQAP Section 4.10), and concludes with final sample disposition (i.e., return to the client or disposal). ALS applies a unique barcode to each sample bottle received, and maintains several scanners and PCs throughout the laboratory to document and assist with sample, aliquot, extract and digestate movement throughout the facility. This electronic process is accomplished through LIMS, which retains records of all sample and fraction transactions made.

4.6 SAMPLE ACCEPTANCE POLICY

ALS' sample acceptance policy requires that a sample meet the following conditions:

- The sample shall be completely documented (sample identification, location, date and time of collection, collector's name, preservation type, sample type, any special remarks concerning the sample);
- The sample shall be identified by a unique identifier using durable labels completed in indelible ink;
- The sample shall be collected in adequate volume;
- The sample shall be collected in an appropriate container;
- The sample shall be delivered to the laboratory with at least one-half the holding time remaining;
- The sample shall not exceed allowed radioactivity levels; and
- The sample shall not show signs of contamination, breakage, or leakage.

Sample receipt discrepancies are documented by Sample Receiving Department personnel on the Condition of Sample Upon Receipt, Form 201 (SOP 008), which is forwarded to the Project Manager as part of the workorder folder. Where samples do not meet the criteria stated above, the Project Manager requests information from the client before proceeding. If the client can provide the information and, in cases of compromised sample integrity, directs the laboratory to proceed, then data acquired from the sample(s) analysis is reported and the problems noted during sample receipt are disclosed in the narrative of the final data report.

In support of the protection of employee health and of ALS's radioactive materials license, ALS observes prescreening protocols that designate or determine samples with radioactive content. Detailed procedures for conducting radiological survey of incoming sample packages are given in **SOP 008**, further details regarding prescreening protocols are given in **SOP 703**.

4.7 SAMPLE RECEIPT PROTOCOLS

Upon receipt of the field samples at the laboratory, personnel ensure that sample bottles are maintained according to storage requirements, and in a manner that does not contaminate the samples (see section 4.9 for further details).

Ascension numbers that increment serially each month of the year are applied as workorder number assignments. Following sample arrival and initial screen for USDOT compliance and removable radioactivity, sample receiving personnel inspect the sample and record any discrepancies using Form 201 (**SOP 008**). The following information is documented:

- client and project name, as applicable;
- presence/absence and condition of (i.e., intact, broken) custody seals on the shipping containers;
- presence/absence of chain-of-custody and completeness;
- sample condition (intact, broken, leaking);
- presence/absence of removable sample tags;
- agreement/non-agreement between the sample labels, tags, chain-of-custody, and any other client documentation;
- receipt of adequate sample volume;
- sample temperature, where applicable;
- presence/absence of headspace in VOA and ^{222}Radon vials; and
- chemical preservation, where applicable.

Sample temperature is verified upon receipt by measuring the temperature of the temperature blank (if available) or by measuring the temperature of a representative samples(s) with an infrared (IR) temperature device. See **SOP 210** for instructions and procedures related to IR temperature guns. Samples that require thermal preservation are considered acceptable if the temperature upon arrival is between just above freezing to 6ºC. Samples that require thermal preservation but are hand-delivered to the laboratory immediately after collection, may not meet the temperature requirement. If the hand-delivered sample is packed in ice, then Sample Receiving personnel record its temperature and note that the chilling process was initiated.

4.8 SAMPLE LOGIN POLICIES AND PROCEDURES

After completing sample receipt procedures, the following sample information and analytical requests are entered into LIMS under the unique workorder number assigned:

- client name, contact, address, phone number;

- ALS Project Manager;
- date and time of sample receipt;
- unique laboratory identifier for each sample;
- sample description, including date/time of collection;
- analyses requested (LIMS calculates holding times for each analysis);
- program specification or other special instructions, if applicable; and
- due date.

In general, a group of received samples is assigned one workorder number in LIMS. Each sample container is assigned a unique ALS identifier (barcode) that is placed on each container. This unique identification includes all samples, subsamples, and subsequent extracts and/or digestates.

See **SOPs 201 and 202** for additional information about sample login and distribution.

4.9 SAMPLE STORAGE

Samples requiring thermal preservation are stored in designated refrigerated storage areas that are maintained just above freezing to 6ºC, centered at 4±2ºC. Freezer storage areas are maintained at freezing to ⁻20ºC, centered at ⁻15±5ºC. The temperature of refrigeration units is monitored continuously using electronic min/max thermometers and recorded each business day, near to the beginning of the work shift. If the temperature exceeds the prescribed range, then corrective action is taken and documented immediately, and the client notified, if appropriate; see **SOP 326** for further details. Directives for corrective action pertaining to catastrophic failure of cooling units (as well as laboratory ovens, etc.) are included in ALS's Emergency and Contingency Plan (ECP).

Samples are stored away from all standards, reagents, food and other sources of contamination. Samples are stored in such a manner as to prevent cross-contamination. For example, pure product or potentially contaminated samples are tagged as "hazardous" and stored within a secured area, separate from other samples. ALS provides designated sample storage areas according to the following parameter groups: metals, inorganics (WetChem), semivolatile organics, volatile organics, fuels, and radiochemical analyses.

Samples having suspected radioactive activity and scheduled also for stable chemical analyses are refrigerated. Samples to receive tritium analyses are refrigerated. Samples designated for radiochemistry analyses ***only***, with the exception of tritium, are segregated and maintained at ambient temperature.

To effectively monitor the storage and potential contamination of volatile organic samples, ALS observes a refrigerator blank program (detailed in **SOPs 511, 512**).

To provide for the safe containment of sample material that could be released as a result of sample container failure, all samples are stored in secondary containment bins. These secondary containment bins are of a sturdy and inert nature, and are sufficient in size to fully contain the sample(s) in the event of a spill, leak or breakage. The bin(s) may be uniquely identified (labeled) to assist in locating samples via the chain-of-custody system. The bins are thoroughly cleaned between uses.

4.10 SAMPLE ACCESS

It is ALS's policy that neither samples nor data may be released to unauthorized personnel. In order to ensure that this policy is maintained, the laboratory facilities are maintained under controlled access and are restricted to authorized personnel only (see **SOP 132** for further details pertaining to building security).

As discussed previously in this section, ALS personnel follow strict sample handling and internal chain-of-custody procedures to ensure the integrity of all data generated. Limited access electronic controls in LIMS further protect the validity of the data results. Samples are scanned and transacted in LIMS when they are removed from a storage area for preparation or analysis. The sample ID, analyst, date, time, and location are recorded with each transaction. Likewise, the samples are scanned and transacted in LIMS upon their return to the storage unit. Barcode scanning and LIMS transaction is also observed for the return of sample remainders to the client, and for disposal (see LQAP Section 4.13). ALS **SOP 318** contains internal chain-of-custody details; procedures for sample return to the client are described in **SOP 027**.

4.11 SAMPLE HOMOGENIZATION AND SUBSAMPLING

Obtaining a representative aliquot of sample for testing is critical to the representativeness of the analytical results obtained. Proper subsampling techniques, particularly for solid matrices, are a component of each bench employee's technical instruction. Sample homogenization procedures prior to radiochemical analysis are prescribed in **SOP 736.** Representative subsampling procedures for stable chemistry analyses is prescribed in SOP 336.Client and method specified procedures for homogenization or aliquotting may also be defined in the applicable LIMS program specification.

4.12 SUBCONTRACTING ANALYTICAL SERVICES

ALS strives to identify the need to subcontract specific analytical procedures during the bid response process. Analyses may also need to be subcontracted, however, in cases of emergency where the ability to meet sample holding time criteria is endangered. In these instances, ALS compiles a list of qualified subcontract laboratories that are suitable to perform the needed analyses, then submits the list to the client for selection and approval. If TNI certified analyses are to be subcontracted, the subcontract laboratory must also hold TNI certification for the analyses that are to be conducted. The same concept regarding subcontract laboratory qualifications may apply for other program

samples (e.g., DOD laboratory approval status is required for the analyses to be conducted in the case of DOD samples that must be subcontracted for analysis). Note that for subcontracted DOD sample analyses, the subcontract laboratory must receive project-specific approval from the DOD client before any samples are analyzed.

ALS's Project Manager must receive permission from the client, in writing, before the subcontract laboratory can be procured and samples forwarded to the laboratory. At a minimum, the specific terms of the subcontract laboratory agreement must include:

- analytical method required (e.g., SW-846, 40 CFR, etc.);
- number and type of samples expected;
- project-specific quality control requirements;
- deliverables required (hardcopy, electronic);
- laboratory certifications required;
- price per analysis; and
- turnaround time requirements.

See **SOP 103** for guidance on evaluating a subcontract laboratory's qualifications. Detailed procedures pertaining to submitting samples to a subcontract laboratory are provided in **SOP 103**.

4.13 SAMPLE DISPOSAL

After completion of sample analysis and submission of the project report, unused portions of samples are retained by the laboratory for a minimum of 30 days or as designated by client and contract requirements from date of invoice. Samples are disposed or returned to the client according to the nature of the samples and the client's specifications. ALS documents and retains all conditions of disposal and correspondence between all parties concerning the final disposition of the sample.

Samples, digestates, leachates, extracts, and process waste that are characterized as hazardous, radioactive, or mixed waste are disposed in accordance with Federal and state laws and regulations. ALS maintains records to demonstrate that all disposal efforts were conducted in compliance with these laws and regulations. This documentation includes the unique sample identity, date of disposal, nature of disposal (e.g., sample depleted, sample disposed in hazardous waste facility, sample disposed in mixed waste facility, sample returned to client); and name of the individual responsible for disposal.

5. LABORATORY FACILITIES

Appendix E contains a diagram of the ALS laboratory facility. ALS maintains constant and consistent test conditions throughout the facility (e.g., temperature, air purification,

lighting). All entrances and exits are wired to a laboratory-wide security system that is monitored continuously. Access to the laboratory area from the front offices is restricted by means of keypad locks requiring numeric security code entry. Visitors must sign in at the front desk and must be escorted at all times (some vendors are allowed access without continuous escort, in order to facilitate repairs or deliveries). Further details pertaining to building security are provided in **SOP 132**.

The following sections highlight areas of the laboratory that are involved with sample receipt, handling, preparation, and analysis of samples.

5.1 SAMPLE RECEIPT AREAS

ALS's sample receiving area consists of a large dedicated room of more than 500 ft^2. It contains two fume hoods and radiation survey equipment to safely handle incoming radioactive and mixed waste samples. There is an outside access door to facilitate sample delivery and shipping of sample kits. Adjacent to the sample receiving area is the bottle storage room and the radioactivity prescreening lab.

5.2 SAMPLE STORAGE AREAS

ALS's sample receiving area has a walk-in cooler and a freezer that are used for temporary storage of samples that require thermal preservation. In addition, there are several designated sample storage locations throughout the laboratory that are used to store samples scheduled for specific analyses (see section 4.9 for further details).

5.3 SAMPLE PREPARATION AREAS

The laboratory has nine sample preparation/extraction/digestion areas. These areas are divided as follows: six radiochemistry preparation laboratories; two organics extraction laboratories; and one metals digestion laboratory. The total floor space of these six laboratories is approximately 4500 ft^2.

Laboratory preparation procedures are segregated as much as possible to minimize the potential for contamination, maximize processing efficiency, and maintain analytical integrity. Rigorous cleaning of glassware (**SOPs 334** and **720**) and apparatus ensures that cross-contamination is minimized. Each laboratory area has a dedicated or locally shared HVAC system that continuously exchanges the laboratory air with filtered and conditioned outside air. There are 34 laboratory hoods in the six sample preparation areas, and each sample preparation area has at least one hood that is capable of maintaining an average face velocity of 100 feet per minute.

5.4 STANDARDS PREPARATION AREAS

A dedicated radiochemical standards preparations room, and an organics standards preparation area are maintained. Metals and inorganic standards are stored independently from sample storage areas and are prepared in their respective laboratory areas.

5.5 ANALYTICAL LABORATORIES

The ALS facility houses a volatile organics analysis (VOAs) laboratory that is on an upper level of the building, away from all other laboratory operations. The ALS facility also houses one general chemistry (WetChem) laboratory, two radiochemical counting rooms, a total organic carbon (TOC) laboratory area, two gas chromatograph (GC)/high performance liquid chromatography (HPLC) labs, a semivolatile organic compounds (SVOCs) laboratory, and a metals laboratory that contains separate inductively coupled plasma (ICP), mercury, and inductively coupled plasma/mass spectrometry (ICP/MS) rooms.

5.6 OTHER LABORATORY AREAS

Other areas of the ALS facility include a tank room for compressed gasses, several waste management areas, telephone and computer storage rooms, staff offices, Reporting Group and Reports Management data processing rooms, and various scanning/reproduction and supply storage areas.

5.7 DEIONIZED WATER SYSTEM

Within the laboratory, there are two main deionized (DI) water distribution systems available for glassware cleaning, bulk reagent preparation, and general use. One system is located in the janitor's area and serves the radiochemistry side of the facility (ASTM Type II water generated). The other system is located adjacent to the metals laboratory area and serves the stable chemistry side of the facility (ASTM Type I water generated). These DI water systems are capable of continuously delivering water that meets the requirements specified for the ASTM water type, and are monitored and documented each business day to ensure that the water meets these criteria. ALS also maintains a third treated water system that is used to support washing of stable chemistry laboratory glassware.

DI water is defined as municipal tap water that has been treated by passing it through a particulate filter, activated carbon unit, cation exchange resin, anion exchange resin, mixed bed resin, and a final "polishing" cartridge. This water contains no detectable heavy metals or inorganic compounds of interest, and is free of organic compounds of analytical interest above ALS's routine reporting limits. Additionally, a benchtop Millipore Synergy 185^{TM} unit is available for laboratory use should further finishing be desired.

SOP 319 provides detailed information pertaining to ALS's DI water systems, including discussions of independent monthly testing to verify that electronic readouts of water quality are accurate, maintenance by a vendor contractor, and corrective measures to be taken should water quality degrade to below acceptable limits.

6. ANALYTICAL PROCEDURES

ALS is capable of analyzing various matrices, including surface and groundwater, drinking water, soil, sediment, vegetation, tissue, filter and aqueous and solid wastes. ALS does not routinely perform analyses on air (non-particulate), however, analysis of these matrices may

be available through our sister laboratories. Analyses are performed using promulgated methodologies as requested by the client and their regulators, and as required by ALS's certifying authorities. *New iterations of established methodologies are evaluated on an ongoing basis and implemented as client needs dictate.* Analytical procedures are conducted in strict adherence with SOPs that describe the preparation, analysis, review and reporting of samples. In some cases, these SOPs may also describe proprietary methods developed by ALS and used per the client's request. A list of ALS's analytical capabilities is presented in **Appendix C.** A list of ALS's SOPs is provided in **Appendix H**. References for analytical procedures used are presented in the attached **Bibliography**. ALS also, upon request, develops and validates procedures that are more applicable to a specific client objective.

6.1 ANALYTICAL METHODS

Selection of the appropriate method is dependent upon data usage and regulatory requirements. ALS may modify existing methods in order to:

- achieve project-specific objectives;
- incorporate modifications or improvements in analytical technology;
- address unusual matrices not covered in available methods; and
- provide analytical capabilities for an analyte for which there are no promulgated methodologies.

ALS discloses method modifications to our clients by providing the appropriate SOP for review.

6.2 METHOD COMPLIANCE

Compliance is the proper execution of recognized, documented procedures that are either approved or required. Strict adherence to these procedures is necessary to provide data acceptable to a regulatory body of competent jurisdiction in a specific regulatory context.

Compliance is, however, separate from, but not inconsistent with, technical scientific quality. ALS understands that the expectations of our clients commonly include the assumption that data and reports will satisfy a regulatory purpose and will be found acceptable and compliant with regulatory requirements.

6.2.1 UNDERSTANDING THE REGULATORY FRAMEWORK

Compliance is not likely to be achieved in the absence of an understanding of the regulatory framework. Upon receipt of a statement of work (SOW), ALS attempts to ascertain, prior to accepting samples:

- what regulatory jurisdiction pertains to a project (USEPA, State Department of Health, etc.)

- within the regulatory jurisdiction, what body of regulations has primacy (RCRA, SDWA, CWA, etc.); and

- within this context, what QA/QC protocols are required (DOE, DoD -- AFCEE, NFESC, etc.).

ALS works with our clients to achieve a mutual understanding of all requirements and makes the following commitments:

- ALS will proactively attempt to identify and understand the regulatory context of client's needs.

- ALS will strive to be expert in understanding and executing the regulatory requirements for compliance.

- ALS will ensure that we have the capabilities, resources and facilities to perform the requested analyses.

- ALS will identify and disclose to clients instances of non-compliance in a forthright and timely fashion.

6.2.2 RESOLVING COMPLIANCE CONTRADICTIONS

Multiple regulatory jurisdictions may overlap for a specific project, which may cause uncertainty or contradictions to arise. Similarly, methods and protocols may be prescribed in a scope of work or QAPjP that either will not achieve stated or implied DQOs, or that conflict with the regulatory requirements. ALS will attempt to detect these inconsistencies and contradictions and will disclose them to clients in a timely fashion. ALS voluntarily accepts a responsibility to provide information to our clients; however, the primary responsibility for resolving inconsistencies with regulators remains with the client.

6.2.3 DISCLOSURE OF NON-COMPLIANCE

As previously stated, it is ALS's policy to disclose in a forthright manner any detected non-compliance that may affect the usability of data produced by ALS. It is not within our expertise to predict the manner in which a specific regulator or regulatory body will interpret the rules governing analysis; therefore, ALS is unable to guarantee compliance. It is ALS's policy that our responsibility begins with a bona-fide and competent attempt to evaluate potential compliance issues, and ends with disclosure of any findings that may enable our clients to make an informed decision.

Procedures for documenting non-compliances and applying corrective actions are given in **SOP 928**.

6.3 NON-STANDARD METHOD VALIDATION

When a non-promulgated method (i.e., methods other than EPA, ASTM, etc.) is required for specific projects or analytes of interest, or when the laboratory develops a procedure, the laboratory must establish the validity of the method prior to extracting or analyzing a client's samples. *Validity is established by meeting criteria for precision and accuracy.* Method development and validation must include the following:

- Initial Demonstration of Capability (IDOC) for each analyst performing the method;
- MDL studies or MDC determination, as applicable, for every analyte, matrix, instrument, and column (if applicable);
- validated extraction and analytical criteria; and
- SOP generation and approval per established processes.

7. MEASUREMENT TRACEABILITY AND CALIBRATION

ALS follows a well-defined calibration routine for all instruments and equipment. Calibration may be performed by laboratory personnel using certified reference materials traceable to NIST or equivalent certified materials, or by external calibration agencies or equipment manufacturers. The discussion in this section of the LQAP is general in nature because the requirements for calibration are instrument or equipment and method specific. Details of calibration procedures and requirements can be found in ALS's standard operating procedures (SOPs), analytical methods and operations manuals.

A list of all major instrumentation available at ALS is provided in **Appendix G**. The Quality Assurance Department maintains this list.

7.1 TRACEABILITY OF CALIBRATION

ALS's program of calibration and/or verification and validation of equipment must ensure that, wherever possible, measurements performed by the laboratory are traceable to national standards of measurement. ALS requests and maintains calibration certificates (e.g., weights, thermometers, balances) that demonstrate traceability to national standards of measurement. If traceability to national standards of measurement is not available or applicable, then ALS provides evidence of correlation of results (e.g., verifying an in-line resistivity meter by reading the system's output with a conductivity meter; participating in a PT studies).

7.2 REFERENCE STANDARDS OF MEASUREMENT

ALS uses reference standards of measurement (such as Class S weights or NIST-traceable thermometers) for calibration verification purposes only (i.e., these reference standards are not available to laboratory staff for general use). Reference standards of measurement are calibrated or verified by a qualified

vendor that must provide, where possible, traceability to a national standard of measurement. Thermometer Masters are independently recertified annually, weight masters are independently recertified every five years. Certificates of vendor calibration/verification for the reference standards recertifications are maintained by the Quality Assurance Department.

The certified reference standards are then used to annually verify other measurement devices (e.g., laboratory thermometers, laboratory weight sets) in-house. The in-house verification efforts are managed by the Quality Assurance Department. All items so verified are tagged with a sticker indicating the unique identity of the device, the date of verification and the initials of the technician who performed the verification, and the date the verification is valid through. Procedures for the in-house verification of thermometers are given in **SOP 923**. Procedures for the verification of weight sets are given in **SOP 901**.

7.3 TRACEABILITY OF STANDARDS, SOLVENTS AND REAGENTS

ALS purchases the highest quality standards, solvents, and reagents appropriate to the analytical methodologies employed. The vendor must supply a Certificate of Analysis, Certificate of Purity, or equivalent. These certificates are maintained by the Department who uses the materials.

With the exception of extraction solvents, each Department documents the date of receipt, date opened and an expiration date for all standards and reagents by labeling the original container, or certificate and/or by entering this information into ALS's Standards and Reagents database. Because of the quantity of solvents consumed in a short time frame, solvents are labeled only with the date received.

Each Department is responsible for the preparation, documentation, storage and disposal of its chemicals. Standards preparation information is documented by entry in a ALS's Standards and Reagents database. The following information, needed to maintain traceability of the standard, is recorded for each standard:

- date of receipt of reference standard;
- unique internal identification number and traceability to purchased stock or neat compounds, as applicable (i.e., vendor/lot numbers; unique ALS identifier);
- date of preparation;
- name of preparer;
- amount of reference material used;
- volume/identity of reagents and solvents used;
- final volume;
- concentration;

- expiration date of the stock and prepared standards.

See **SOP 300** for additional information about standards preparation, storage, and expiration. Verification (re-verification) of radiochemical standards is also addressed in SOP 710.

7.4 GENERAL REQUIREMENTS FOR CALIBRATION

Each calibration is dated and documented to ensure that it is traceable to the method, instrument, date of analysis, analyte, concentration, and response. Sufficient information must be documented to permit reconstruction of the calibration. Acceptance criteria for calibrations must comply with method requirements.

7.5 INSTRUMENT CALIBRATION

This section defines the essential elements of initial instrument calibration (ICAL) and continuing instrument calibration verification (CCV). These procedures ensure that the data will be of known, documented, and appropriate quality for a given application. *Samples yielding concentrations that exceed the upper limit of the calibration curve shall be diluted and reanalyzed, if possible, to bring the results within the calibrated range. Results of samples outside the known calibration range, above or below, must be reported as qualified values and discussed in the case narrative.*

Initial instrument calibration is used for quantitation and continuing instrument calibration verification is used to confirm the validity of the initial calibration. The following items are required of both initial and continuing instrument calibrations:

- The details of the instrument calibration procedures, including evaluation and acceptance criteria, and corrective measures to be taken in the event that these acceptance criteria are not met, must be included or referenced in the test method SOP.

- Sufficient raw data records must be retained to allow reconstruction of the instrument calibration (e.g., calibration date, test method, instrument, date of analysis, name of analyst, concentration of standard(s), response, response factor).

Additional essential elements of initial as well as continuing instrument calibrations are discussed below.

7.5.1 INITIAL INSTRUMENT CALIBRATION

The following items are essential elements of initial instrument calibration:

- Samples must be quantitated from the ICAL, unless the reference method states otherwise.

- The initial calibration range must consist of at least the minimum number of calibration points specified by the reference method. If the reference method does not specify the number of calibration standards, then the minimum number is two, not including blanks or a zero standard. Exception: multi-component analytes, such as chlordane, toxaphene or Aroclors, may be analyzed using a one-point calibration, per SW-846 guidance, if so requested by the client.

- The lowest calibration standard must be above the detection limit (MDL) and at or below the RL (i.e., the method reporting limit must be within the calibrated range of the method).

- Calibration standards must include concentrations at or below the regulatory limits, if these limits are known to the laboratory.

- Criteria for the acceptance of an initial instrument calibration must be established (e.g., RSD, correlation coefficient, etc.).

- If ICAL results are outside acceptance criteria, then corrective action must be performed, and the instrument recalibrated before analyzing samples.

- Exclusion of initial calibration points without technical justification is not allowed (poor injection or power failure are valid reasons to exclude a calibration point).

- All reported target analytes and surrogates must be included in the initial calibration.

- The ICAL must be verified (see section 7.5.3) before samples can be analyzed.

7.5.2 CONTINUING INSTRUMENT CALIBRATION

A continuing calibration verification (CCV) standard must be analyzed with the frequency prescribed in the reference method, or as dictated by the applicable LIMS program specification (typically within every 12hr time period). For example:

- When an ICAL is not performed on the day of analysis, then validity of the initial calibration must be verified with an acceptable CCV prior to sample analysis.

- A CCV must be repeated at the beginning and end of each analytical sequence. (For GC/MS methods that use an internal standard, only one CCV must be analyzed before each analytical sequence). Some methods additionally prescribe that a CCV must be analyzed after every 10 (or 20) samples analyzed.

The following items are essential elements of continuing instrument calibration:

- With the exception of multi-component analytes, all reported target analytes must be included in the continuing instrument calibration standard.

- Criteria for the acceptance of a CCV must be established (e.g., %D, %Drift, from the initial calibration).

- If the CCV results exceed acceptance criteria, then corrective actions must be performed. If routine corrective action procedures do not produce a second consecutive CCV within acceptance criteria, then a new calibration must be performed and successfully verified.

Additional aspects of calibration verification are discussed below.

7.5.3 CALIBRATION VERIFICATIONS

All ICALs must be verified with a ***second source*** standard obtained from a different manufacturer/vendor and traceable to a national standard, when available. If a different manufacturer/vendor is not available, the laboratory must request a different lot number of the standard.

In most cases, a second-source initial calibration verification (ICV) standard is analyzed immediately after the ICAL and before any samples are analyzed. However, analysis of an ICV is not required, if the continuing calibration verification (CCV) standard is from a second source.

Sample data associated with an unacceptable calibration verification standard may be reported as qualified data in the following cases:

- When the acceptance criteria for the CCV is exceeded high (i.e., high bias), and only non-detects were determined for the affected analyte(s) in associated samples, then those non-detects may be reported.

- When the acceptance criteria for the CCV is exceeded low (i.e., low bias), then these sample results may be reported if they exceed a maximum regulatory limit.

- When the acceptance criteria for the CCV are exceeded (high or low), and the effect on the system from previous sample analysis is substantiated (e.g., by reanalysis or sample response characteristics on a different detector), then the sample results may be reported.

Other levels of concentrations and frequencies of analysis for calibration checks (ICVs, CCVs) may be required by specific client programs. These requirements, which supercede method, SOP or LQAP requirements otherwise stated, are communicated to the laboratory staff via LIMS program specifications.

8. PREVENTIVE MAINTENANCE AND REPAIR OF EQUIPMENT

ALS maintains an organized maintenance program that is broader than the particular instruments or devices a specific employee may operate or is familiar with. The objective of ALS's equipment maintenance program is to provide a structure of care that prevents quality control failures and minimizes lost productivity that results from equipment malfunction or failure. Within this program are provisions for corrective actions, maintaining spare parts, and a contingency plan in the event of catastrophic failure (e.g., loss of power for a significant period of time).

See Appendix G for a comprehensive list of ALS's equipment.

ALS's maintenance program is based on equipment manufacturer's recommendations, operator training guidance, and other considerations (e.g., sample throughput). The established maintenance program applies to all laboratory primary instrumentation, as well as support equipment (see Section 8.6 for a definition of what constitutes support equipment). Provisions for documenting all routine and non-routine instrument equipment maintenance and repairs is also established within the maintenance program.

Responsibilities for applying ALS's maintenance program rests with the Department that utilizes the equipment, the Quality Assurance Department bears responsibility for certain support equipment such as balances, ovens, refrigerators, freezers, and temperature measurement devices. Only authorized personnel are permitted to perform maintenance.

Culturally, ALS makes a distinction between 'operational' and 'routine' maintenance, that external parties generally do not. ALS considers the normal/typical things that operators do

to keep the equipment functioning properly (e.g., septum replacement, reagent refill, etc.), as 'operational' maintenance, and does not generally view these tasks as routine maintenance events that require specific documentation in a dedicated maintenance log. ALS's view is that the fact that the equipment is performing properly and yielding acceptable QC results, evidences that these maintenance tasks were performed as needed. ALS's maintenance system does, however, provide for attestations that this maintenance was performed, where applicable. In contrast, ALS defines routine maintenance as those things done in-house only periodically (i.e., that are beyond what is performed as usual 'operational' maintenance), that are short of vendor repair (e.g., annual GFPC drawer evaluation).

Documentation requirements are discussed further in Section 8.4 below.

Note that ALS does not consider 'priming', or analysis of solvent blanks, which generally get recorded in the instrument run log, as maintenance.

8.1 MAINTENANCE SCHEDULES

In general, ALS performs maintenance as needed (including preventive considerations). Certain aspects of routine maintenance are considered to be 'operational', and are performed each time the instrument is run. Other maintenance is performed 'periodically' (e.g., roughly monthly, contingent upon sample throughput). Each instrument operator is responsible for the performance of their own instrument, and may perform maintenance duties at their discretion. For these reasons, ALS's culture is not one of 'scheduled' maintenance, in the traditional (calendar) sense. Consequently, although the Department Manager provides oversight, it is not necessary or practicable to create formal maintenance schedules, or to have maintenance performance synchronized within the Department.

ALS maintains service contracts for most major analytical equipment, including gas and high-performance liquid chromatographs, mass spectrometers, liquid scintillation counters, and cold vapor atomic absorption and inductively coupled plasma spectrophotometers. Preventive maintenance is included in most of these service contracts. Service contracts that include preventive maintenance are also retained for ALS balances and the DI water system.

8.2 SETTINGS

ALS's equipment list (Appendix G) depicts the following information: a) the identity and type of equipment and its software; b) the equipment's serial number or other unique identification; c) the current location; d) the date received and date placed in service (if available); and e) the condition when it was received (e.g., new, used, reconditioned).

While it is true that some settings (e.g., detector wavelength) may be stipulated in reference methods, most instrument settings are not specifically prescribed, as they are instead, dictated by acceptable outcome (e.g., peak resolution, etc.). In a

similar vein, ALS provides typical instrument settings in the associated determinative SOP, but actual settings may vary contingent upon instrument performance and contributing factors, such as ambient conditions and operator subjectivity.

For the most part (i.e., not applicable to some types of equipment), instrument configuration and settings information is captured electronically by the instrument's 'method' files. Typically there is an 'acquisition' method file and a 'quantitation' method file that together, control the manner in which the data are obtained and subsequently calculated. These instrument files are archived via established laboratory electronic backup protocols (Form 159 – IS / LIMS Policy Statement), and are retrievable, thus providing for the reconstruction of data. The utilization of proper settings is evidenced by analytical data and QC results that meet performance criteria.

8.3 TRENDS

The dominant focus of trending contained in pertinent guidance documents relates to the generation of acceptable 'at on-set' and 'continuing' method QC checks. Concurrent with these requirements, ALS's culture for trending observation labwide consists of ensuring that acceptable instrument checks are generated, and that the system is not producing any artifacts at levels of concern, prior to analyzing sample sets.

The expertise of the operator is a major component in effective equipment operation. Experienced operators develop an intuitive sense as to how their instrument is performing. Generally this sense is not based on a specific indicator, as there may be many contributing factors to that particular indicator, but rather on an accumulation of ques (similar to those factors that would be considered during the troubleshooting process). Because this type of expertise does not lend itself well to documentation, ALS emphasizes cross-training to ensure consistent data generation, and the retention of 'corporate knowledge'.

8.4 EQUIPMENT DOCUMENTATION REQUIREMENTS

Analysts are responsible for maintaining calibration/verification and maintenance records of all instruments and equipment involved in the creation of the analytical data they generate. Considerations of maintenance, settings and trends, and their documentation, vary widely contingent upon the type of equipment, how automated it is, and the degree of sample throughput. Documentation can be accomplished by various means, electronically and via hardcopy. For example, ICP, ICP/MS and CVAA routine maintenance is entered into the instrument's PC and printed out in the raw data header, while service contract maintenance and repair are documented in hardcover logbooks. Labwide, dedicated hardcover maintenance logbooks are assigned to each piece of major ALS instrumentation, however, the manner is which equipment documentation is recorded, is at the discretion of the Department Manager. It is not ALS's intent to unify or centralize maintenance information.

Although the manner of record keeping varies, in order to provide a clear and complete history of repairs and maintenance associated with the instrument, each entry may, but not limited to, include the following elements:

- the date of the maintenance or repair:
- the reason for the maintenance or repair (e.g., was this action taken to correct a problem or was this action routine instrument maintenance);
- a full description of the maintenance or repair conducted;

- the name of the analyst or vendor who performed the maintenance or repair;

- reference that it was verified that the equipment is operating properly before being placed back in service (SOP 317), and where this information can be found; and

- the initials of the analyst making the entry and date of entry.

Where applicable, the identity of the reference material used as an instrument check must also be recorded, and where applicable, a statement as to the calibration's expiration must also be made.

Details regarding equipment documentation are also provided in SOP 303. Note that maintenance logs are included in monthly logbook review.

Table 8.1 (Maintenance Snapshot) following provides a brief summary of laboratory equipment, an overview of associated maintenance performed, and comments regarding how associated maintenance documentation is accomplished.

8.5 CORRECTIVE ACTIONS, SPARE PARTS, CONTINGENCY PLAN

8.5.1 CORRECTIVE ACTIONS

Corrective measures for failed QC checks are given in the associated determinative SOP. General procedures for removing equipment from service and placing new or repaired equipment into service, are provided in SOP 317. Detail regarding corrective measures and repair for support equipment failures (e.g., ovens, cooling units, pipets, DI water system), are discussed in SOPs 320, 326, 321 and 319, respectively. Actions to be taken in the event of catastrophic failure are discussed in Section 8.5.3 below.

ALS maintains service contracts (preventive maintenance, repair) for most major analytical equipment. Some equipment (particularly some support equipment) does not lend itself to repair and would likely be replaced instead, per requirements given in SOP 127.

8.5.2 SPARE PARTS

An adequate inventory of spare parts is required to minimize equipment downtime. This inventory should include those parts and supplies that:

- are subject to frequent failure;

- have limited useful lifetimes, or

- cannot be obtained in a timely manner should failure occur.

Department Managers are responsible for maintaining an adequate inventory of necessary spare parts for all major instruments and equipment items. Examples of spare parts maintained for major instrumentation include: septa, inserts, columns, tube fittings, filaments, source parts, and traps.

8.5.3 CONTINGENCY PLAN

In the event of a catastrophic instrument failure, ALS will make every effort to analyze samples within holding times by alternate means. If the redundancy in instrumentation is insufficient to handle the affected samples, then the Department Manager will notify the Project Manager immediately. In turn, the PM will notify the client to discuss options that will ensure successful completion of the project.

ALS will also take appropriate mitigating steps and notify the client should significant power, cooling unit, etc. failures occur that create circumstances which could adversely impact the client's sample results. An automated system is in place to notify the IS Manager and Laboratory Director should a power outage of significant duration occur. However, any employee who notes an outage or unit failure is responsible for contacting the Department Manager or Laboratory Director, who will in turn direct the necessary actions. The specific course of action taken is dependent upon the nature and extent of the failure. General procedures to be followed in the event of catastrophic failure are provided as an appendix to ALS's Emergency and Contingency Plan (ECP).

8.6 SUPPORT EQUIPMENT

ALS defines support equipment as all those devices which are not the primary determinative instrument defined by the analytical method, which support laboratory operations. Support equipment includes balances, ovens, refrigerators, freezers, water baths, temperature measurement devices, and mechanical (e.g., Eppendorf ^{TM} pipets. Per ALS's definition, support equipment also includes: desiccators; centrifuges; vortex mixers; sonicators; homogenizers (including ball mills, riffle splitters and shatter boxes); pressure filters; vacuum pumps; zero headspace (ZHE) extractors; tumbling devices; platform shakers; water baths; chillers; heating blocks, mantles, hot and stir plates; evaporators; muffle furnaces; kilns and cleanup apparati.

Additionally, ALS's deionized (DI) water systems (SOP 319) and health physics equipment (Appendix G) and are also considered to be support equipment.

Requirements pertaining to glassware are given in SOPs 334 and 720. Procedures for maintaining computers and other electronic devices (e.g., printers, backup devices, etc.) are developed, implemented and maintained by the IS Department (Form 159, et. al.)

Support equipment must be calibrated or verified, typically annually, within the applied range of use. NIST-traceable references must be used when available, and the results of the calibration/verification must be documented and within the specifications required of the application for which the equipment is intended.

All support equipment must be maintained in proper working order, and records must be retained to document the equipment's performance, maintenance, and repair. *Each business day, near to the beginning of the work shift, the proper functioning and calibration of the following equipment must be verified: balances, ovens, refrigerators, freezers*. Water bath temperatures must be verified each day of use. Additional monitoring must also be performed and documented, if so prescribed by a test method.

Per **SOP 321**, the volumes dispensed from mechanical pipets are verified prior to each use, as these volumes are critical measurements. Because automatic dispensing devices used to deliver solvents or reagents (e.g., for sample preservation and extractions) are not used to deliver critical volumes, these devices are exempt from daily verification.

Where necessary, in-house verifications are performed to document the capability of any measuring device when data is of importance to the final result.

Certificates of Accuracy are acquired from the manufacturer and are retained on file within each Department for glass microliter syringes.

The following SOPs provide additional information about calibration and verification of support equipment:

- **SOP 305** -- balance calibration and verification
- **SOP 320** -- monitoring and recording of oven temperatures
- **SOP 326** -- monitoring refrigerator and freezer temperatures.

9. QUALITY CONTROL PROCEDURES

ALS' quality control program provides a systematic process that enables the laboratory to evaluate and control the validity of analytical results, by measuring and monitoring accuracy and precision by method and matrix; by developing control limits and using these limits to detect errors or out-of-control events; and by requiring corrective actions to prevent or minimize the recurrence of these events. ALS observes QC procedures to ensure that sample data meet laboratory and client quality objectives.

The purpose of preparing and analyzing QC samples is to demonstrate accuracy and precision of the sample data and efficacy of the method for the target analytes being investigated. Acceptance criteria may be dictated by reference methods or by project

requirements. All assessments of QC data are performed after all rounding and significant figure truncations have been performed.

For all analyses performed by ALS, the QC concepts and samples described in the following sections are mandatory. Determinative SOPs contain a Table that summarizes the types and frequency of QC samples, acceptance criteria, and corrective actions required. Observation of maximum holding time allowance is discussed in LQAP Chapter 4.

9.1 DEFINITION OF BATCH

9.1.1 PREPARATION BATCH

A preparation batch consists of as many as 20 field samples of the same or similar matrix, that are prepared together by the same analyst(s) within a limited or continuous time period, following the same method, and using the same kind of equipment and same lots of reagents. Each batch must contain the appropriate number and kind of method control samples (e.g., MB, LCS) and matrix-specific QC samples (e.g., MS/MSD, DUP). Cleanup procedures may be included as part of the preparation batch. All field and QC samples in the batch should be subjected to the same preparation and cleanup procedures.

9.1.2 ANALYSIS BATCH

The analysis batch (or sequence) consists of samples that are analyzed together within the same or continuous time period, on the same instrument, and processed using the same calibration. Each analysis sequence must contain the appropriate number and kind of standards and samples as defined by the method. If samples from a preparation batch are analyzed in multiple analysis batches, extended method control and matrix-specific QC samples need not be analyzed with every analysis batch.

Where no sample pre-treatment (such as extraction or digestion) is required prior to analysis (e.g., analysis of volatile organic compounds, anions analysis by ion chromatography, etc.), the preparation batch and analysis sequence are equivalent.

9.2 PREPARATION BATCH QC SAMPLES AND STANDARDS – DEFINITION AND USE

The results of quality control samples provide an estimate of accuracy and precision for the preparation and analysis steps of sample handling. The following sections describe the QC information provided by each of these analytical measurements.

9.2.1 METHOD BLANK

A method blank (MB) consists of an aliquot of well-characterized, controlled, or certified matrix (e.g., reagent water, Ottawa sand, solid reference material, boiling chips) that is processed through the entire sample preparation, cleanup, and analysis procedure. For radiochemical analyses, a suitable blank solid matrix has not been identified; therefore, reagent water is routinely used for the blank for most solid matrices. The volume or weight of the blank must be approximately equal to the sample volume or weight processed for sample analyses.

The purpose of the MB is to demonstrate that interferences caused by contaminants in solvents, reagents, glassware, and other sample processing hardware, are known and minimized. A method blank should not contain target analytes at or above the reporting limit, unless otherwise permitted in the method. Other maximum blank contamination control criteria may apply, as indicated in the associated LIMS program specification.

While some methods may require background correction, sample results are typically not corrected for blank contamination.

9.2.2 LABORATORY CONTROL SAMPLE

A Laboratory Control Sample (LCS) consists of an aliquot of well-characterized, controlled, certified matrix (e.g., reagent water, sand, solid reference material, Teflon^{TM} chips) that is spiked with analytes of interest and processed through the sample preparation, cleanup, and analysis procedure.

The purpose of the LCS is to provide an estimate of bias based on recovery of the compounds from the clean, controlled matrix, and to demonstrate that the laboratory is performing the method within accepted guidelines without potential non-matrix interferences.

Where sample pretreatment is not required, such as with ion chromatography or gamma spectroscopy analysis, or the analysis of volatile organic compounds, the ICV standard or other appropriate control standard may be employed as the LCS.

An LCS for methods with extensive lists of analytes that may interfere with one another may include a limited number of analytes, but the analytes included must be representative of as many analytes as is practical.

Other client-specific QC requirements may be prescribed in the applicable LIMS program specification. The requirements set forth in

the LIMS program specification supercede those stated in the method, SOP or LQAP.

9.2.3 MATRIX SPIKE/MATRIX SPIKE DUPLICATE

A matrix spike (MS) or matrix spike duplicate (MSD) is a field sample to which known concentrations of target analytes are added before the sample is processed. The purpose of MS/MSD samples is to assess the performance of the method for a particular matrix and to provide information about the sample's homogeneity. Results of the MS/MSD samples are evaluated in relation to the method QC samples to determine the effect of the matrix in regards to accuracy and precision. Sample results are not corrected for MS/MSD excursions.

To generate MS/MSD pairs for any analysis, there must be an adequate volume/weight of field sample available. Inadequate sample volumes preclude the possibility of generating this pair of QC samples. ALS asks clients to designate the sample to be used for MS/MSD analysis to ensure that adequate sample volumes are collected.

For some analyses, changing the composition of the sample in any way invalidates the analysis to be performed (e.g., hardness, alkalinity, pH). Therefore, an MS/MSD pair cannot be generated for these analyses. Normally, duplicate sample aliquots are analyzed in order to generate an estimate of the method's precision.

Other client-specific quality control requirements may be prescribed in the applicable LIMS program specification. The requirements set forth in the LIMS program specification supercede those stated in the method, SOP or LQAP.

9.2.4 SAMPLE DUPLICATE

A sample duplicate (DUP) is a second representative portion of sample that is carried through the preparation, cleanup and analysis process. Results for the duplicate sample are compared to the initial sample analysis results as a means of evaluating precision. For organic analyses, the MS/MSDs fulfill this function. The degree of sample homogeneity directly impacts the integrity of the sample duplicate analysis.

Precision criteria for sample duplicate analyses are those prescribed in the reference method and/or SOP, unless otherwise superceded by client-specific requirements contained in the applicable LIMS program specification.

9.2.5 SURROGATES

Surrogates are organic compounds that are similar to the target analytes, but are unlikely to be present in actual field samples. They are introduced into all field and QC samples in a batch prior to sample preparation, and provide an estimate of bias based on recovery of similar compounds, for a given extraction technique and analysis method combination. Sample results are not corrected for surrogate recoveries.

Acceptance criteria for surrogates are those prescribed in the reference method and/or SOP, unless otherwise superceded by client-specific requirements contained in the applicable LIMS program specification.

9.2.6 CHEMICAL YIELD MONITORS OR ISOTOPIC TRACERS

Chemical yield monitors are used in radiochemical analyses and provide information similar to the surrogate spikes discussed above. The primary difference between a chemical yield monitor and a surrogate is that sample results are corrected for chemical yield recoveries and not corrected for surrogate recoveries. A chemical yield monitor is a substance that has similar chemical characteristics as the parameter being measured. It is introduced into all field and QC samples in a batch during the preparation procedure. Chemical yield monitors provide information regarding the performance of a method on a sample-by-sample basis.

Chemical yield monitors are evaluated against established laboratory control limits. These ALS default control limits may be superceded by other quality control criteria specified in the applicable LIMS program specification.

9.3 CONTROL CHARTS

Control charts are a tool that can assist the laboratory in evaluating process control and trends. Control charts are used as a visual queue giving warning before a measurement system drifts into an out-of-control situation. Information such as radiochemical calibration parameters, results of daily efficiency checks, etc. can be documented in control charts. Accuracy control charts, discussed further below, that contain method LCS (and surrogate, as applicable) performance information, are managed through LIMS. Although the QAM is responsible to annually reviewLCS information, and determine is significant change to a method or process has occurred. The QAM then notifies technical management is the mean and standard deviation of LCS data show significant change (>10%). QC limits can be updated after review by technical personnel as

appropriate.LCS information is accessible to *all* bench personnel **for their consideration,** through LIMS.

Further discussions of control charts and control limits and other considerations such as outlier rejection and trend evaluation follow below.

9.3.1 ACCURACY CONTROL CHARTS

Accuracy (recovery) for a batch can be evaluated by plotting the individual percent recovery points for analytes on a control chart and comparing the values against the current control limits. If the spike recovery values for the current analytical batch meets the acceptance criteria for that method, then the data point (and batch) are accepted. **If not, and re-preparation/analysis is possible, the batch is generally reprocessed. At minimum, the failure(s) is considered a non conformance and is narrated in the laboratory data package. See the QC Table of each determinative SOP for further details as to the appropriate corrective actions to be taken for controlled failures.**

Accuracy control charts are generally maintained for each method that utilizes an LCS. For methods that cannot use LCS samples (e.g., pH, flashpoint, conductivity), other tools, **such as periodic participation in 3rd party Performance Test sample analysis,** are used to assess method control.

If fewer than 20 data points for a method, matrix, and analyte combination are acquired, then control charts yield scant information.

9.3.2 CONTROL LIMITS

Control limits for each controlled analyte are calculated, and can be updated, using ALS's LIMS. The recovery values from all data processed within a specified date range, are used to calculate the control limits and compile the control chart. **Standard outlier tests, based on the population number evaluated (e.g., Dixon n=<20; Grubbs n=3-147; etc.), per their restrictions/requirements, may be applied.**

The upper and lower control limits of the control chart are designated as the value equal to the average recovery plus or minus three times the standard deviation (i.e., 99% confidence interval).

The upper and lower warning limits for the control chart are designated as the value equal to the average recovery plus or minus two times the standard deviation (i.e., 95% confidence interval).

The average recovery, standard deviation, minimum value, maximum value, and population are displayed on each control chart.

Control limits are updated as needed (e.g., acquisition of a sufficient number of data points to establish meaningful control limits for a newly implemented method; if deemed appropriate as a result of a corrective action investigation; etc.). The frequency with which control limits are updated may vary for different methods. Generally, intra-laboratory historical control limits are not updated more than once per year.

9.3.3 OUTLIER REJECTION

For the generation of control charts, and other quality control data that monitor the laboratory's performance, it is essential to prevent spurious or erroneous data from being incorporated. It may be necessary to reject data as an outlier to prevent an adverse effect on the values being calculated. **Only established statistical approaches may be used, such as application of the Grubbs, Dixion, etc., tests, to identify and handle outliers. Any data point meeting established outlier criteria is justified to be rejected, however, the analyst has the discretion to reaccept the data point where it is technically sound to do so.** In every case, the cause of the outlier rejection must be clearly understood before any data point is ~~**manually**~~ rejected.

For the purposes of statistically determining whether a data point is an outlier or not, ALS may use the procedures discussed in the Dixon Rank Sum Test, the Grubbs Test, **or other established appropriate statistical treatment.** If a data point is determined to be an outlier, it **generally** will not be incorporated into the dataset when updating QC limits.

See SOP 329 for further details regarding the processing of MDL studies and evaluation of outliers.

9.3.4 TREND EVALUATION

Trend analysis techniques can be applied to control charts as a preventive tool to help indicate conditions that could cause an analysis to become out of control. In evaluating control charts, a trend is recognized if one or more of the following situations exist:

- A series of seven successive points occur on the same side of the mean;
- A series of five successive points occur going in the same direction;

- Two consecutive points occur between the warning and control limits;
- A single value occurs outside of control limits.

Actions may be employed for trends identified. Items which might be considered but not limited to include:

- Has there been a change in instrumentation or personnel?
- Has instrument maintenance been properly performed?
- What conditions have changed since the trend began?
- Have standard or spike solutions changed?

9.4 SECOND COLUMN OR SECOND DETECTOR CONFIRMATION

Second column or detector confirmation is performed for several GC and HPLC methods. Whenever two dissimilar chromatography columns or two detectors of a different nature are available for a given method, the laboratory performs second column or second detector confirmation analysis to confirm the identity of target analytes in field samples. When second column analysis is performed for any chromatography technique, the following policies apply:

- Every attempt will be made to calibrate the second (confirmatory) column in the same manner as the quantitative (primary) column. The same initial and continuing calibration standards will be analyzed on the confirmation column in the same manner as the quantitation column. The purpose of this dual calibration requirement is to allow the possibility of reporting quantitative results from the confirmation column if interferences on the primary column prevent accurate target analyte quantitation.
- For chromatographic techniques, the determination of target analytes in a sample depends solely on peak retention times observed in both primary and secondary column chromatograms. If target analyte peaks are present at the proper retention times in both confirmation and quantitation column chromatograms at levels above the MDL, then ALS considers this analyte to be confirmed.
- In general, ALS reports the higher value of the two columns per SW8000C guidance (e.g., 8011, 8081, 8082, 8141, 8151, 8021). It is also ALS's policy to report the higher value of the two columns for other EPA methods (e.g., 608, 615).

If no interferences are present, and an analyte's value from either the primary or secondary column is greater than the reporting limit but between the MDL and the reporting limit on the other column, then ALS reports the higher value that is greater than the reporting limit for that analyte.

- ALS customarily reports the value from the primary column for methods SW8330 and SW8332. Co-elutions or interferences are frequently observed on the secondary column for these HPLC methods.

- Other reporting rules may apply as dictated in the applicable LIMS program specification. The rules of the LIMS program specification supercede standard ALS policy.

9.5 MANUAL RE-INTEGRATION POLICIES AND PROCEDURES

Many data collection systems allow the analyst to reprocess data, thereby allowing for the manual re-integration of analyte peaks. ALS makes every attempt to optimize peak integration parameters; however, manual reprocessing of data must be performed to correct a data system's integration error (e.g., incorrect or missed peak assignment, over- or under-integration of area). Manual re-integrations may not be performed solely to meet initial or continuing calibration criteria or any QC criteria (e.g., tuning, or surrogate or spiking compound recovery).

Whenever a manual integration is performed, the analyst performing this process must include a hardcopy of the original and re-integrated peak in the final data report. In addition, the analyst must initial and date the re-integrated page and document the reason for re-integration on the printout. The re-integration must be documented in the case narrative.

Further details regarding manual integration procedures are given in **SOP 939**.

10. DATA REDUCTION, VALIDATION AND REPORTING

Data transfer and reduction are essential functions in summarizing information to support conclusions. It is essential that these processes are performed accurately and are followed by multiple reviews before data are submitted to the client. All analytical data generated by ALS are extensively reviewed for accuracy and completeness. The data validation process consists of data generation, reduction, and multiple levels of review, as described below.

10.1 DOCUMENTATION OF RAW DATA

Where possible, raw data are captured and processed electronically using verified software programs (see **SOPs 709 and 1400** for further information regarding software verification).

To facilitate manual documentation of raw data (where suitable LIMS benchsheet interfaces do not yet exist), ALS creates custom logbooks comprised of forms or

benchsheets that are tailored to contain the information required to adequately document the process being performed, and the associated data. The Quality Assurance Department controls these forms and benchsheets, and issues bound and paginated logbooks to the laboratory as needed via controlled distribution.

As applicable, hardcover, bound laboratory notebooks (most frequently used for instrument maintenance logs or Project Manager notebooks) are also issued via controlled distribution to laboratory staff as needed.

The manually recorded raw data are entered into the laboratory logbook directly, promptly, and legibly in indelible ink. All raw data entries must, at a minimum, contain the following information:

- the initials of the individual who performed the process;
- the date the process was performed;
- the methodology used; and
- the identity of all samples or standard solutions that were employed in carrying out the process.

Raw data must be maintained as part of the laboratory's records. Raw data not only includes instrument outputs, but sample preparation, standard materials documentation, and equipment maintenance information as well. Raw data may be archived electronically or as hardcopy.

10.2 CORRECTION OF ERRORS IN DOCUMENTS

During the course of processing and reviewing sample preparations and analysis results, it may be necessary to correct documentation errors. Detailed requirements for the correction of manual documentation errors are prescribed in **SOP 303**; the correction of electronic information is governed by LIMS controls and audit trails. In summary, manual entries may not be obliterated by erasure, use of correction fluid, or other means. In order to maintain the integrity of the documentation generated by the laboratory, changes to hardcopy documentation must be made in the following manner:

- A single line must be struck through the error so that the original text remains legible;
- As applicable, a corrected entry must be made adjacent to the error; and
- The person making the change must initial and date the corrective entry.

If not clearly evident, the reason for the data change must be indicated.

10.3 DATA REDUCTION

ALS analysts perform data reduction. This process consists of interpreting instrument results and verifying calculated concentrations in samples from the raw data. The complexity of the data reduction is dependent on the specific analytical method and the number of discrete operations involved in obtaining a measurement (e.g., digestions, dilutions, cleanups, concentrations). The analyst calculates the final reportable values from raw data or enters all necessary raw data into the LIMS so that the LIMS can calculate the final reportable values.

Data are reduced according to protocols described in SOPs and method-specific review checklists. Computer software used for data reduction is validated before use and verified regularly by manual calculations. All information used in calculation is recorded in order to facilitate reconstruction of the final results (e.g., raw data, calibration files, tuning records, results of standard additions, interference check results, sample response, and blank or background-correction protocols). Information about the preparation of the samples is maintained in order to facilitate reconstruction of the final results (e.g., weight or volume, percent moisture for solids, extract volume, dilution factor).

Copies of all raw data and the calculations used to generate the final results, as recorded in hardbound laboratory notebooks, spreadsheets, electronic data files and LIMS record files, are retained in the project file to allow reconstruction of the data reduction process.

10.4 REPORTING OF SAMPLE RESULTS

Sample results are reported either on an "as-received" basis, or in units of dry-weight measure. The number of significant figures reported is consistent with the limits of uncertainty inherent to the analytical method. In most cases, results are reported to no more than two or three significant figures. Analytical problems, and/or any modifications of referenced methods are noted in the data package case narrative.

Standard units appropriate to the analytical method are used to report all sample results. Measurements for radiochemical analyses are reported in units of activity such as:

- picocuries per liter (pCi/L), aqueous; or picocuries per gram (pCi/g), solid matrix samples.
- disintegrations per minute per liter (dpm/L) or disintegrations per minute per gram (dpm/g).

- Becquerels per liter (Bq/L) or Becquerels per gram (Bq/g).

It should be noted that one (1) Curie is equal to 2.22 X 10^{12} dpm; and is also equal to 3.7 X 10^{10} Bq.

Standard units for inorganic and organic analyses are units of mass per volume (aqueous samples), or mass per weight (solid matrix samples). For example, Wet Chemistry parameters such as hardness, total organic carbon (TOC), etc., are typically reported in milligrams per liter (mg/L) or milligrams per kilogram (mg/kg). Metals results for liquid samples may be reported as mg/L or as micrograms per liter (µg/L). Some methods have specific reporting units mandated by their analysis technique. For example, pH is reported as pH units, and specific conductance is reported as milli-Siemens (mmho/cm) or micro-Siemens (µmho/cm).

10.5 DATA REVIEW

ALS employs multiple levels of data review. All data generated and reduced follow review protocols specified in laboratory SOPs (such as **SOPs 052** and **715**), and method-specific checklists. The preparatory technician and analyst who generates the analytical data perform a **Level 1** review of the data for correctness and completeness. This data review verifies that:

- the appropriate SOPs have been followed;
- any special sample preparation or analytical requirements that were communicated to the laboratory via the LIMS program specification have been met;
- all sample preparation information is correct and complete;
- all analysis information is correct and complete;
- QC samples meet criteria for frequency, accuracy and precision;
- all calculations, conversions, and data transfers are accurate;
- all documentation is present and complete, including benchsheets and/or run logs, any applicable NCRs, and documentation and presentation of manual integrations per SOP 939, as applicable.

Procedures for handling unacceptable data are discussed subsequently (LQAP Section 10.6).

Following completion of the Level 1 Review, the analyst then forwards the data to the Department Manager or another qualified reviewer whose function is to provide an independent **Level 2** review of the data. In addition to the elements

evaluated in the Level 1 review described above, the Level 2 reviewer verifies that:

- the calibration data are scientifically sound, appropriate to the method, and completely documented;
- qualitative identification of target analytes is correct;
- quantitative results are correct.

The Level 2 reviewer selects a sample and verifies it to the benchsheet. If no errors are found, then the review is considered complete. If any problems are discovered, then additional samples are verified to the benchsheet with the process continuing until no additional errors are found or until the data package has been reviewed in its entirety. The Level 2 review is documented by recording the date and initials of the reviewer on the checklist employed. This sign-off signifies that the data are approved for release and a final report is prepared.

Once the final report is prepared, an additional overall technical review is performed before it is routed to the Project Manager for a **Level 3** review. The intent of this review is to verify that the report is complete and that the data meet the overall objectives of the project.

Each step of the review process involves evaluation of data quality based on both the results of the QC data and the professional judgment of those conducting the analysis and/or review. This application of technical knowledge and experience to the evaluation of the data is essential in ensuring that data produced are consistently of known, documented, and appropriate quality.

10.6 PROCEDURES FOR HANDLING UNACCEPTABLE DATA

All QC information is recorded in the same format, with the same units, as that of the associated sample results. It is the analyst's responsibility to evaluate QC data against applicable prescribed limits. When an analysis of a QC sample (e.g., MB, LCS, CCV, etc.), indicates that the associated samples do not meet requirements, the analyst must immediately notify the Department Manager. The Department Manager then consults with the PM (and QAM, as applicable) to determine whether or not the affected samples must be re-prepped and/or re-analyzed, and/or if specific corrective action needs to be taken before additional analysis may proceed. A Nonconformance Report (NCR) as discussed in Chapter 11 of this LQAP, is initiated per **SOP 928**, as applicable. If the non-compliant data cannot be corrected, then the affected results must be flagged as discussed below, and the discrepancy disclosed in the data package case narrative. The completed NCR Form is included in the data report

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10.7 DATA REPORTING

Data reports contain final sample results, the methods of analysis used and limits of detection, and QC data. The extent of supportive data included (e.g., benchsheets, run logs, calibration data, instrument raw data printouts, etc.), is contingent upon the type of report contracted by the client.

Results of subcontracted data are clearly indicated as subcontract laboratory results when incorporated into the final data package report.

10.7.1 FACSIMILE OR IMAGED REPORTS

For projects that require rapid turnaround of sample analysis results, the laboratory may provide a facsimile or imaged e-mail attachment to the client, followed by the full data report at a later date. If the analysis results provided by facsimile or imaged e-mail attachment have undergone the same review processes followed for final data packages, then this forwarded report indicates that the sample analysis results are final. However, if the accelerated turnaround time requirements preclude a full review/validation of the sample data, then the report is marked as "PRELIMINARY" to indicate that results may change as the review process is completed.

10.7.2 HARDCOPY DATA PACKAGES

The format and content of a data report is dependent upon project specifications, and it is beyond the scope of this document to describe project-specific report requirements. In the absence of client-specified data package deliverables, the following sections describe the items that must be included in all data reports.

10.7.2.1 COVER LETTER

Items contained in the cover letter include:

- the client's name and address;
- ALS's name and address, name of contact and telephone number;
- a tabular presentation of field/client sample ID, ALS Sample ID, date received, matrix, and date collected. This item is typically presented as an attachment, the Sample Cross Reference Table;
- a list of each analysis performed and total number of pages for each analytical report;
- identification of all test data provided by a subcontract laboratory;

- a discussion of previously submitted or partial reports that pertain to the samples discussed in the current report; and
- the signature of ALS's Project Manager or designee.

10.7.2.2 REPORT FORMAT

Analysis reports are presented in tabular format, and consistent significant figures and units of measurement are used. The following information is included in each report:

- laboratory name, client name, project name and/or number;
- client/field sample ID and ALS sample ID;
- date of sample receipt, date and time of sample collection, and date/time of sample preparation and/or analysis;
- sample matrix;
- reporting units and identification of whether the sample results are reported on an "as-received" or dry weight basis;
- method reference for the parameter analyzed and method reporting limits;
- identification of numerical results with values below the method reporting limit;
- case narrative that identifies test methods, describes any deviation from the method or contractual requirements, additions or exceptions to the SOP, and discloses any conditions that may affect the quality of the results;
- identification of sample results that did not meet sample acceptance criteria;
- footnotes or qualifiers referenced to specific data (as applicable) and explanations or keys to flags and abbreviations used;
- surrogate and tracer recoveries, where applicable;
- where applicable, a statement of the estimated uncertainty of the test result; and

- a signature and title, or equivalent electronic identification, of the personnel who accepts responsibility for the content of the report, and the date of issue.

If a report is reissued, the amendments must clearly state that the report is reissued. The cover letter and case narrative must describe why the report has been reissued and which sample results have been reissued.

10.7.2.3 QC REPORTS

Each final report includes QC reports that summarize results from the associated LCS, MB, and matrix QC samples. Additional QC samples may be prepared and reported to comply with project-specific requirements.

10.7.2.4 DATA QUALIFIERS – FLAGGING CODES

Whenever the data quality objectives of the LQAP are not met, the associated sample results must be flagged with the appropriate flagging codes. These codes are applied only in the event that the laboratory cannot generate (through reanalysis) fully compliant data. If sample values are reported outside the calibration range of the method or unreliable interferences exist in the sample, then descriptive codes are applied to the result.

Data qualifiers are added by the laboratory prior to reporting the analysis results. The laboratory appends data qualifiers to each environmental field sample based on an evaluation of all available QC information (e.g., MS/MSD samples, laboratory blanks, LCSs, calibration verification standards, etc.). Analytical batch comments are added to the narrative section of each data report to explain any nonconformance or other issues.

Other flagging practices may be observed if so dictated by the applicable LIMS program specification.

10.7.3 ELECTRONIC DATA DELIVERABLES (EDDS)

The electronic data deliverables generated by the laboratory are project-specific and are produced in a format specified by the client. *Information presented in corresponding fields of the hardcopy report and EDD are identical as both are generated from LIMS.* Before submitting the EDD file, the Project Manager or designee verifies that the EDD is complete and meets the client's format requirements. All

EDDs are submitted to the client on computer disks or are transmitted electronically.

10.8 RECORDS AND DATA STORAGE

Records provide the direct evidence and support for the necessary technical interpretations, judgments, and discussion concerning laboratory results. These records, particularly those that are anticipated to be used as evidentiary data, provide the historical evidence needed for later review and evaluation. Records must be legible, identifiable, and retrievable. They must be protected against damage, deterioration, fire, theft, vermin, and loss. Though only 5-year retention is required by TNI, ALS retains all records for a minimum of seven (7) years, or as otherwise specified per the client's contract.

Laboratory records include the following kinds of documentation:

- personnel qualifications, experience, and training;
- correspondence between ALS and clients;
- quality assurance records (e.g., retired SOPs and LQAPs, PT study results, internal and external audit reports and responses);
- contents of laboratory logbooks;
- equipment maintenance records;
- traceability of standards, solvents and reagents;
- instrument checks and calibrations;
- raw data;
- final data reports; and
- sample management records (e.g., sample login, field and internal chain-of-custody, storage, disposal).

10.8.1 ELECTRONIC RECORDS

ALS employs a multi-level system that addresses both the frequent backup of sample results (in LIMS) and the periodic backup of raw data (from both networked and non-networked instruments). Additionally, the software that ALS uses for these backups, contains a disaster recovery module that allows for the complete recovery of the backup database, in its entirety. In short, ALS's LIMS is backed up hourly, and, along with all network servers, is additionally backed up to tape each business day. As indicated in the IS and LIMS Policy Statement (SOP 143 and SOP 1401), instrument backups are performed approximately monthly. Contingent upon the volume of analysis, the frequency of backup might vary.

Backup of the instrument computers is done centrally by the IS Manager if the instrument computer is on the network. It is the responsibility of the operator\user to coordinate a convenient time for both the IS Manager and the user for non-network instrument backup. The instruments that are not on the network are backed up using portable devices. These devices, as well as media, are checked out from the IS Manager, then are returned to the IS Manager for safe storage.

An electronic archive for maintaining final project reports was implemented in 2001. Upon completion of a workorder, all data reports are scanned to create image files that are catalogued and saved to a dedicated server that is backed up daily as described above. The scanned images remain available on the network for review should any questions regarding the data arise.

10.8.2 TRANSFER OF RECORDS

In the event that the laboratory changes ownership, the responsibility for the retention of records in accordance with the guidelines established in this LQAP, is conferred to the new owner. Should ALS go out of business, ALS will inform our clients in writing of this business decision, and will transfer records at the client's request.

10.9 CLIENT INQUIRIES/COMPLAINTS

The focal point of contact with the client is the ALS Project Manager. If a complaint or any circumstance raises doubt concerning ALS's compliance with its policies or procedures, or with the requirement of a method or quality system, it is the Project Manager who initiates investigation and follows through to resolution. The QAM, Department Managers, and Laboratory Director are made aware of, and involved in, the resolution process as needed. Documentation of the complaint and its resolution are maintained as part of the project records. Where resubmission of data is required and/or implementation of preventive measures is necessary, it is processed (**SOP 928**), through the QAM. ALS will respond to all complaints in a timely fashion.

10.10 CONFIDENTIALITY

All laboratory results and associated raw data are confidential and may not be released to or discussed with any party other than the client who requested the analytical services. Access to laboratory records and LIMS is limited to laboratory personnel, on a restricted basis, based on need (i.e., job function). Records are available for an accrediting authority's on-site review, and records specific to the client (as well as quality system records) are available to the client for client audits. ALS requires that auditors will honor our clients' and ALS's confidentiality requirements, and will not discuss any results, documents, or records viewed during the course of an audit.

Confidentiality is included as a component of ALS's ethics training, which is provided to each person as they join the ALS staff, and annually, as a refresher training, thereafter.

11. CORRECTIVE ACTION, PREVENTIVE ACTION AND IMPROVEMENT

Corrective action is necessary when any measurement system fails to meet the requirements of this LQAP, the appropriate SOP or project-specific instructions, or whenever an error is detected. Items that may need corrective action range from a minor problem such as an analyst failing to initial a form, to a major problem such as a chemist preparing a sample using the wrong reference method.

Corrective actions fall into two general categories: short-term and long-term. Short-term corrective actions are those that can be applied immediately. Examples include: having an analyst initial a form where the initial was missed, or correcting an error in a logbook entry per procedures described in SOP 303. Long-term corrective actions are those that require a clarification of practice or a change in policy in order to effectively resolve the problem. Corrective actions must be completed by the date designated by the QA Department (i.e., within 21 calendar days or less, unless otherwise provided for). Associated SOPs may need to be revised and republished for long-term corrective actions, laboratory staff must be re-trained in accordance with the updated procedures.

11.1 RESPONSIBILITIES FOR CORRECTIVE ACTION INITIATION

The type of corrective action taken is coordinated by the Department, Quality Assurance and applicable Project Managers. A controlled Nonconformance Report is used to document the corrective action. *Any* individual who notes a problem or deviation is responsible for initiating the NCR in a timely manner.

It is the responsibility all personnel who work with samples to note any discrepancies or nonconformances that occur with sample handling. It is the responsibility of the chemists who prepare samples for analysis to document any problems that are noted during sample preparation. It is the analyst's responsibility to monitor the proper functioning of the analytical system prior to, during and following sample analysis. To accomplish this, various DQIs as discussed in Chapter 3 of this LQAP are monitored and evaluated against laboratory established or project-specific QA/QC requirements. If the evaluation reveals that any of the QC acceptance criteria are not met, then the analyst must immediately correct the problem. When an acceptable resolution cannot be achieved and/or data quality is negatively impacted, the analyst must notify the Department and Project Managers and must initiate an NCR (**SOP 928**) immediately. Per the guidance contained in SOP 928, the laboratory shall notify all affected clients of potential data quality issues in a timely manner, and corrective actions taken to resolve the issue shall be completed in a reasonable timeframe, with documentation submitted to the client.

- **ALS NONCONFORMANCE AND CORRECTIVE ~~LABORATORY GROUP, FORT COLLINS CORRECTIVE~~ ACTION PROCESS**

Non-conformances are reported (documented) electronically through a LIMS interface that is available to all staff. The individual who discovered the problem or deviation is responsible for initiating the next sequential NCR in LIMS. Note that in addition to documenting laboratory sample or test issues, NCRs are also used to address client inquiries, and to investigate Performance Test (PT) sample failures.

Documented on the NCR are the initials of the initiator and descriptions of the method, workorder(s) and samples affected; the type, content and extent of the problem noted; the probable cause and the root of the problem (if known); measures taken to prevent recurrence; the specific corrective actions taken and their outcome; and the final disposition/resolution of the data.

As described in **SOP 928**, the processing of the NCR flows from the initiator, to their immediate Supervisor and/or Department Manager and the relevant Project Manager(s), and finally to the Quality Assurance Manager. In this manner, a consensus is achieved as to what specific corrective actions are to be taken. The Project Manager, at his or her discretion, may or may not contact the client to discuss options based on the nature of the nonconformance. Whether or not the client is contacted is noted on the NCR, if the client is contacted, the Project Manager documents who was contacted and when. The Project, Department and Quality Assurance Managers electronically sign and date the NCR, documenting their final approval and verification of the disposition of the data. The LIMS provides for delegation of signature authority as needed to cover key staff outages.

The LIMS, which is subject to ALS's frequent backup protocols, maintains an archive of all NCRs generated. In this manner, NCRs are retained as part of the laboratory's electronic records. Also, contingent upon the level of data deliverable specified by the client, a copy of the associated NCR report is included in the analytical data package.

Corrective actions that require follow-up, including those initiated by internal or external audits and systematic non conformances, are catalogued in a separate database that tracks audit findings, root cause, corrective actions, follow up for effectiveness, and closure. This database is managed by the QA Department but is available to all staff on a read-only basis.

11.3 IMPROVEMENT AND PREVENTIVE ACTION

At ALS, improvement of the quality systems and preventive action is effected through an ongoing systems review by management using input from all staff.

ALS actively seeks employee and client input for improvements through surveys and questionnaires. ALS maintains a process improvement website for employees to provide suggestions for improvements. For clients, ALS provides surveys and

feedback on services provided. These automated systems report directly to the laboratory director for input into the management review process.

Preventive actions include preventive instrument maintenance as listed in all ALS Testing SOPs. These actions are documented in run logbooks and maintenance logbooks.

The laboratory Non conformance system within the LIMS identifies events as non conformance or incidence. The incidence is considered a potential non conformance and is evaluated along with all events for needed potential improvements to the ALS testing processes.

Management and key personnel review strategic goals and necessary improvements through a planning process (Balanced Scorecard). This process and review of actions items is available in monthly reports for the laboratory to corporate operations. All employees are asked to participate these goal setting sessions on a regular basis.
The top laboratory management team conducts an ongoing review of the operations and quality system. This review process includes daily, weekly and monthly status meetings.

11.4 IDENTIFICATION OF TRENDS IN QC DATA

Preventive Actions using QC sample trending although not required is available to help prevent non compliance QC situations from occurring. The trending rules used by ALS are in the following table. In most instances experience chemists identify trends and take action upon reviewing analytical data. Control Charts can be generated, if needed using the last twenty data points and historical control limits as an aide to this process.

Method QC data for each method are evaluated daily for trends by chemists. The occurrence of a trend does not necessarily invalidate analysis data for field samples; data are used by analysts to determine a course of action to keep analyses in control. Control limits are guides used for data evaluation. Verifying that QC sample values are not trending toward a control limit ensures that the method may continue to be used for the analysis of field samples. If an undesirable trend appears in the analytical QC data, field sample data for samples analyzed with the QC samples might also be trending in the same manner.

To identify a trend in surrogate or tracer recovery data, all surrogate or tracer values for a sample batch must be evaluated collectively as a single event, since the values were generated during the same analysis event. Trends should be evaluated between sample batches.

RULE	DESCRIPTION	POSSIBLE PREVENTIVE ACTIONS
Above Warning Limits	Two of three data points above warning limits	Check Calibration and Spiking Solutions Instrument Maintenance
Below Warning Limits	Two of three data points below warning limits.	Check Calibration and Spiking Solutions Instrument Maintenance
Above Mean	Seven consecutive data points above the mean	Check Calibration and Spiking Solutions Instrument Maintenance
Below Mean	Seven consecutive data points below the mean	Check Calibration and Spiking Solutions Instrument Maintenance
Ascending Data	Seven consecutive data points in ascending direction	Check Calibration and Spiking Solutions Instrument Maintenance
Descending Data	Seven consecutive data points in descending direction	Check Calibration and Spiking Solutions Instrument Maintenance

12. AUDITS

12.1 INTERNAL AUDITS

Periodic evaluations conducted by the Quality Assurance Department and the analysis of Proficiency Test (PT) samples are two types of internal audits used to assess and document the performance of laboratory staff and processes. Audit documentation constitutes a permanent record of the conformance of ALS's measurement systems to quality system requirements.

Internal audits include both technical and systems audits, and are performed periodically per an annual schedule developed and maintained by the Quality Assurance Department. Considerations taken into account in developing the internal audit schedule include, but are not limited to, requests made by the Laboratory Director; the scheduled occurrence of external audits; as needed to

support a specific project's requirements; to verify the continued effectiveness of corrective actions previously taken; or in response to an identified need to evaluate compliance in any area of laboratory operations. The intention of the internal audit schedule is to provide for the evaluation of each laboratory area or system at least once annually, thereby providing an overview of laboratory operations. Form 168 or other audit questionnaire may be used as a guide to conduct and document internal audits. Each year, the internal audits conducted are compiled into the annual Quality Systems Audit (QSA), which is discussed subsequently (LQAP Section 12.1.3).

All internal audits are conducted by QA staff or designees who, by experience, are deemed to be knowledgeable in the area assessed. The assigned auditor identifies the scope, time frame and expected duration of the audit, and communicates this information to the applicable Department Manager. The auditor reviews relevant information such as regulations, contract requirements, published procedures, SOPs, etc., prior to the audit. The criteria set forth in these applicable guidances establish the basis of the audit. These reference materials may also be used as auditor's aids.

The audit is conducted in an efficient and professional manner. Findings, Observations and comments are communicated to the Department Manager.

Short-term corrective actions may be taken at the time an item is noted, or an appropriate long-term corrective action plan may be developed. An audit is considered to be closed-out when deficiencies have been satisfactorily corrected.

An audit report summarizing the Determinations made and the corrective actions taken or planned is compiled; the original auditor's notes are customarily included as an attachment of the audit report. The outcome of the audit is communicated to the Laboratory Director. Internal audit corrective actions requiring follow up are tracked in a LIMS Table that is available for viewing to all laboratory personnel. The QAM oversees satisfactory completion of corrective measures taken. Internal audit records are maintained by the Quality Assurance Department.

See **SOP 937** for additional information pertaining to internal audit procedures.

12.1.1 INTERNAL TECHNICAL AUDITS

Departmental functions that may be reviewed during a technical audit may include, but are not limited to:

- Adherence to SOPs and compliance with promulgated method requirements during sample preparation and analysis;
- Maintenance of internal chain-of-custody;

- Proper preparation, storage, use and documentation of standards;
- Performance and documentation of instrument maintenance;
- Performance and documentation of data review;
- Evaluation of documentation practices pertaining to benchsheet and logbook entries, Nonconformance Report (NCR) generation and analyst demonstration of capability.

12.1.2 INTERNAL SYSTEM AUDITS

Examples of elements that may be reviewed as a system audit may include, but are not limited to:

- An assessment of the SOP process, including procedures for submitting and approving revisions, update and distribution of SOPs, tracking of employee SOP assignments and sign-offs, SOP electronic file management, and archiving of older SOP iterations and records.
- LIMS data capture and reporting processes.
- Sample handling, storage and disposal practices, including maintenance of sample storage areas, sample tracking and internal chain-of-custody documentation, duration of retention, and disposal designation and documentation.
- Use of ALS's Standards and Reagents database.
- Performance and documentation of laboratory logbook review.

12.1.3 ANNUAL QUALITY SYSTEMS AUDIT

A lab-wide review of conformance to ALS's quality system is conducted annually by the QA Manager or designee(s) as required by the TNI Standard. The annual Quality Systems Audit (QSA) shall be managed, conducted and reported according to the audit procedures described above. Inputs to the QSA may include, but are not limited to, summaries of the following: Nonconformance Reports (NCRs), Proficiency Testing (PT) study results, deficiencies noted during data review, internal audit Determinations, and Determinations made via external audits.

12.1.4 PROFICIENCY TESTING STUDIES

ALS participates in agency studies and/or contracts approved vendors to provide PT samples in accordance with a schedule developed and maintained by the Quality Assurance Department. Participation in PT studies enables ALS to demonstrate capability for continued accreditation, competency in a newly developed method, or the effectiveness of corrective actions taken.

ALS participates in the following inter-laboratory proficiency testing studies:

- Water Supply (WS) -- twice annually
- Water Pollution (WP) -- twice annually
- Soil/Hazardous Waste and UST -- twice annually
- Radiochemistry -- twice annually
- US Department of Energy (USDOE) Mixed Analyte Performance Evaluation Program (MAPEP) -- twice annually

These PT studies support various regulatory programs (SDWA, CWA, RCRA) and require that the laboratory perform analyses per various methodologies (e.g., EPA 600 series, MCAWW, ASTM, SW-846), matrices and analytes. Analyte lists include: volatile organics, semivolatile organics, organochlorine pesticides, polychlorinated biphenyls, organophosphorous pesticides, phenoxyacid herbicides, high explosives, petroleum hydrocarbons, metals, minerals, nutrients and radionuclides. The analyses of PT samples are conducted in-house, in the manner prescribed by the provider, and within the turnaround time stipulated. The PT samples are distributed to the laboratory and are

processed by qualified analysts who routinely perform the analytical method.

PT study results are evaluated by the Quality Assurance Department and the applicable Department Manager as they become available. The NCR and corrective action process as described in Chapter 11 of this LQAP, is used to address any deficiencies that are noted. An archive of PT study reports, maintained by the QA Department, is posted to the network for lab-wide access.

12.1.5 ANNUAL MANAGERIAL REVIEW

A lab-wide Managerial Review is performed annually. The Managerial Review assesses operational effectiveness in terms of meeting ALS's business goals. It is a tool used to document and facilitate the consideration and introduction of needed operational changes and improvements.

The Managerial Review is performed by a designee under the direction of the Laboratory Director. The general techniques of scoping, assessment interview, reporting and follow-up as described in the internal audit procedures discussed above and outlined in SOP 937, are used to conduct the annual Managerial Review. The contents of the annual Managerial Review are considered to be confidential. A confidential footer must, therefore, appear as a component of the annual Managerial Review report.

Inputs to the Managerial Review may include, but are not limited to the following: a snapshot summary of product generated (i.e., number of samples analyzed and the types of analyses performed), various business assessment reports (e.g., TAT, on- time delivery), output from the annual QSA (i.e., problem areas identified), interview of laboratory staff, and presentation of items discussed during strategic planning sessions and/or Manager's meetings.

12.2 EXTERNAL AUDITS

External audits may be performed by a state or Federal agency or a client as part of an ongoing certification process. Items evaluated by external assessors may include, but are not limited to, reviews of the following: analytical capabilities and procedures; COC procedures; document control; quality systems; and QC procedures. Blind PT samples may be submitted to the laboratory as a form of external audit.

ALS certifications are maintained on the internal network folders and are available by request. Should ALS drop or lose an accreditation, the PMs must notify all clients that may be affected in a timely manner.

13. PERSONNEL TRAINING

The selection of well-qualified personnel is a factor that contributes to ALS's success. Therefore, qualifications of personnel are based upon education and experience. In order to maintain qualified staff, provide personnel advancement within the laboratory, and to provide for personnel's ongoing awareness of potential hazards and protective measures, ALS follows a formal documented program of orientation and training. Records of Health & Safety and waste training are maintained by the Health & Safety Manager/RSO and Facilities/Waste Compliance Manager. Technical training records are forwarded to the Quality Assurance Department for retention.

13.1 ORIENTATION

Before working in the laboratory, new employees receive a four-part orientation as described below:

- Human resources -- involves matters of immediate personal concern, such as benefits and company policies
- Quality assurance -- addresses topics related to ethical conduct, good laboratory practices and ongoing documentation of employee capability demonstrations. Required readings (SOPs, LQAP) are assigned at this time. See ALS SOP 143.
- Health & safety -- provides for a review of ALS's various safety program documents (Chemical Hygiene Plan, CHP; Radiation Protection Plan, RPP; Emergency and Contingency Plan, ECP; Respiratory Protection Plan, ResPP; Waste Management Plan, WMP); as well as other safety and security training.
- Department functional orientation -- focuses on the new employee's basic understanding of their role within the Department and the overall role of Operations within the structure of ALS. The Departmental training expands upon the employee's scientific background and work experience to provide the employee with a level of competence that enables the individual to successfully function within the defined responsibilities of his/her position.

Temporary employees receive the same orientation as regular staff, with the exception of the human resources orientation.

SOP 143 details information regarding quality assurance orientation and training for new employees.

13.2 TECHNICAL TRAINING

Chemists (analysts) and technicians are qualified to perform specific analytical procedures and methods. The qualification process, at a minimum, consists of background/theory training, on-the-job training, and demonstration of proficiency.

Additional training may include further individualized instruction, programmed learning, conferences and seminars, and specialized training by instrument manufacturers.

Department Managers are responsible for providing documentation of analytical training and proficiency for each employee in their group(s) to the Quality Assurance Department for retention. See ALS SOP 150

13.2.1 INITIAL DEMONSTRATION OF CAPABILITY (IDOC)

New analysts and technicians are trained by Department Managers according to the following guidelines:

- The new employee reads the SOP(s) pertinent to the analytical method being learned, and receives background/theory instruction, as applicable.

- The new employee observes the procedure in which the analytical method and required process documentation is demonstrated by trained personnel. Job requirements are outlined and quality control measurements are defined. For most methods, the trainee performs an Initial Demonstration of Capability (IDOC) by preparing and/or analyzing four (4) blank spike samples under the supervision of the Technical or Department Manager, or an analyst proficient in that method.

- The results of the new employee's preparation and/or analysis are evaluated and problems and corrective actions are discussed. If the blank spike recovery and precision data meet quality control criteria for that method, the employee is deemed to have demonstrated proficiency and is allowed to work on client samples. If the values generated are outside acceptance limits, then training continues until the trainee can consistently meet the acceptance criteria for the method.

- After the certification process has been successfully completed, the Department Manager forwards the documentation to the Quality Assurance Department for retention.

13.2.2 CONTINUING DEMONSTRATION OF CAPABILITY (CDOC)

ALS's personnel are required to demonstrate their proficiency upon hire and with each batch of samples. Results from the laboratory control sample (LCS) spike performed by the chemist (analyst) or technician is evaluated ongoing and significant problems are dealt with immediately through the peer review process, non conformance system, and training. This LCS data is available to review upon request.

Alternately, RVS samples and PT sample analysis may also be used to demonstrate an employee's capability.

13.3 TRAINING RECORDS

Technical and quality assurance training records are maintained on network servers by the Quality Assurance Department. Health & Safety training records are also maintained on network servers Waste management training records are managed and maintained by the Facilities/Waste Compliance Manager. Training records are designated for storage using the ALS SOP 150.

14.1 GLOSSARY, ACRONYMS AND SYMBOLS GLOSSARY

TERM	**DEFINITION**
Acceptance Criteria:	Specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQ)
Accreditation:	The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. In the context of the National Environmental Laboratory Accreditation Program (NELAP), this process is a voluntary one. (TNI)
Accrediting Authority, Primary:	The agency or department designated at the Territory, State, or Federal level as the recognized authority with responsibility and accountability for granting TNI accreditation for a specified field of testing. (TNI)
Accuracy:	The degree of agreement between a observed value and the accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations. (QAMS)
Aliquot:	A discrete, measured, representative portion of a sample taken for analysis. (EPA QAD)
Ambient:	Usual or natural surrounding conditions, e.g. ambient temperature – the natural, uninfluenced temperature of the surroundings. (NIRP Glossary)
Analyte:	The specific chemicals or components for which a sample is analyzed; may be a group of chemicals that belong to the same chemical family and that are analyzed together. (DoD QSM)
Audit:	A systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity. (EPA-QAD)

TERM	**DEFINITION**
Background:	Ambient signal response recorded by measuring instruments that is independent of radioactivity contributed by the radionuclides being measured in the sample. (DOE QSM)
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 twenty environmental samples of the same TNI-defined matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch is composed of prepared environmental samples (extracts, digestates, or concentrates) which are analyzed together as a group. An **analytical batch** can include prepared samples originating from various environmental matrices and can exceed 20 samples. (TNI Quality Systems Committee)
Bias:	The deviation of a single measured value of a random variable from a corresponding expected value, or a fixed mean deviation from the expected value that remains constant over replicated measurements within the statistical precision of the measurement (Synonyms: deterministic error, fixed error, systematic error). (DOE QSM)
Blank:	A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, or analysis. The blank is subjected to the same analytical and measurement process as the associated samples. Blanks include: Equipment blank: a sample of analyte free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures. (TNI) Field blank: a blank prepared in the field by filling a clean container with pure deionized water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA OSWER) Trip blank: Contaminant free water, or appropriate matrix, which accompanies bottles and samples during shipment to assess the potential for sample contamination during shipment. Trip blanks are not opened in the field, and are required for Volatile Organic Analysis only. (NIRP) Instrument Blank: A clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD) Method blank: a sample of a matrix similar to the batch of associated

TERM	**DEFINITION**
	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 the steps of the analytical procedures. (TNI)
	Reagent blank: a sample consisting of reagent(s), without the target analyte(s) or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps. (QAMS)
Blind Sample:	A sub-sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample, but not the composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process. (TNI)
Calibration:	To determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument, or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements. See Initial Calibration. (TNI)
Calibration, Continuing:	The process of analyzing standards periodically to verify the maintenance of calibration of the analytical system.
Calibration Curve:	The graphical relationship between the known values, such as
	concentrations, of a series of calibration standards and their instrument response. (TNI)
Calibration, Initial:	The process of analyzing standards, prepared at specified concentrations, to define the quantitative response, linearity and dynamic range of the instrument to the analytes of interest. Initial calibration is performed whenever the results of a continuing calibration do not conform to the requirements of the method in use or at a frequency specified in the method. See Calibration.
Calibration, Initial Check/Verification (ICV):	Verification of the ratio of instrument response to analyte amount, a calibration check is done by analyzing for analyte standards in an appropriate solvent. Calibration check solutions are made from a stock solution which is different from the stock used to prepare calibration standards. (NIRP Glossary)
Carrier:	Carriers are typically non-radioactive (e.g. natural strontium, barium, yttrium) elements. They follow similar chemical reactions as the analyte during processing and are added to samples to determine the overall chemical yield for the analytical preparation steps. The yield of the carrier is typically determined

TERM	**DEFINITION**
	gravimetrically or by ICP and is used to correct radiochemical results for acceptable losses occurring during the preparation process. (DOE QSM)
Chain-of-Custody (COC) Form:	Record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers, the mode of collection, preservation, and requested samples. (TNI)
Confidential Business Information (CBI):	Information that an organization designates as having the potential of providing a competitor with inappropriate insight into its management, operation or products. TNI and its representatives agree to safeguarding identified CBI and to maintain information identified as such in full confidentiality. (TNI)
Confirmation:	Verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to: second column calibration, alternate wavelength, derivatization, mass spectral interpretation, alternative detectors, or additional cleanup procedures. (TNI)
Conformance:	An affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements. (ANSI/ASQC E4-1994)
Control Chart:	A graphical plot of test results with respect to time or sequence of measurement, together with limits within which they are expected to lie when the system is in a state of statistical control.
Control Limit:	A range within which specified measurement results must fall to signify compliance. Control limits may be mandatory, requiring corrective action if exceeded, or advisory, requiring that nonconforming data be investigated and flagged.
Corrective Action:	The action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence. (ISO 8402)
Counting Efficiency:	The ratio of the net count rate of a radionuclide standard source to its corresponding known activity. (DOE QSM)
Counting Uncertainty (Poissonian):	A statistical estimate of uncertainty in a radiochemical measurement due to the random nature of decay. Every radiochemical result is reported with an associated counting uncertainty, usually at the 95%

TERM	DEFINITION
	confidence interval.
Data Quality Indicators:	The qualitative or quantitative statements that specify the quality of data required to support decision for any process requiring chemical or physical analysis.
Data Reduction:	The process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useable form. (EPA-QAD)
Daughter:	A nuclide formed by radioactive decay of a parent radionuclide.
Deficiency:	An unauthorized deviation from acceptable procedures or practices, or a defect in an item. (ASQC)
Demonstration of Capability (DOC):	A procedure to establish the ability of the analyst to generate acceptable accuracy. (TNI)
Detection Limit, Analyte:	The lowest concentration or amount of the target analyte that can be identified, measured, and reported with confidence that the analyte concentration is not a false positive value. See Method Detection Limit. (TNI)
Detection Limit, Instrument (IDL):	The concentration of an analyte that produces an output signal twice the root mean square of the background noise, or the parameter determined by multiplying by three the standard deviation obtained of three to five times the desired IDL on three nonconsecutive days with seven consecutive measurements per day. IDL is only required for the metals and analysis. (DOE QSM)
Detection Limit, Method (MDL):	The Method Detection Limit (MDL) is defined as the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero. It may be determined using replicate spike samples prepared by the lab and taken through all steps of the method. The detection limit is calculated using the ALS SOP 329
Digestion:	A process in which a sample is treated (usually in conjunction with heat) to convert the sample into a more easily measured form. (DoD QSM)
Dilution Factor:	The factor by which the dilution level of the sample differs from that of a predefined method blank. The method blank is prepared within the prescribed parameters of the method, and has a dilution factor of one. The dilution factor does not include a dryness factor. (DOE QSM)

TERM	**DEFINITION**
Document Control:	The act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly, and controlled to ensure use of the correct version at the location where the prescribed activity is performed. (ASQC)
Dry Weight:	The weight of a sample based on percent solids. The weight after drying in an oven at $105 \pm 5^{o}C$.
Duplicate, Replicate Analysis:	The analyses or measurements of the variable of interest performed identically on two sub samples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation, or storage internal to the laboratory. (EPA-QAD) The measurements of the variable of interest performed identically on two or more sub-samples of the same samples within a short time interval. (TNI)
Duplicate (Replicate) Error Ratio (DER/RER):	A measure of precision used to assess agreement between radiochemical duplicates (replicates) that compares the discrepancy between two measurements to the associated uncertainties.
Duplicate, Replicate Sample:	A second aliquot of the same sample that is treated the same as the original sample in order to determine the precision of the method. A second, separate sample collected at the same time, from the same place, for the same analysis, as the original sample in order to determine overall precision.
Eluent:	A solvent used to carry the components of a mixture through a stationary phase. (DoD QSM)
Elution:	A process in which solutes are washed through a stationary phase by the movement of a mobile phase. (DoD QSM)
Energy Calibration:	The correlation of the multi-channel analyzer (MCA) channel number to decay energy, obtained from the location of peaks from known radioactive standards. (DOE QSM)
False Negative:	An analyte incorrectly reported as absent from the sample, resulting in potential risks from their presence. (DoD QSM)
False Positive:	An item incorrectly identified as present in the sample, resulting in a high reporting value for the analyte of concern. (DoD QSM)
Finding:	An assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding is

TERM	**DEFINITION**
	normally a deficiency and is normally accompanied by specific examples of the observed condition. (TNI)
Half Life ($T_{½}$):	The time required for 50% of a radioactive isotope to decay. (DOE QSM)
Holding Time (Maximum Allowable):	The maximum times that samples may be held prior to analysis and still be considered valid or not compromised. (40 CFR Part 136)
Homogeneity:	The degree to which a property or substance is evenly distributed throughout a material.
Interference, Spectral:	Occurs when particulate matter from the atomization scatters the incident radiation from the source or when the absorption or emission of an interfering species either overlaps or is so close to the analyte wavelength that resolution becomes impossible. (DoD QSM)
Interference, Chemical:	Results from the various chemical processes that occur during atomization and later the absorption characteristics of the analyte. (DoD QSM)
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. (TNI)
Isomer:	Generally, any two chemicals with the same chemical formula but with a different structure. (DoD QSM)
Isotope:	A variation of an element that has the same atomic number of protons but a different weight because of the number of neutrons. Various isotopes of the same elements may have different radioactive behaviors, some are highly unstable. (NIRP Glossary)
Lot:	A quantity of bulk material of similar composition processed or manufactured at the same time.
Matrix:	The substrate of a test sample. **Field of Accreditation Matrix:** these matrix definitions shall be used when accrediting a laboratory: Drinking Water: any aqueous sample that has been designated a potable or potential potable water source. Non-Potable Water: any aqueous sample excluded from the definition of Drinking Water matrix. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts. Solid and Chemical Materials: includes soils, sediments, sludges,

TERM	DEFINITION
	products, and by-products of an industrial process that results in a matrix not previously defined. Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin. 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 or vapor that are collected with a sorbent tube, impinger solution, filter, or other device. (TNI) Non-aqueous Liquid: any organic liquid with <15% settleable solids.
Minimum Detectable Activity (MDA, Lower Limit of Detection):	The minimum detectable activity is the smallest amount (activity or mass) of an analyte in a sample that will be detected with a probability beta of nondetection (Type II error) while accepting the probability alpha of erroneously deciding that a positive (non-zero) quantity of analyte is present in an appropriate blank sample (Type I error). For the purposes of this standard, the alpha and beta probabilities are both set at 0.05 unless otherwise specified. (ANSI N 13.30 and ANSI N42.23)
Minimum Detectable Concentration (MDC):	The Minimum Detectable Activity expressed in concentration units.
National Voluntary Laboratory Accreditation Program (NVLAP):	A program administered by NIST that is used by providers of proficiency testing to gain accreditation for all compounds/matrices for which NVLAP accreditation is available, and for which the provider intends to provide NELAP PT samples. (TNI)
Negative Control:	Measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results. (TNI)
Nonconformance:	An indication or judgment that a product or service has not met the requirements of the relevant specifications, contract or regulation, also the state of failing to meet the requirements. (DoD QSM)
Performance Based Measurement System (PBMS):	A set of processes wherein the data quality needs, mandates, or limitations of a program or project are specified and serve as criteria for selecting measurement processes which will meet those needs in a cost effective manner. (TNI)
Positive Control:	Measures taken to ensure that a test and/or its components are working properly and producing correct or expected results from

TERM	**DEFINITION**
	positive test subjects. (TNI)
Precision:	The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance, or range, in either absolute or relative terms. (TNI)
Proficiency Test Sample:	A sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria. (QAMS)
Qualitative:	Analysis without regard to quantity or specific numeric values. (NIRP Glossary)
Quality Assurance:	An integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. (QAMS)
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 the users. (QAMS)
Quality Control Sample:	An uncontaminated matrix spiked with 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. (EPA-QAD) Laboratory Control Sample (LCS): (However named, also Laboratory Fortified Blank, Blank Spike, or QC Check Sample): A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias, or to assess the performance of all or a portion of the measurement system. (TNI) Laboratory Duplicate (DUP): Aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently. (TNI) Matrix Spike (spiked sample or fortified sample): A sample prepared by adding a known mass 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, for example, to determine the effect of the matrix on a method's recovery efficiency.

TERM	**DEFINITION**
	(QAMS)
Quantitation Limits, Practical (PQL):	Levels, concentrations, or quantities of a target variable (e.g. target analyte) that can be reported at a specified degree of confidence. (TNI) The value at which an instrument can accurately measure an analyte at a specific concentration (i.e. a specific numeric concentration can be quantified). These points are established by the upper and lower limits of the calibration range. (DoD clarification) The lowest concentration where the 95% confidence interval is within 20% of the true concentration of the sample. The percent uncertainty at the 95% confidence level shall not exceed 20% of the results for concentrations greater than the practical quantitation limit. (DOE QSM)
Quantitative:	Analysis with regard to quantities or specific numeric values. (NIRP Glossary)
Radioactive Decay:	The process by which a spontaneous change in nuclear state takes place. This process is accompanied by the emission of energy and subatomic particles. (DOE QSM)
Radiation Yield:	The amount of radiation of the type being measured that is produced per each disintegration, which occurs. For gamma spectrometry, this is commonly called gamma abundance. (DOE QSM)
Raw Data:	Any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm, or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g. tapes which have been transcribed verbatim, data and verified accurate by signature), the exact copy or exact transcript may be submitted. (EPA-QAD)
Reagent Water:	Shall be water (defined by national or international standard) in which no target analytes or interferences are detected as required by the analytical method. (TNI)
Region of Interest (ROI):	In radiochemical analysis, the Multi-channel Analyzer region defining the isotope of interest displayed in terms of energy or channels. (DOE QSM)
Relative Percent	A measure of precision between two duplicate (replicate) results

TERM	**DEFINITION**
Difference (RPD):	expressed as the percent difference between the results relative to the average of the results.
Reliability Check (Daily):	A periodic check of the Continuing Calibration of an instrument used for radiochemical measurements.
Reporting Limit:	The level at which method, permit, regulatory and client specific objectives are met. The reporting limit may never be lower than the statistically determined MDL, but may be higher based on any of the above considerations. Reporting limits are corrected for sample amounts, including the dry weight of solids, unless otherwise specified.
Retention Time:	The time between sample injection and the appearance of a solute peak at the detector. (DoD QSM)
Rounding Rules:	If the figure following those to be retained is less than 5, the figure is dropped, and the retained figures are kept unchanged. As an example, 11.443 is rounded to 11.44. If the figure following those to be retained is greater than 5, the figure is dropped, and the last retained figure is raised by 1. As an example, 11.446 is rounded to 11.45. If the figure following those to be retained is 5, and if there are no figures other than zeros beyond the five, the figure 5 is dropped, and the last-place figure retained is increased by one if it is an odd number or it is kept unchanged if an even number. As an example, 11.435 is rounded to 11.44, while 11.425 is rounded to 11.42. If a series of multiple operations is to be performed (add, subtract, divide, multiply), all figures are carried through the calculations. Then the final answer is rounded to the proper number of significant figures.
Sample:	A single container or series of containers identified by a unique number comprised of material drawn from a single location or a composite of locations during a fixed period representative of that location (s) and time period(s) for the purpose of analytical testing or physical evaluation. (DOE QSM)
Selectivity:	(Analytical chemistry) The capability of a test method or instrument to respond to a target substance in the presence of non-target substances. (EPA-QAD)
Sensitivity:	Capability of method or instrument to discriminate between measurement responses representing different levels (e.g. concentrations) of a variable of interest. (TNI)
Signal-to-Noise Ratio:	The signal carries information about the analyte, while noise is made up of extraneous information that is unwanted because it degrades the

TERM	**DEFINITION**
	accuracy and precision of an analysis and also places a lower limit on the amount of analyte that can be detected. In most measurements, the average strength of the noise is constant and independent of the magnitude of the signal. Thus, the effect of noise on the relative error of a measurement becomes greater and greater as the quantity being measured (producing the signal) decreases in amplitude. (DoD QSM)
Split Sample:	A portion or subsample of a total sample obtained in such a manner that is not believed to differ significantly from other portions of the same sample.
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 routine and repetitive tasks. (QAMS)
Reference Material:	A certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method. (EPA-QAD) A reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body. (ISO Guide 30 – 2.2)
Standard (Spike) Addition:	In radiochemistry, the addition of a known quantity of a radiotracer to a sample and to a split or splits of a sample. Both the sample and split(s) are then processed through the method and the difference in response between the samples used to correct for overall bias resulting measurement bias and from losses during preparation. This method of internal calibration is used in radiochemical determinations where isotopic differentiation between target analyte and tracer is not possible.
Statistical Minimum Significant Difference (SMSD):	The minimum difference between the control and a test concentration that is statistically significant, a measure of test sensitivity or power. The power of a test depends in part on the number of replicates per concentration, the significance level selected, and the type of statistical analysis. If the viability remains constant, the sensitivity of the test increases as the number of replicates is increased. (TNI)
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. (QAMS)

TERM	**DEFINITION**
Target Analytes:	Identified on a list of project-specific analytes for which laboratory analysis is required.
Tolerance Chart:	A chart in which the plotted quality control data is assessed via a tolerance level (e.g. +/-10% of a mean) based on the precision level judged to be acceptable to meet overall quality/data use requirements instead of a statistical acceptance criteria (e.g. +/- 3 sigma) (applies to radio bioassay laboratories). (ANSI)
Total Propagated Uncertainty (TPU):	An estimate or approximation of the total error associated with a measured value by propagation of individual (preparation, determination) uncertainties.
Traceability:	The property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons. (VIM-6.12)
Tracer:	A traceable internal standard, usually a unique isotope of the element being determined, added to each sample in known amount which enables quantitation of analytes of interest independent of external means of calibration.
Tracer Chemical Recovery:	The percent yield of the recovered radioisotope after the sample/tracer aliquot has undergone preparation and instrument analysis. (DOE QSM)
Tune:	An injected standard required by the method as a check on instrument performance for mass spectrometry. (DoD QSM)
Validation:	Confirmation by examination and provision of evidence that specified requirements have been met. (EPA-QAD)
Verification:	Confirmation by examination and provision of evidence that specified requirements have been met. (TNI) NOTE: In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment. The result of verification leads to a decision either to restore in service, to perform adjustment, to repair or downgrade, or declare obsolete. In all cases, it is required that a written trace of the verification performed shall be kept on the measuring instrument's

TERM	**DEFINITION**
	individual record.
Warning Limits:	The limits (typically 2 standard deviations either side of the mean) shown on a control chart within which most results are expected to lie (within a 95% probability) while the system remains in a state of statistical control.

14.2 ACRONYMS

TERM	DEFINITION
AA	Atomic Absorption
AFCEE	Air Force Center for Environmental Excellence
ANSI/ASQ	American National Standards Institute/American Society for Quality
APHIS	USDA Animal and Plant Health Inspection Service
API	American Petroleum Institute
ARAR	Applicable or Relevant and Appropriate Requirement
ASCII	American Standard Code Information Interchange
ASTM	American Society for Testing and Materials
BFB	Bromofluorobenzene
BNA	Base-Neutral and Acid Extractable Organic Compounds
BS	Blank Spike
BTEX	Benzene, Toluene, Ethylbenzene, Xylene
°C	Degrees Celsius
CAS	Chemical Abstract Service
CCC	Calibration Check Compound
CCB	Continuing Calibration Blank
CCV	Continuing Calibration Verification
CDPHE	Colorado State Department of Public Health and the Environment
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CF	Calibration Factor
CFR	Code of Federal Regulation
CLLE, CLE	Continuous Liquid-Liquid Extractor
CLP	Contract Laboratory Program
COC	Chain of Custody
CVAA	Cold Vapor Atomic Absorption Spectroscopy.

TERM	**DEFINITION**
CWA	Clean Water Act
D	Drift or Difference
DBCP	1,2-Dibromo-3-chloropropane
DCM	Dichloromethane
DENIX	Defense Environmental Management Information Exchange
DER	Duplicate Error Ratio
DFTPP	Decafluorotriphenylphosphine
DI	Deionized
DOC	Demonstration of Capability
DoD	Department of Defense
DOE	Department of Energy
DOT	Department of Transportation
DPM	Disintegrations per Minute
DQI	Data Quality Indicator
DRO	Diesel Range Organics
ECD	Electron Capture Detector
EDB	Ethylene Dibromide
EDD	Electronic Data Deliverable
EERF	Eastern Environmental Radiation Facility
EMSL	Environmental Monitoring Systems Laboratory
EPA	Environmental Protection Agency
FID	Flame Ionization Detector
FPD	Flame Photometric Detector
GALP	Good Automated Lab Practice
GC	Gas Chromatography
GC/MS	Gas Chromatography/Mass Spectrometry

TERM	DEFINITION
GFAA	Graphite Furnace Atomic Absorption
GFPC	Gas Flow Proportional Counting
GPC	Gel Permeation Chromatography
GRO	Gasoline range organics
HECD	(Hall) Electrolytic Conductivity Detector
HEM	Hexane Extractable Material
HDPE	High-Density Polyethylene
HPGe	High Purity Germanium Gamma Spectrometer
HPLC	High-Performance Liquid Chromatography
3.7	Ion Chromatography
ICAP-AES	Inductively Coupled Argon Plasma -Atomic Emission Spectroscopy
ICB	Initial Calibration Blank
ICP	Inductively Coupled Plasma
ICP-MS	Inductively Coupled Plasma - Mass Spectrometry
ICS	Interference Check Standard
ICV	Initial Calibration Verification
IDL	Instrument Detection Limit
IPC	Instrument Performance Check
IPN	Incoming Project Notice
IRPIMS	Installation Restoration Program Information Management System
IS	Internal Standard
ISO/IEC	International Standards Organization/International Electrotechnical Commission
KD	Kuderna Danish
LCS	Laboratory Control Sample
LD	Laboratory Duplicate

TERM	**DEFINITION**
LFB	Laboratory Fortified Blank
LFM	Laboratory Fortified Matrix
LIMS	Laboratory Information Management System
LLRW	Low Level Radioactive Waste
LQAP	Laboratory Quality Assurance Plan
LRB	Laboratory Reagent Blank
LSC	Liquid Scintillation Counting
LUFT	Leaking Underground Fuel Tank
LUST	Leaking Underground Storage Tank
MAPEP	Mixed Analyte Performance Evaluation Program
MCAWW	Methods for Chemical Analysis of Waters and Wastes
MDA	Minimum Detectable Activity
MDC	Minimum Detectable Concentration
MDL	Method Detection Limit
MEK	Methyl Ethyl Ketone (2-Butanone)
MIBK	Methyl Isobutyl Ketone
MSA	Method of Standard Additions
MSD	Matrix Spike Duplicate
MSDS	Material Safety Data Sheet
MTBE	Methyl tert-butyl ether
N/A	Not applicable
NIST	National Institute of Standards
NCR	Nonconformance Report
ND	Non Detect
NEIC	National Enforcement and Investigations Center
NELAC	National Environmental Laboratory Accreditation Conference

TERM	**DEFINITION**
NELAP	National Environmental Laboratory Accreditation Program
NEPA	National Environmental Policy Act
NFESC	Naval Facilities Engineering Service Center
NIRP	Navy Installation Restoration Program
NIST	National Institute of Standards and Technology
NPDES	National Pollutant Discharge Elimination System
NVLAP	National Voluntary Laboratory Accreditation Program
OSHA	Occupational Safety and Health Administration
PAH	Polynuclear Aromatic Hydrocarbon
PARCC	Precision, Accuracy, Representativeness, Completeness, Comparability
PBMS	Performance Based Measurement System
PCB	Polychlorinated biphenyl
PCDD	Polychlorinated dibenzo-p-dioxin
PCDF	Polychlorinated dibenzofuran
PEG	Polyethylene Glycol
PEL	Permissible Exposure Limit
PETN	Pentaerthrite tetranitrate
PID	Photoionization Detector
PM	Project Manager
PNA	Polynuclear Aromatic Hydrocarbon
PQL	Practical Quantitation Limit
psi	pounds per square inch
PT	Proficiency Testing
PTFE	Polytetrafluoroethylene
QA	Quality Assurance
QAPjP	Quality assurance project plan

TERM	**DEFINITION**
QASS	Quality Assurance Summary Sheet
QC	Quality Control
QIP	Quench Indicating Parameter
r^2	Correlation Coefficient
RCRA	Resource Conservation and Recovery Act
RDX	Hexahydro-1,3,5-trinitro-1,3,5-triazine
RFP	Request for Proposal
RI	Remedial Investigation
RI/FS	Remedial Investigation/Feasibility Study
RL	Reporting Limit
ROI	Region of Interest
RPD	Relative Percent Difference
RPM	Revolutions Per Minute
RRT	Relative Retention Time
RSD	Relative Standard Deviation
RSO	Radiation Safety Officer
RT	Retention Time
RTW	Retention Time Window
TNI	The NELAC Institute
SARA	Superfund Amendments and Reauthorization Act
SDWA	Safe Drinking Water Act
SMSD	Statistical Minimum Significant Difference
SOP	Standard Operating Procedure
SOW	Statement of Work
SPCC	System Performance Check Compound
SPLP, SLP	Synthetic Precipitation Leaching Procedure

TERM	**DEFINITION**
SVOC	Semivolatile Organic Compound
TAL	Target Analyte List
TCLP	Toxicity Characteristic Leaching Procedure
TCMX	Tetrachlorometaxylene
TCL	Target Compound List
TDS	Total Dissolved Solids
TIC	Tentatively Identified Compound
TLV	Threshold Limit Value
TNI	The NELAC Institute
TOC	Total Organic Carbon
TPH	Total petroleum hydrocarbon
TPU	Total Propagated Uncertainty
TRPH	Total Recoverable Petroleum Hydrocarbons
TSCA	Toxic Substances Control Act
TSDF	Treatment, Storage, and Disposal Facility
TSS	Total Suspended Solids
TVPH	Total Volatile Petroleum Hydrocarbons
USACE	United Stated Army Corp of Engineers
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
USGS	United States Geological Survey
UST	Underground Storage Tank
VOA	Volatile Organic Analysis
VOC	Volatile Organic Compound
WET	Waste Extraction Test
ZHE	Zero Headspace Extraction

14.3 SYMBOLS

LENGTH	DEFINITION	SYNOMYM
um	micrometer	10^{-6} meter
mm	millimeter	10^{-3} meter
cm	centimeter	0.01 meter
dm	decimeter	0.1 meter
m	meter	

WEIGHT	DEFINITION	SYNOMYM
pg	picogram	10^{-12} gram
ng	nanogram	10^{-9} gram
ug	microgram	10^{-6} gram
mg	milligram	10^{-3} gram
g	gram	
kg	kilogram	10^{3} gram

VOLUME	DEFINITION	SYNOMYM
uL	microliter	10^{-6} Liter
mL	milliliter	10^{-3} Liter
dL	deciliter	0.1 Liter
L	Liter	

CONCENTRATION	DEFINITION
ng/uL	nanograms per microliter
ug/L	micrograms per liter
ug/kg	microgram per kilogram
ug/g	microgram per gram
ug/mL	microgram per milliliter
mg/kg	milligram per kilogram
mg/L	milligram per liter
ug/m^3	microgram per cubic meter
ppb	part per billion
ppm	part per million

TIME	**DEFINITION**	**SYNOMYM**
s or sec	second	1/60 minute
m or min	minute	60 seconds, 1/60 h
h	hour	60 minutes

TEMPERATURE	**DEFINITION**
^{o}C	Degrees Celsius
^{o}F	Degrees Fahrenheit
^{o} K	Degrees Kelvin

ACTIVITY	**DEFINITION**	**SYNOMYM**
Bq	Bequerels	Disintegration/s
Ci	Curie	3.7×10^{10} Bq
dpm	Disintegrations per minute	

ELECTRICAL	**DEFINITION**
V	Volt
A	Ampere
EV	Electron Volt
F	Farad
Ω	Ohm
S or mho	Siemens
W	Watt

PREFIXES	**NUMERIC AMOUNT**
tera	10^{12}
giga	10^{9}
mega	10^{6}
kilo	10^{3}
hecto	10^{2}
deca	10
deci	0.1
centi	10^{-2}
milli	10^{-3}
micro	10^{-6}
nano	10^{-9}
pico	10^{-12}
femto	10^{-15}

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