Volume 1 Module 2: Quality Systems General requirements

1.0 INTRODUCTION, SCOPE, AND APPLICABILITY

1.1 Introduction

1.2 Scope DoD/DOE (Clarification)

The following is a clarification of TNI 1.2:

The Department of Defense (DoD) Environmental Data Quality Workgroup (EDQW) and the Department of Energy Consolidated Audit Program (DOECAP) Operations Team developed the DoD/DOE Quality Systems Manual (QSM). This manual provides baseline requirements for the establishment and management of quality systems for laboratories performing analytical testing services for the Department of Defense and the Department of Energy. Version 1.0 of the QSM is based on Volume 1 of The NELAC Institute (TNI) Standards (September 2009), which incorporates ISO/IEC 17025:2005(E), *General requirements for the competence of testing and calibration laboratories*. Conformance to the requirements contained in this manual is mandatory for any laboratory that is 1) seeking or maintaining accreditation in accordance with the DoD Environmental Laboratory Accreditation Program (ELAP) or 2) seeking or maintaining qualification in accordance with the DOECAP and DOE-related contract awards. Laboratories that comply with the requirements of this manual must also comply with the TNI standards and ISO/IEC 17025:2005(E).

This manual is presented in a new format, which is designed for use in conjunction with the TNI and ISO/IEC 17025:2005(E) standards. DoD/DOE specific language is presented as text and appendices in the order in which topics are addressed in the TNI standard. DoD/DOE text contains additional requirements, clarifications, and guidance to supplement the TNI and ISO/IEC language. Information that may be beneficial to a laboratory, but is not required, is marked as guidance. To the extent possible, DoD and DOE requirements have been consolidated. Text or appendices that are unique to either DoD or DOE are marked as such.

The DoD/DOE QSM is international in scope and applies to all laboratories regardless of size or complexity. Nothing in this document relieves any laboratory from complying with more stringent contract specifications, host-nation final governing standards, or Federal, State, Tribal, and local regulations.

To ensure that laboratories are capable of generating data that will meet project-specific requirements, the EDQW and the DOECAP Operations Team strongly encourages the involvement of project chemists and laboratories during project-planning activities.

2.0 NORMATIVE REFERENCES (*ISO/IEC 17025:2005(E), Clause 2)*

3.0 TERMS AND DEFINITIONS

3.1 Additional Terms and Definitions

The following are clarifications and additions to TNI 3.1:

Accreditation (DoD only Clarification): Refers to accreditation in accordance with the DoD ELAP.

Accreditation Body (DoD only Clarification): Entities recognized in accordance with the DoD ELAP that are required to operate in accordance with ISO/IEC 17011, *Conformity assessment: General requirements for accreditation bodies accrediting conformity assessment bodies*. The AB must be a signatory, in good standing, to an International Laboratory Accreditation Cooperation (ILAC) mutual recognition arrangement (MRA) that verifies, by evaluation and peer assessment, that its signatory members are in full compliance with ISO/IEC 17011 and that its accredited laboratories comply with ISO/IEC 17025.

Aliquot: A discrete, measured, representative portion of a sample taken for analysis.

Analysis: A combination of sample preparation and instrument determination.

Analyte: The specific chemicals or components for which a sample is analyzed; it may be a group of chemicals that belong to the same chemical family, and which are analyzed together.

Assessment (Clarification): Assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, peer review, inspection, or surveillance.

Blank (Clarification): Blank samples are negative control samples, which typically include field blank samples (e.g., trip blank, equipment (rinsate) blank, and temperature blank) and laboratory blank samples (e.g., method blank, reagent blank, instrument blank, calibration blank, and storage blank.)

Calibration Range: The range of values (concentrations) between the lowest and highest calibration standards of a multi-level calibration curve. For metals analysis with a single-point calibration, the low-level calibration check standard and the high standard establish the linear calibration range, which lies within the linear dynamic range.

Client: Any individual or organization for which products or services are furnished or work performed in response to defined requirements and expectations.

Confirmation (Clarification) – includes verification of the identity and quantity of the analyte being measured. Additional cleanup procedures alone are not considered confirmation techniques.

Consensus Standard: A standard established by a group representing a cross-section of a particular industry or trade, or a part thereof.

Continuing Calibration Verification: The verification of the initial calibration. Required prior to sample analysis and at periodic intervals. Continuing calibration verification applies to both external standard and internal standard calibration techniques, as well as to linear and non-linear calibration models.

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

Definitive Data: Analytical data of known quality, concentration, and level of uncertainty. The levels of quality and uncertainty of the analytical data are consistent with the requirements for the decision to be made. Data that is suitable for final decision-making.

Demonstration of Capability (Clarification): A procedure to establish the ability of the analyst to generate analytical results that meet measurement quality objectives (e.g., for precision and bias).

Detection Limit (DL): The smallest analyte concentration that can be demonstrated to be different from zero or a blank concentration at the 99% level of confidence. At the DL, the false positive rate (Type I error) is 1%. A DL may be used as the lowest concentration for reliably reporting a detection of a specific analyte in a specific matrix with a specific method at 99% confidence.

Digestion: A process in which a sample is treated (usually in conjunction with heat and acid) to convert the sample to a more easily measured form.

Environmental Data: Any measurements or information that describe environmental processes, locations, or conditions; ecological or health effects and consequences; or the performance of environmental technology.

False Negative: A result that fails to identify or detect an analyte at or below a certain level when the analyte is actually present.

False Positive: A result that erroneously identifies or detects an analyte at or above a certain level.

Finding (Clarification): An assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding may be positive or negative and is normally accompanied by specific examples of the observed condition. The finding must be linked to a specific requirement (e.g., this standard, ISO requirements, analytical methods, or contract specifications).

Holding Times (Clarification): The maximum time that may elapse from the time of sampling to the time of extraction or analysis, or from extraction to analysis, as appropriate.

Initial Calibration Verification (ICV): Analysis of a standard obtained or prepared from a source independent of the source of standards used for the initial calibration. It is used to check potential bias of the initial calibration standard. The ICV is sometimes called a Second Source standard.

Improper Actions: Intentional or unintentional deviations from contract-specified or method-specified analytical practices that have not been authorized by the client (i.e., DoD or DOE).

Limit of Detection (LOD) (Clarification): The smallest amount or concentration of a substance that must be present in a sample in order to be detected at a high level of confidence (99%). At the LOD, the false negative rate (Type II error) is 1%. A LOD may be used as the lowest concentration for reliably reporting a non-detect of a specific analyte in a specific matrix with a specific method at 99% confidence.

Limit of Quantitation (LOQ) (Clarification): The lowest concentration that produces a quantitative result within specified limits of precision and bias. For DoD/DOE projects, the LOQ shall be set at or above the concentration of the lowest initial calibration standard and within the calibration range.

Linear Dynamic Range: Concentration range where the instrument provides a linear response.

Measurement Performance Criteria (MPC): Criteria that may be general (such as completion of all tests) or specific (such as QC method acceptance limits) that are used by a project to judge whether a laboratory can perform a specified activity to the defined standard.

Measurement System (Clarification): A test method, as implemented at a particular laboratory and which includes the equipment used to perform the sample preparation, test, and the operator(s).

Measurement Uncertainty: An estimate of the error in a measurement often stated as a range of values that contain the true value, within a certain confidence level. The uncertainty generally includes many components which may be evaluated from experimental standard deviations based on repeated observations or by standard deviations evaluated from assumed probability distributions based on experience or other information. The term uncertainty is preferred over measurement error because the latter can never be known. For DoD/DOE, a laboratory's Analytical Uncertainty (such as an LCS) can be reported as the minimum uncertainty.

Operator Aid: A technical posting (such as poster, operating manual or notepad) that assists workers in performing routine tasks.

Preservation (Clarification): Any conditions under which a sample must be kept in order to maintain chemical, physical, and/or biological integrity prior to analysis.

Procedure (Clarification): This standard requires that all standard operating procedures be documented.

Qualitative Analysis: analysis designed to identify the components of a substance or mixture.

Quality System Matrix (Clarification): The matrix definitions in the TNI standard shall be used for purposes of batch and quality control requirements and may be different from a field of accreditation matrix.

Quantitation Range: The range of values (concentrations) in a calibration curve between the LOQ and the highest successfully analyzed initial calibration standard. The quantitation range

lies within the calibration range. In the case of single point calibration for metals, this does not apply.

Quantitative Analysis: analysis designed to determine the amounts or proportions of the components of a substance.

Reporting Limit: A client-specified lowest concentration value that meets project requirements for quantitative data with known precision and bias for a specific analyte in a specific matrix.

Signal to Noise Ratio (S/N): S/N is a measure of signal strength relative to background noise. The average strength of the noise of most measurements is constant and independent of the magnitude of the signal. Thus, as the quantity being measured (producing the signal) decreases in magnitude, S/N decreases and the effect of noise on the relative error of a measurement increases.

Storage Blank: A sample of analyte-free media prepared by the laboratory and retained in the sample storage area of the laboratory. Storage blank is used to document contamination attributable to sample storage at the laboratory.

Surrogate: A substance with properties that mimic the analyte of interest. It is unlikely to be found in environment samples and is added to them for quality control purposes.

Target analytes: Analytes of primary concern, identified by the client on a project-specific basis.

Test Method: A definitive procedure that produces a result. A test method can be considered a technical operation that determines one or more characteristics of a given product according to a procedure specific to that product.

Unethical (illegal) actions: Deliberate falsification of analytical or quality control results, where failed method or contractual requirements are made to appear acceptable.

Validation: The confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

3.2 Sources

3.3 Exclusions and Exceptions

4.0 MANAGEMENT REQUIREMENTS

4.1 Organization

4.1.5. j) DoD/DOE (Requirement)

The following shall be implemented in addition to ISO Clause 4.1.5 j)

At a minimum, the following laboratory management staff (however named) shall be considered key managerial personnel:

i) Management (e.g., President, Chief Executive Officer, Chief Operating Officer, Laboratory Director);
ii) Technical managers (e.g., Technical Director, Section Supervisors);
iii) Quality managers;
iv) Support systems and administrative managers (e.g., LIMS manager, purchasing manager, project managers); and
v) Client services managers.

4.1.7.1 DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 4.1.7.1 a) through h):

i) Implementing, maintaining, and improving the quality system by using available tools such as audit and surveillance results, control charts, proficiency testing results, data analysis, corrective and preventive actions, customer feedback, and management reviews in efforts to monitor trends;

4.2 Management

4.2.3. DoD/DOE (Requirement)

The following shall be implemented in addition to ISO Clause 4.2.3:

Top management shall be responsible for:

a) Defining the minimum qualifications, experience and skills necessary for all positions in the laboratory.

b) Ensuring that all technical laboratory staff have demonstrated capability in the activities for which they are responsible. Such demonstration shall be documented.

c) Ensuring that the training of each member of the technical staff is kept up-to-date (on-going) by the following:

i) Each employee training file must contain a certification that the employee has read, understands, and is using the latest version of the quality system documentation relating to his/her job responsibilities.
ii) Training courses or workshops on specific equipment, analytical techniques or laboratory procedures shall all be documented.
iii) Documentation of continued proficiency by at least one of the following once per year:

a. Acceptable performance of a blind sample (single blind to the analyst);
b. an initial measurement system evaluation or another demonstration of capability;

c. At least four consecutive laboratory control samples with acceptable levels of precision and accuracy. The laboratory must determine the acceptable levels of precision and accuracy prior to analysis; or

d. If i-iii cannot be performed, analysis of authentic samples with results statistically indistinguishable from those obtained by another trained analyst.

d) Documenting all analytical and operational activities of the laboratory;

e) Supervising all personnel employed by the laboratory;

f) Ensuring that all sample acceptance criteria are verified and that samples are logged into the sample tracking system and properly labeled and stored; and

g) Documenting the quality of all data reported by the laboratory.

4.2.8.1 DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 4.2.8.1

The laboratory shall have a documented program to detect and deter improper, unethical, or illegal actions. Data shall be produced according to the project-specific requirements as specified in the final, approved project-planning documents, such as the approved QAPP, when these documents are provided to the laboratory. Following are the minimum elements of an acceptable program for detecting and deterring improper, unethical, or illegal actions:

a) An ethics policy must be read and signed by all personnel;

b) Initial and annual ethics training must be conducted as described in Section 5.2.7;

c) Analysts must explain and sign off on all manual changes to data; and

d) Where available in the instrument software, all electronic tracking and audit functions must be enabled.

4.2.8.2 DoD/DOE (Clarification)

The following shall be implemented in addition to TNI 4.2.8.2:

The quality manager shall review the quality manual at least annually, and updated it if necessary.

4.2.8.4 DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 4.2.8.4 a) through r):

s) Procurement of standards;

t) Data management including validation, verification, retention, documentation and control of electronic data and data systems

u) Manual entry of raw data from analytical measurements that are not interfaced to LIMS and the verification and documentation of the accuracy of manually entered data;

v) Making changes to electronic data (including establishing the requirements for a hardcopy or electronic log to document all changes to electronic data that affect data quality);

w) How electronic data are processed, maintained, and reported by LIMS;

x) Ensuring that data review includes all quality-related steps in the analytical process, including sample preparation, dilution calculations, chromatography evaluation, and spectral interpretations. The SOP shall require that documentation of data review be maintained and available for review;

y) Health and Safety, (e.g., Chemical Hygiene Plan) **(DOE only)**;

z) Materials (Waste) Management **(DOE only)**; and

aa) A list of all current certifications and accreditations that the laboratory holds and the scope of certification or accreditation for each.

4.2.8.4. p) DoD/DOE (Clarification)

The following shall be implemented in addition to TNI 4.2.8.4. p):

The procedures for audits and data review shall specify which records must be included in the review. Internal data reviews shall consist of a tiered or sequential system of verification, consisting of at least three tiers, 100% review by the analyst, 100% verification review by a technically qualified supervisor or data review specialist, and a final administrative review.

The analyst and verification review must include at least the following procedures:

i) Determination of whether the results meet the laboratory-specific quality control criteria;
ii) Checks to determine consistency with project-specific measurement performance criteria (MPCs);
iii) Checks to ensure that the appropriate sample preparatory and analytical SOPs and methods were followed, and that chain-of-custody and holding time requirements were met;
iv) Checks to ensure that all calibration and quality control requirements were met; and
v) Checks for complete and accurate explanations of anomalous results, corrective action, and the use of data qualifiers in the case narrative.

The final administrative review shall verify that previous reviews were documented properly and that the data package is complete.

In addition, the quality manager or designee shall review a minimum of 10% of all data packages for technical completeness and accuracy. This review is part of the management review and does not need to be completed before the data package is issued to the client.

If electronic audit trail functions are available, they must be in use at all times, and associated data must be accessible. If the instrument does not have an audit trail, the laboratory must have procedures to document the integrity of the data.

4.2.8.5 DOD/DOE (Requirement)

The following shall be implemented in addition to TNI 4.2.8.5.a) thru f):

g) All technical SOPs (e.g., sample preparation, analytical procedures, sample storage, or sample receipt) shall be reviewed for accuracy and adequacy at least annually, and updated if necessary. All such reviews shall be documented and made available for assessment.

h) The laboratory shall develop, maintain, and implement procedures, however named, for Chemical Hygiene, Waste Management, and Radiation Protection **(DOE only)**.

4.2.8.5 DOD/DOE (Guidance)

The following is guidance to TNI 4.2.8.5.a) thru f):

Non-technical SOPs that are not required elements of the quality manual (e.g., personnel policies, timekeeping procedures, or payroll) are considered administrative SOPs and do not require an annual review.

4.2.8.5 f DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 4.2.8.5.f) i) thru xxiii):

xxiv) Equipment/instrument maintenance;

xxv) Computer hardware and software; and

xxvi) Troubleshooting

4.3 Document Control

4.3.2.2 DoD/DOE (Requirement)

The following shall be implemented in addition to ISO clause 4.3.2.2.a) through d):

e) Affected personnel are notified of changes to quality systems documents and supporting procedures, including technical documents;

f) Copies of all quality system documentation provided to DoD ELAP Accreditation Bodies, DOECAP Operations Teams, or to personnel on behalf of DoD/DOE shall be in English;

g) Reviews (internal or external) of quality system documentation shall be maintained and made available for assessment; and

h) Any documents providing instructions to laboratory personnel (e.g. operator aids) are considered part of the quality system and are subject to document control procedures.

4.4 Review of Requests, Tenders and Contracts

4.5 Subcontracting of Environmental Tests

4.5 DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 4.5.5:

4.5.6 Laboratories must ensure and document that subcontracted (sub-tier) laboratories meet the requirements of the DoD/DOE QSM.

4.5.7 Subcontracted laboratories performing analytical services in support of the Environmental Restoration projects must be accredited in accordance with the DoD ELAP. Subcontracted laboratories performing analytical services for the DOE must be approved by the appropriate DOE subcontractor representative.

4.5.8 Subcontracted laboratories must receive project-specific approval from the DoD or DOE client before any samples are analyzed.

4.5.9 These requirements also apply to the use of any laboratory under the same corporate umbrella, but at a different facility or location.

4.5.10 All subcontracted or outsourced quality systems elements (such as data review) or outsourced personnel must comply with the laboratory's overall quality system, must comply with the requirements of the QSM, and are subject to review/approval by the DoD/DOE client.

4.6 Purchasing Services and Supplies

4.6.1 DoD/DOE (Requirement)

The following shall be implemented in addition to ISO clause 4.6.1:

Records for services and supplies that may affect the quality of environmental tests must include the following, where applicable:

a) Date of receipt;

b) Expiration date;

c) Source;

d) Lot or serial number;

e) Calibration and verification records; and

f) Certifications.

(**Guidance**)

Examples of services and supplies that may affect the quality of environmental tests include, but are not limited to: balance calibration, solvents, standards, reagents, and sample containers.

4.7 Service to the Client

4.7.1 DoD/DOE (Clarification)

The following is a clarification of ISO clause 4.7.1:

Examples of situations for which immediate clarification or feedback shall be sought from the client include the following:

a) The client has specified incorrect, obsolete, or improper methods;

b) Methods require modifications to ensure achievement of project-specific objectives contained in planning documents (e.g., difficult matrix, poor performing analyte);

c) Project planning documents (e.g., Quality Assurance Project Plan (QAPP) or Sampling and Analysis Plan (SAP)) are missing or requirements in the documents (e.g., action levels, detection and quantification capabilities) require clarification; or

d) The laboratory has encountered problems with sampling or analysis that may impact results (e.g., improper preservation of sample).

4.8 Complaints

4.9 DoD/DOE (Requirement)

The following shall be implemented in addition to ISO clauses 4.9.1 and 4.9.2:

4.9.3 The laboratory shall immediately upon discovery and prior to implementation of corrective action, notify all affected clients of potential data quality issues resulting from nonconforming work. Notification shall be performed according to documented procedures. Documentation of corrective actions taken to resolve the nonconformance shall be submitted to the client(s) in a timely and responsive manner.

4.10 Improvement

4.11 Corrective Action

4.11 DoD/DOE (Requirement)

4.11.6

The following shall be implemented in addition to ISO clauses 4.11.1 thru 4.11.7:

4.11.8 The laboratory shall have and use a documented system for tracking corrective actions to completion and for analyzing trends to prevent the recurrence of the nonconformance. Approved corrective actions developed to address findings during DOECAP or DoD ELAP assessments must be implemented. Any changes to approved corrective action plans must be approved by the DOECAP Operations Team or the DoD ELAP Accreditation Bodies, as appropriate. Willful avoidance of approved corrective action implementation may result in DOECAP Priority I findings or loss of DoD ELAP accreditation. As a result, work may be discontinued until implementation is verified by the DOECAP Operations Team or DoD ELAP Accreditation Body, as appropriate.

4.12 Preventive Action

4.12.1 DoD/DOE (Clarification)

The following is a clarification of ISO clause 4.12.1

Documentation of preventive actions shall be maintained for review.

4.13 Control of Records

4.13.1.2 (Clarification)

The following is a clarification of ISO clause 4.13.1.2

Dual storage of records at separate locations is considered an acceptable option for the purpose of protecting records against fire, theft, or loss.

4.13.3 DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 4.13.3 g) i) and ii):

iii) Documentation for changes made to data (either hardcopy or electronic) shall include the identification of the person who authorized the change.

The following shall be implemented in addition to TNI 4.13.3:

4.13.4 The laboratory shall maintain a log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.

4.13.5 Permanent, bound laboratory notebooks (logbooks) or notebooks with measures in place to prevent the removal or addition of pages are required.

a) Laboratory notebook pages shall be pre-numbered, all entries shall be signed by the person responsible for performing the activity at the time the activity is performed, and all entries shall be recorded in chronological order;

b) All notebook pages must be closed when the activities documented are completed or carried over to another page. The person responsible for performing the closure shall be the one who performed the last activity documented. Closure shall occur at the end of the last activity documented on a page, as soon as practicable thereafter. Satisfactory documentation of closure includes analyst initials, date, and time.

c) Each laboratory notebook shall have a unique serial number clearly displayed.

4.13.6 The laboratory shall have procedures for the independent review of technical and quality records to ensure they are legible, accurate, and complete.

4.13.7 Laboratories must establish a review frequency for all records such as laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, verification, validation, and archival. Documentation of the reviews shall be maintained and made available for review.

4.13.8 If not self-explanatory, corrections to technical and quality records shall also include a justification for the change.

4.13.9 The records control system SOP shall address the requirements for access to and control of the files, including accountability for any records removed from storage.

4.13.10 Written approval must be received from all affected clients prior to disposal of any records associated with DoD/DOE analytical data. All SOPs shall be archived for historical reference, per regulatory or client requirements.

4.13.11 The laboratory shall have a system in place to record incidents involving spillage of chemicals or client samples.

4.14 Internal Audits

4.14 DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 4.14.5:

4.14.6 The audit schedule shall ensure that all areas of the laboratory are reviewed over the course of one year.

4.14.7 Audit personnel shall be trained and qualified in the specific quality system element or technical area under review. Laboratories shall determine the training and qualification requirements for audit personnel, including quality managers, and shall establish procedures to

ensure that audit personnel are trained and qualified (i.e., have the necessary education or experience required for their assigned positions). These requirements and procedures must be documented.

4.14.8 Management shall ensure that sufficient resources are available so that all internal audits shall be conducted by personnel independent of the activity to be audited. Personnel conducting independent assessments shall have sufficient authority, access to work areas, and organizational freedom necessary to observe all activities affecting quality and to report the results of such assessments to laboratory management.

4.15 Management Reviews

4.15.1 DoD/DOE (Clarification)

The following is a clarification of ISO clause 4.15.1.

Management reviews and internal audits are separate activities. The management review shall not be performed in lieu of an internal audit. It is an independent, executive review.

Management reviews shall also include laboratory health and safety, hazardous waste, and radioactive materials management functions, where applicable. **(DOE only)**

4.16 Data Integrity Investigations

5.0 TECHNICAL REQUIREMENTS

5.1 General

5.2 Personnel

5.2.3 DoD/DOE (Clarification)

The following is a clarification of ISO clause 5.2.3:

The laboratory shall ensure that all personnel, including part-time, temporary, contracted, and administrative personnel, are trained in the basic laboratory QA and health and safety programs.

5.2.4 DoD/DOE (Requirement)

The following shall be implemented in addition to ISO clause 5.2.4:

The job description elements itemized in the note following ISO clause 5.2.4 are minimum requirements.

5.2.7 Data Integrity Training DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 5.2.7:

Top management acknowledges its support of these procedures by 1) upholding the spirit and intent of the organization's data integrity procedures and 2) effectively implementing the specific requirements of the procedures.

The following practices are prohibited:

a) Fabrication, falsification, or misrepresentation of data.

   i) Creating data for an analysis that was not performed (dry lab).
   ii) Creating information for a sample that was not collected (dry lab).
   iii) Using external analysts, equipment, and/or laboratories to perform analyses when not allowed by contract.

b) Improper clock setting (time traveling) or improper date/time recording.

   i) Resetting the internal clock on an instrument to make it appear that a sample was analyzed with holding time when in fact it was not.
   ii) Changing the actual time or recording a false time for sample collection, extractions, or other steps to make it appear that holding times were met.

c) Unwarranted manipulation of samples, software, or analytical conditions.

   i) Unjustified dilution of samples.
   ii) Manipulating instrument set-up parameters to create the appearance that specific QC criteria have been met (e.g., GC/MS tuning data to produce an ion abundance result)
   iii) Changing the instrument conditions for sample analysis from the conditions used for standard analysis (e.g., changing electron multiplier voltage).
   iv) Unwarranted manipulation of computer software (e.g., forcing calibration or QC data to meet criteria, removing computer operational codes such as the "M" flag, inappropriately subtracting background, or improperly manipulating the chromatographic or spectrophotometric baseline).
   v) Turning off, or otherwise disabling, electronic instrument audit/tracking functions.

d) Misrepresenting or misreporting QC samples.

   i) Representing spiked samples as being digested or extracted when this was not performed.
   ii) Substituting previously generated runs for a non-compliant calibration or QC run to make it appear that an acceptable run was performed.
   iii) Failing to prepare or analyze method blanks and the laboratory control sample (LCS) in the same manner that samples were prepared or analyzed.
   iv) Tampering with QC samples and results, including special treatments for QC samples (e.g., running extra rinse blanks prior to QC samples), over-spiking,

and adding spike (e.g., matrix spike or surrogates) before or after sample extraction, transferring aqueous samples to extractors, or certain sample processing procedures such as pH adjustment of aqueous samples and drying soil samples.

v) Performing multiple calibrations or QC runs (including continuing calibration verifications (CCVs), LCSs, spikes, duplicates, and blanks) until one meets criteria, rather than taking needed corrective actions, and not documenting or retaining data for the other unacceptable data.

vi) Deleting or failing to record non-compliant QC data to conceal the fact that calibration or other QC analyses were non-compliant.

e) Improper calibration

i) Discarding mid-level points in the initial calibration to meet calibration criteria.

ii) Discarding points from a Detection Limit (DL) study to force the calculated DL to be lower than the actual value.

iii) Using the initial calibration that does not correspond to the actual run sequence to make continuing calibration data look acceptable when in fact is was not.

iv) Performing improper manual integrations, including peak shaving, peak enhancing, or baseline manipulation to meet QC criteria or to avoid corrective actions.

f) Concealing a known analytical or sample problem.

g) Concealing a known improper or unethical behavior or action.

h) Failing to report the occurrence of a prohibited practice or known improper or unethical act to the appropriate laboratory or contract representative, or to an appropriate government official.

5.3 Accommodations and Environmental Conditions

5.3.3 DoD/DOE (Requirement)

The following shall be implemented in addition to ISO clause 5.3.3:

a) When cross-contamination is a possibility, samples suspected of containing high concentrations of target analytes shall be isolated from other samples. Potentially high radiation samples must be segregated from other samples. Samples or extracts designated for volatile organics analysis must be segregated from other samples and extracts. Samples suspected of containing high concentrations of volatile organics shall be further isolated from other volatile organics samples.

b) A storage blank must be stored with all volatile organic samples, regardless of suspected concentration levels. Storage blanks shall be used to determine if cross-contamination may have occurred. Laboratories shall have documented procedures and criteria for evaluating storage blanks, appropriate to the types of samples being stored. The storage blanks shall be stored in the same manner as the client samples. The storage blanks shall be analyzed at a minimum, every 14 days. The data from the analysis of the storage blanks shall be available for review.

c) If contamination is discovered, the laboratory shall have a corrective action plan in place to identify and eliminate the source; determine which samples may have been impacted and implement measures to prevent recurrence.

5.3.5 DOE (Requirement)

The following shall be implemented in addition to ISO clause 5.3.5.

The laboratory shall have a safety inspection program in place that includes routine walk-downs of laboratory areas for safety-related concerns.

5.4.6 DoD/DOE (Requirement)

In addition:

a) In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid calculation of uncertainty of measurement. In these cases the laboratory shall attempt to identify all components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the results does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of method performance and previous experience. When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

b) In those cases where a well-recognized test method specifies limits to the values of the major source of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions.

c) The laboratory is only responsible for estimating the portion of measurement uncertainty that is under its control. As stated in Section 5.10.3.1.c, test reports shall include a statement of the estimated uncertainty of measurement only when required by client instruction. If a project requires measurement uncertainty to be reported, the laboratory shall report the estimated uncertainty based on project-specific procedures or, if not available, any other scientifically valid and documented procedures. The estimated measurement uncertainty can be expressed as a range (±) around the reported analytical results at a specified

confidence level. A laboratory may report the in-house, statistically-derived LCS control limits based on historical LCS recovery data as an estimate of the minimum laboratory contribution to measurement uncertainty at a 99% confidence level. For testing laboratories, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.

5.4.7.1 DoD/DOE (Requirement)

The following is implemented in addition to ISO clause 5.4.7.1:

The laboratory shall establish SOPs:

a) To ensure that the reported data are free from transcription and calculation errors;

b) To ensure that all quality control measures are reviewed, and evaluated before data are reported;

c) Address manual calculations; and

d) Address manual integrations.

When manual integrations are performed, raw data records shall include a complete audit trail for those manipulations (i.e., the chromatograms obtained before and after the manual integration must be retained to permit reconstruction of the results). This requirement applies to all analytical runs including calibration standards and QC samples. The person performing the manual integration must sign and date each chromatogram and document the rationale for performing manual integration (electronic signature is acceptable). Records for manual integrations may be maintained electronically as long as all requirements, including signature requirements, are met and the results can be historically reconstructed.

5.4.7.2. DoD/DOE (Requirement)

d) Individual user names and passwords are required for all LIMS users. LIMS passwords shall be changed on a regular basis, at a minimum of once per year.

e) Upon employment, laboratory employees shall have initial training in computer security awareness and shall have ongoing refresher training on annual basis. Documentation of the training shall be maintained and available for review.

f) Periodic inspections of the electronic operations shall be performed by the QA Manager to ensure the integrity of electronic data. The QA Manager shall maintain records of inspections and submit reports to laboratory management, noting any problems identified with electronic data processing stating the corrective actions taken.

g) The laboratory shall notify the client prior to major changes in software or hardware configuration of the electronic data management system.

h) Spreadsheets used for calculations shall be verified before initial use and following any changes to equations or formulas, including software revision upgrades, and documentation shall be readily available for review. Formula cells must be write-protected to minimize inadvertent changes to the formulas. Printouts from any spreadsheets shall include all information used to calculate the data.

i) The laboratory shall have SOPs for:

i) Software development methodologies that are based on the size and nature of the software being developed;
ii) Testing and QA methods to ensure that all software accurately performs its intended functions, including:

a. Acceptance criteria;
b. Tests to be used;
c. Personnel responsible for conducting the tests;
d. Documentation of test results;
e. Frequency of continuing verification of the software; and,
f. Test review and approvals.

iii) Software change control methods that include instructions for requesting, authorizing, requirements to be met by the software change, testing, QA, approving, implementing changes, and establishing priority of change requests.
iv) Software version control methods that document the software version currently used. Data sets are documented with the date and time of generation and/or the software version used to generate the data set; and'
v) Maintaining a historical file of software, software operating procedures, software changes, and software version numbers.
vi) Defining the acceptance criteria, testing, documentation, and approval required for changes to LIMS hardware and communication equipment.

j) Documents available in the laboratory to demonstrate the validity of laboratory-generated software include:

i) Software description and functional requirements;
ii) Listing of algorithms and formulas;
iii) Testing and QA documentation; and,
iv) Installation, operation and maintenance records.

k) LIMS Safeguards

i) Fire extinguishers designed to avoid damage to computer equipment must be available and mounted in visible, accessible areas.

l) Electronic Data Security

i) Individual user names and passwords have been implemented;
ii) Operating system privileges and file access safeguards are implemented to restrict the user of the LIMS data to users with unauthorized access;
iii) All LIMS Users are trained in computer awareness security on an annual basis;
iv) System events, such as log-on failures or break-in attempts are monitored;
v) The electronic data management system is protected from the introduction of computer viruses;
vi) System backups occur on a regular and published schedule and can be performed by more than one person within an organization;
vii) Testing of the system backups must be performed and documented to demonstrate that the backup systems contain all required data; and
viii) Physical access to the servers is limited by security measures such as locating the system within a secured facility or room, and/or utilizing cipher locks or key cards.

5.5 Calibration Requirements

5.5.5 DoD/DOE (Requirement)

The following shall be implemented in addition to ISO clause 5.5.5 a) through h):

i) Date placed in service

j) Condition when received (e.g., new, used, reconditioned); and

k) Operational status.

l) Instrument configuration and settings.

5.5.13.1 a) DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 5.5.13.1 a)

The laboratory shall have procedures for documenting catastrophic failure of support equipment (e.g., refrigerators, freezers) and addresses identification of affected samples and client notification.

5.5.13.1 d) DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 5.3.13.1 d)

These checks must be performed in the expected use range using a National Metrology Institute (MNI) such as NIST certified or traceable references where commercially available.

5.5.13.1 f) DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 5.5.13.1 a) through e):

f) The results of calibration and verification of support equipment must be within the specifications required of the application for which this equipment is used or the equipment must be removed from service until repaired. Calibration and verification records, including those of established correction factors must be maintained. In the absence of method-specific requirements, the minimum requirements are as follows:

Performance Check	Frequency	Acceptance Criteria
Balance calibration check using two traceable standard weights that bracket the expected weight	Daily prior to use	Top-loading balance: ±2% or ±0.02g, whichever is greater Analytical balance: ±0.1% or ±0.5 mg, whichever is greater
Verification of standard weight, using weights traceable to the International System of Units (SI) through a National Metrology Institute (MNI) such as NIST	Every 5 years	Certificate of Calibration from accredited calibration laboratory or NMI
Monitoring of refrigerator/freezer temperatures	Daily (i.e. 7 days per week) (MIN/MAX thermometers or data loggers equipped with notification of out of control event capabilities))	Refrigerators: 0˚C to 6˚C Freezers: ≤-10˚C
Thermometer calibration check, using a thermometer traceable to the SI through an NMI such as NIST, at two temperatures that bracket the target temperature(s) (if only a single temperature is used, at the temperature of use)	Liquid in glass: Before first use and annually Electronic: Before first use and quarterly;	Apply correction factors or replace thermometer
Volumetric labware	Class B: By lot before first use; Class A and B: Upon evidence of deterioration	Bias: Mean within ±2% of nominal volume Precision: RSD ≤1% of nominal volume (based on 10 replicate

		measurements)
Non-volumetric labware (Applicable only when used for measuring initial sample volume or final extract/digestate volume)	By lot before first use or upon deterioration	Bias: Mean within ±3% of nominal volume Precision: RSD ≤3% of nominal volume (based on 10 replicate measurements)
Mechanical volumetric pipette	By lot before first use, quarterly, and upon evidence of deterioration	Bias: Mean within ±2% of nominal volume Precision: RSD ≤1% of nominal volume (based on 10 replicate measurements) [Note: for variable volume pipettes, the nominal volume is the largest user-selectable volume setting]
Glass microliter syringe (volumes above 100uL)	Upon receipt or upon evidence of deterioration	Certificate of Calibration or replace if deterioration if evident
Drying oven temperature check	Daily prior to and after use	Within ±5% of set temperature
Water purification system	Daily prior to use	Per laboratory SOP
Radiological Survey Equipment	Daily prior to use the battery is checked , a background reading is taken, verification with a radiological source	Per laboratory's SOP

5.6 Measurement Traceability

5.6.4.2 a) DoD/DOE (Requirement)

The following is required in addition to 5.6.4.2 a)

Records for standards, reagents, and reference materials shall include lot numbers. Reagents and solvents shall be checked for purity prior to use and the supporting documentation of the checks shall be filed in a manner that is easily retrievable.

5.6.4.2 b) DoD/DOE (Requirement)

The following statement replaces the second sentence in TNI 5.6.4.2 b).

The laboratory must establish an expiration date when the manufacturer does not provide one.

5.6.4.2 d) DoD/DOE (Requirement)

The following shall be implemented in addition to 5.6.4.2 d).

The expiration date of the prepared standard shall not exceed the expiration date of the primary standard. All containers must bear a preparation date.

5.6.4.2 f) DoD/DOE (Requirement)

The following shall be implemented in addition to 5.6.4.2 f)

If a standard exceeds its expiration date and is not re-verified, the laboratory shall remove the standard or clearly designate is as acceptable for qualitative purposes only.

g) Standards and reference materials shall be stored separately from samples, extracts, and digestates and protected in a controlled cabinet or refrigerator.

5.7 Collection of Samples

5.7.1 DoD/DOE (Requirement)

The following shall be implemented in addition to ISO clause 5.7.1.

Sample handling procedures shall address laboratory practices for documenting the presence of extraneous materials (e.g., rocks, twigs, vegetation) present in samples in the case of heterogeneous materials. To avoid preparing non-representative samples, the laboratory shall not "target" a specific sample weight (i.e., the laboratory shall not manipulate the sample material so the sample aliquot weighs exactly 1.00g ± 0.01g). The handling of multiphase samples shall be addressed in specific sampling procedures, as appropriate. The laboratory's sampling procedures shall comply with recognized consensus standards (for example, ASTM standards or EPA's *Guidance for Obtaining Representative Laboratory Analytical Subsamples from Particulate Laboratory Samples* (EPA/600/R-03/027)) where available.

5.8 Handling Samples and Test Items

5.8.1 DoD/DOE (Requirement)

The following shall be implemented in addition to ISO clause 5.8.1.

Personnel dealing with sample receipt, radioactive waste management and materials shipping shall be trained in waste management, shipping (49 CFR 172) and handling, and radioactive material control.

5.8.3 DoD/DOE (Requirement)

The following shall be implemented in addition to ISO clause 5.8.3.

The laboratory must have a procedure addressing instances when it receives samples that require non-routine or additional sample preparation steps.

5.8.4 DoD/DOE (Requirement)

The following shall be implemented in addition to ISO clause 5.8.4:

a) The laboratory shall have SOPs in place to address the use of ventilation hoods or suitable containment for opening shipping containers, and radiation screening of samples, laboratory notification and labeling requirements for radioactive samples.

b) Shipping containers must be opened under a ventilation hood. All shipping containers from known radiological areas must be surveyed for radiological contamination on all external surfaces. The laboratory must develop and implement administrative policies for the receipt of radiological shipping containers and samples. Radiological surveys of sample shipping containers shall be performed as soon as possible from the time of receipt by the laboratory.

   Instrumentation and equipment used for monitoring shall be:

   i) Periodically maintained and calibration on an established frequency;
   ii) Appropriate for the type(s), levels, and energies of the radiation encountered;
   iii) Appropriate for existing environmental conditions; and
   iv) Routinely tested for operability (10 CFR 835.401(b)).

c) The laboratory shall have a system in place to record incidents involving spillage of reagents and client samples.

5.8.6 h) DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 5.8.6 a) through g):

h) The sample acceptance policy must also clearly outline the circumstances under which samples shall be accepted or rejected.

5.8.7.1 DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 5.8.7.1.

The temperature measurement shall be verified through the use of one or more temperature blanks for each transport container, if provided. If a temperature blank is not available, other temperature measurement procedures may be used.

Chemical preservation is matrix specific. The laboratory shall refer to the COC for the matrix definition. In the case where the matrix is not identified on the COC, the laboratory shall contact the client prior to proceeding.

Chemical preservation must be checked at the time of sample receipt for all samples, unless it is not technically acceptable to check preservation upon receipt (e.g., in the case of VOA samples. If any of the following conditions exist, chemical preservation must be rechecked in the laboratory:

a) Continued preservation of the sample is in question (e.g., the sample may not be compatible with the preservation); or

b) Deterioration of the preservation is suspected.

The laboratory shall have procedures in place that ensure that the appropriate laboratory personnel are notified when samples are received with short hold times or a short amount of hold time is remaining.

5.8.8 DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 5.8.8:

Legal/Evidentiary Custody

When the legal COC protocols is not provided by a State or federal program and legal custody is required to be maintained, the following protocols shall be incorporated.

Basic Requirements

The legal COC records shall establish an intact, continuous recorded of the physical possession, storage and disposal of sample containers, collected samples, sample aliquots, and sample extracts or digestates, collectively referred to below as “samples”. The COC records shall account for all time periods associated with the samples. For ease of discussion, the above-mentioned items shall be referred to as samples:

a) A sample is in someone’s custody if:

   i) It is in one’s actual physical possession;
   ii) It is in one’s view, after being in one’s physical possession;
   iii) It has been in one’s physical possession and then locked or sealed so that no one can tamper with it; and/or
   iv) It is kept in a secure area, restricted to authorized personnel only.

b) The COC records shall identify all individuals who physically handled individual samples.

c) In order to simplify record keeping, the number of people who physically handle the sample should be minimized. (guidance)

d) It is recommended that a designated sample custodian be appointed to be responsible for receiving, storing and distributing samples. (guidance)

e) The COC records are not limited to a single form or document; however, organizations should attempt to limit the number of documents that would be required to establish COC. (guidance)

f) Legal COC shall begin at the point established by the federal or State oversight program. This may begin at the point that cleaned sample containers are provided by the laboratory or the time sample collection occurs.

g) The COC forms shall remain with the samples during transport or shipment.

h) If shipping containers and/or individual sample containers are submitted with sample custody seals and any seals are not intact, the custodian shall note this on the COC.

i) Mailed packages should be registered with return receipt requested. If packages are sent by common carrier, receipts should be retained as part of the permanent COC documentation. (guidance)

j) Once received by the laboratory, laboratory personnel are responsible for the care and custody of the sample and must be to testify that the sample was in their possession and within view or secured in the laboratory at all times, form the moment it was received from the custodian until the time that the analyses are completed or the time of sample disposal.

Required Information in Custody Records

Tracking records shall be maintained until final disposition or return of samples to the client. Tracking records shall include, by direct entry or linkage to other records:

a) Time of day and calendar date of each transfer or handling;

b) Signatures of all personnel who physically handled the samples;

c) All information necessary to produce unequivocal, accurate records that document the laboratory activities associated with sample receipt, preparation, analysis and reporting; and

d) Common carrier documents.

5.8.9 c) DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 5.8.9 c):

Disposal of the physical sample shall occur only with the concurrence of the client who submitted the sample.

All conditions of disposal and all correspondence concerning the final disposition of the physical sample shall be recorded and retained.

Records shall indicate the date of disposal, the nature of disposal (such as sample depleted, sample disposed in hazardous waste facility, or sample returned to client), and the name of the individual who performed the task.

5.8.9 d) DoD/DOE (Requirement)

The following shall be implemented in addition to TNI 5.8.9 a) through c):

d) Access to all legal samples and subsamples shall be controlled and documented.

i) A clean, dry, isolated room, building, and/or refrigerated space that can be securely locked from the outside must be designated as a custody room.

ii) Where possible, distribution of samples to the analyst performing the analysis must be made by the custodian(s).

iii) The laboratory area must be maintained as a secured area, restricted to authorized personnel only.

iv) Once the sample analyses are completed, the unused portion of the sample, together with all identifying labels, must be returned to the custodian. The returned sample must be retained in the custody room until permission to dispose of the sample is received by the custodian or other authority.

e) Transfer of samples, subsamples, digestates or extracts to another party are subject to all of the requirements for legal COC.

5.9 Quality Assurance of Environmental Testing

5.9.1 DoD/DOE (Requirement)

The following shall be implemented in addition to ISO clause 5.9.1:

Quality control samples must be processed in the same manner as field samples. They must be analyzed and reported with their associated field samples.

5.10 Reporting the Results

5.10.2 b) DoD/DOE (Requirement)

The following shall be implemented in addition to ISO clause 5.10.2 b)

In addition, the name of a contact person and their phone number must also be included in the laboratory information.

5.10.2 l) DoD.DOE (Requirement)

The following shall be implemented in addition to ISO clause 5.10.2 a) through k)

l) Any failures identified;

m) Statement of whether results are reported on a dry weight or wet weight basis;

n) For Whole Effluent Toxicity, identification of the statistical method used to provide data; and

o) The date of issuance.

5.10.3.1. DoD/DOE (Requirement)

The following shall be implemented in addition to 5.10.3.1 a) through e):

f) Information on any non-standard conditions that may have affected the quality of the results, including the use and definitions of data qualifiers;

g) Where quality system requirements are met, a statement of compliance/noncompliance requirements and/or specifications, including identification of test results derived from any sample that did not meet sample acceptance requirements such as improper container, holding time, or temperature.

h) Laboratories must have a documented procedure for communicating with the client for the purpose of establishing project-specific data reporting requirements, including 1) conventions for reporting results below the LOQ and 2) specification for the use of data qualifiers. The basis for the use of all data qualifiers must be adequately explained in the test report.

DoD/DOE (Requirement) In the absence of project-specific requirements, the minimum standard data qualifiers to be used by laboratories are listed below:

U – Analyte was not detected and is reported as less than the LOD or as defined by the client. The LOD has been adjusted for any dilution or concentration of the sample (* see Example below).

J – The reported result is an estimated value (e.g., matrix interference was observed or the analyte was detected at a concentration outside the quantitation range.

B – Blank contamination. The recorded result is associated with a contaminated blank.

N – Non-target analyte. The analyte is a tentatively indentified compound using mass spectrometry.

Q – One or more quality control criteria failed (e.g., LCS recovery, surrogate spike recovery, or CCV recovery).

The laboratory may use additional data qualifiers, or different letters or symbols to denote the qualifiers listed above, as long as they are appropriately defined and their use is consistent with

project-specific requirements (e.g., this document, the contract, and project-planning documents).

[Note: These data qualifiers are for laboratory use only. Data usability must be determined by the project team.]

(DoD ONLY Guidance) *Example: Detection Limit (DL) = 2, Limit of Detection (LOD) = 4, Limit of Quantitation (LOQ) = 15, sample is undiluted.

Sample #1: Analytical Result: Not detected; Reported result: 4U

Sample #2: Analytical Result: 2; Reported result: 2J

Sample #3: Analytical Result: 10; Reported result: 10J

Sample #4: Analytical Result: 15; Reported result: 15

5.10.5 DoD/DOE (Requirement)

When included, opinions and interpretations shall be contained only in the case narrative.

5.10.6 DoD/DOE (Requirement)

The laboratory shall make a copy of the subcontractor's report available to the client when requested by the client.

5.10.11 a) DoD/DOE (Requirement)

The date and time of sample collection, preparation and analysis are required to be included as part of the laboratory report, regardless of the length of holding time. If the time of the sample collection is not provided, the laboratory must assume the most conservative time of day. For the purpose of batch processing, the start and stop dates and times of the batch preparation shall be recorded.

5.10.11 d) DoD/DOE (Requirement)

The following shall be implemented in addition to 5.10.11 a) through d):

e) Values reported outside the quantitation range must be qualified.

6.0 Hazardous and Radioactive Materials Management and Health and Safety Practices (DOE Only Requirement)

DOE is concerned with ensuring that analytical laboratories handling samples and analysis-derived waste conduct these operations in a manner that is protective of human health and the environment. DOE frequently sends samples with hazardous and/or radioactive constituents that require special handling to avoid worker, public, and environmental vulnerabilities and risks. The emphasis of DOE on general safety in the workplace is paramount. DOE chooses to use

only those analytical laboratories that can demonstrate management controls and good health and safety practices.

All DOE sites submitting environmental and waste samples to environmental laboratories shall disclose known or suspected hazards associated with the samples. Based on a good faith effort based on available process knowledge or other information, hazards (radiological, toxicity, or biological) shall be provided to the receiving laboratories prior to shipment of the samples unless prior arrangements have been made regarding sample receipt. Laboratories shall determine their ability to receive the samples. Laboratories shall have the appropriate capabilities, procedures, licenses to receive samples from a DOE site. After receipt of any samples, the laboratories shall assume the responsibility and liability for the safe and compliant management of all samples, including regulatory storage and disposal of all samples and associated derived wastes. Some DOE sites permit the return of sample residuals and prior arrangements must be established prior to the receipt of samples. In most cases, derived wastes must be disposed by the laboratory.

6.1 Radioactive Materials Management and Control

6.1.1 The laboratory shall comply with all applicable federal and state regulations governing radioactive materials control and radiological protection.

6.1.2 The radioactive materials license shall authorize possession of isotopes, quantity, physical form and use of radioactive material sufficient for the laboratory's scope of work in support of DOE sites.

6.1.3 The laboratory shall have facilities and current procedures in place to handle the isotopes, quantity and physical form of radioactive material specified on the radioactive material license. The laboratory shall ensure adherence to all radioactive materials license and procedural requirements.

6.1.4 The Radiation Safety Officer (RSO) listed in the Radioactive Materials License shall be available to monitor the radioactive materials and control programs and provide rapid response to any radiological emergencies. The laboratory shall have an alternate or backup RSO that shall have the necessary training and experience to perform the duties of the RSO in the event that the RSO is not available.

6.1.5 The laboratory shall have in place a radioactive materials inventory program capable of tracking standards, tracers and all radiological samples. The radioactive material inventory shall be updated according to the schedule established by laboratory Radioactive Material License. If no schedule is established by the license, then the laboratory shall update the inventory within seven days of receipt of radioactive materials.

6.1.6 Radioactive and mixed wastes shall be segregated from non-radioactive waste.

6.2 TSCA Material

6.2.1 The laboratory shall comply with all federal regulations governing TSCA materials control and protection.

6.2.2 The laboratory shall segregate all radioactive TSCA materials from all other analytical samples and residues.

6.2.3 The laboratory shall have a procedure for return of radioactive TSCA materials for which there is no commercial treatment or disposal options to the DoD/DOE client**.**

6.3 Laboratory Safety and Health

6.3.1 The laboratory shall comply with all state and federal regulations governing laboratory health and safety.

6.3.2 A laboratory safety inspection program is in place that includes routine walk-downs of laboratory areas for safety related concerns.

6.3.3 Chemical hazards labeling on chemical containers is in accordance with the laboratory's approved Chemical Hygiene Plan.

6.3.4 On an annual frequency, all visitors, maintenance personnel and auditors shall have a documented safety orientation prior to entering the laboratory. All visitors shall be briefed on the safety practices and policies.

6.3.5 The laboratory shall have a Hazardous Waste Operator and Emergency Response (HAZWOPER) trained person on staff. Backup personnel with appropriate training for the Emergency Response (HAZWOPER) trained personnel shall be required.

6.3.6 The laboratory shall have reentry procedures defined in the Emergency Action Plan.

6.4 Waste Management and Disposal

6.4.1 The laboratory shall comply with all federal and state regulations governing waste management and disposal.

6.4.2 The laboratory shall have a waste management plan in place which is capable of:

a) Identifying all waste streams generated by the laboratory including universal wastes such as batteries, thermostats, etc.;

b) Identifying the process for managing and disposition of the various waste streams; and

c) Tracking the disposition of waste samples by Sample Delivery Group (SDG).

6.4.3 The waste management plan shall include (but not limited to) the following:

a) Administrative programs to demonstrate compliance for effluent discharges as required by regulatory agencies and applicable DOE Orders;

b) Training procedures, schedules and management of training records in the areas of waste management, shipping, waste handling and radioactive materials control;

c) Radioactive volumetric and surface release policies;

d) Permits and licenses to handle hazardous and radioactive waste;

e) Policy or direction on how to conduct waste brokering and Transport, Storage, and Disposal Facility (TSDF) evaluation to ensure proper disposition of waste;

f) Tracking of individual sample container from receipt to final disposition; and

g) Waste minimization and pollution prevention programs including substitution (when permitted), segregation, recycling, etc.

Waste brokering and TSDF evaluation shall be based upon the results of a site visit to the waste facility or a desktop review that includes information from audits of the facilities conducted by state or federal agencies. The evaluation shall include liability coverage, financial stability, any notices of violations from the last three years, relevant permits, and licenses to accept the waste, and other relevant information. Reviews of waste brokering and TSDF evaluation shall be performed every three years, unless there are changes in the facilities operations that require the reviews to be conducted on a more frequent basis (NOVs, change of ownership, notices of fines and penalties, etc.).

6.4.4 The laboratory shall remove or deface all samples container labels prior to container disposal such that they are rendered illegible.

6.4.5 Analytical process waste is segregated and removed to a designated storage area to minimize the potential for cross contamination.

6.4.6 Laboratory analysis derived waste characterization is repeated at a frequency adequate to account for all known variation in the waste streams.

6.4.7 Samples that are consumed during analysis must be included in the sample accountability tracking.

6.4.8 The laboratory shall have provisions for the disposition of excess samples.

6.4.9 For excess samples that are bulked and drain disposed, the laboratory is aware of the requirements for the receiving POTW or wastewater treatment system and has a program that meets and demonstrates compliance with these requirements.