

Hanford Analytical Services Quality Assurance Requirements Document

Volume 1: Administrative Requirements

Prepared for the U.S. Department of Energy
Assistant Secretary for Environmental Management



P.O. Box 550
Richland, Washington 99352

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HASQARD Section	Subject of Section
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LIST OF TERMS

ANSI	American National Standards Institute
CFR	Code of Federal Regulations
DOE	U.S. Department of Energy
DQO	Data Quality Objective
EM	Environmental Restoration and Waste Management
EPA	U.S. Environmental Protection Agency
HASQARD	Hanford Analytical Services Quality Assurance Requirements Document
LIMS	Laboratory Information Management System
QA	Quality Assurance
QC	Quality Control
R&D	Research and Development
RCRA	Resource Conservation and Recovery Act of 1976
SOP	Standard Operating Procedure
SQA	Software Quality Assurance
TPA	Hanford Federal Facility Agreement and Consent Order (Tri-Party Agreement)
V&V	Verification and Validation

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1.0 INTRODUCTION

The Hanford Analytical Services Quality Assurance Requirements Document (HASQARD), Volumes 1 through 4, is issued by the U.S. Department of Energy (DOE) Richland Operations Office and Office of River Protection. The HASQARD establishes quality requirements in response to DOE Order 414.1C or 414.1D, “Quality Assurance” (as applicable). The HASQARD satisfies the requirements from the *Hanford Federal Facility Agreement and Consent Order* (Tri-Party Agreement [TPA]) Article XXXI and the TPA Action Plan, Sections 6.5 and 7.8. The HASQARD is designed to meet the needs of the Hanford Site for maintaining a consistent level of quality for sampling and for field and laboratory analytical services provided by contractor and commercial field and laboratory analytical operations.

The HASQARD serves as the quality basis for all sampling and field/laboratory analytical services provided to support the Hanford Site environmental clean-up mission. This includes services performed by contractors, subcontractors, and/or commercial laboratories and covers both radiological and non-radiological analyses. The HASQARD also applies to field sampling, field analytical, and research and development (R&D) activities that support work conducted under the TPA and regulatory permit applications, and applicable permit requirements to the extent described in Section 1.1.1 of this volume. HASQARD applies to work done to support process chemistry analysis (e.g., on-going site waste treatment and characterization operations) and R&D projects related to the Hanford Site environmental clean-up mission. This ensures a uniform umbrella of quality to analytical site activities predicated on the concepts contained in the HASQARD. The use of the HASQARD will ensure data of known quality and technical defensibility of the methods used to obtain that data.

The HASQARD is made up of four volumes: Volume 1, Administrative Requirements; Volume 2, Sampling Technical Requirements; Volume 3, Field Analytical Technical Requirements; and Volume 4, Laboratory Technical Requirements. Volume 1 describes the administrative requirements applicable to each of the other three volumes and is intended to be used in conjunction with the technical volumes (e.g., Volumes 1 and 2 describe the requirements for sample collection and handling, Volumes 1 and 3 describe the requirements for field analytical activities, and Volumes 1 and 4 describe the requirements for laboratory analytical activities).

1.1 SCOPE

HASQARD is based on professional and regulatory quality assurance (QA) principles and practices that cover environmental sampling and field/laboratory analytical chemistry activities. Some requirements for sample collection design and the field and laboratory analyses detailed in Volumes 2, 3, and 4 were drawn from:

- The U.S. Environmental Protection Agency (EPA), EPA/240/B-01/003, *EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5*, provides the basis for quality requirements for planning, implementation, and assessment of data collection operations.

- The American National Standards Institute (ANSI) N42.23-1996, *American National Standard Measurement and Associated Instrumentation Quality Assurance for Radioassay Laboratories*, is the primary source for the radiochemical QA/quality control (QA/QC).
- EPA 402-B-04-001A – C (Volumes I – III), *Multi-Agency Radiological Laboratory Analytical Protocols Manual (Final)*, is a recommended guidance document to be used as a reference to improve radiological measurements.
- EPA SW-846, *Test Methods for Evaluating Solid Wastes, Physical and Chemical Methods*, and the statements of work for the EPA Contract Laboratory Program for organic and inorganic analysis are the models for organic and inorganic analytical QA/QC.

The HASQARD specifies the quality principles, practices, and procedures for sampling and the analytical service provider's QA documents covering regulatory analysis (e.g., TPA, permits, process chemistry, and R&D efforts related to Hanford Site clean-up activities).

The QA plans and/or QA manuals of the affected organizations or subcontractors shall implement the requirements specified in the HASQARD.

The HASQARD provides the following:

- A basis for sampling and for field and laboratory analytical services to meet professional standards of QA/QC, and the regulatory requirements of the TPA and site permits (see Sections 1.1.1 and 1.1.2 of this volume).
- A flexible framework for meeting the client's special QC criteria based on project needs, as determined by the data quality objective (DQO) planning process.
- A basis for site contractor and commercial QA documents and for sampling and analytical service contracts.
- A uniform set of criteria and standards by which sampling and analysis performance can be compared and assessed.
- A cost effective/project-specific QA/QC structure that maintains data quality and method technical defensibility, while allowing efficient field/laboratory management and operation of sampling and analysis services.
- Data of known quality to sampling and analysis customers from which they can make decisions to facilitate the Hanford Site environmental clean-up objectives.

1.1.1 Activities Within the Scope of HASQARD

HASQARD is designed to support sampling and analytical services related to Hanford Site clean-up activities. This provides an unbroken chain of data quality over the variety of activities currently supporting the Hanford Site environmental clean-up mission. All work including

initial R&D investigations (after exploratory research has been completed), permitting, waste characterization and treatment, and clean site closure and long-term monitoring, will have a measurable level of quality for data usage and technical defensibility. This ensures the integrity of the Hanford Site environmental sampling and analysis database over time and facilitates the use of R&D and process chemistry knowledge in support of project decisions. For those techniques not specifically identified, HASQARD should be applied in conjunction with client agreement on method and QC requirements.

Subject to exceptions and limitations described below, sample collection and analysis shall be in compliance with this document when in support of the following:

- Dangerous or mixed waste permitting, closure, and post-closure activities, including baseline characterization, clean-up operations, clean closure determinations, and long-term site monitoring
- Dangerous or mixed waste treatment, storage, and disposal units, including waste characterization, and inlet and outlet waste stream analysis
- Remedial and corrective action activities
- R&D efforts supporting any of the above
- Waste remediation activities
- Environmental Monitoring.

In the area of R&D, HASQARD applies after exploratory research has been completed. After the new methodology or technology has been identified as useful for providing data related to the efforts described in Section 1.1.1, further method development and testing is required to comply with HASQARD (see Section 4.0). All sections of HASQARD are applicable to the work.

Questions regarding the application of specific requirements from HASQARD in field/laboratory operations should be directed to the appropriate field/laboratory QA representative or technical supervisor for assistance. Further assistance is available from DOE.

Additionally, sampling and analytical services can be performed under regulatory requirements other than the *Resource Conservation and Recovery Act of 1976 (RCRA)* or the *Comprehensive Environmental Response, Compensation, and Liability Act of 1980*. Sample collection and analysis supporting other regulatory programs may have QC requirements different than HASQARD that apply to methodologies not specified in HASQARD at this time. These other programs include but are not limited to the following:

- Clean Air Act
- Clean Water Act
- Safe Drinking Water Act

- Occupational Safety and Health Act, including clinical analyses
- Washington State Waste Discharge Permit Program (WAC 173-216).
- National Pollutant Discharge Elimination System
- Model Toxics Control Act Cleanup Regulations (WAC 173-340)
- Dangerous Waste Regulations (WAC 173-303)

Where a Hanford Site activity requires using a specific regulatory method, and the regulatory method is in conflict with HASQARD, the calibration and QC requirements in the regulatory method shall take precedence over Sections 4.0 and 6.0 in Volume 4 of HASQARD. All other sections of HASQARD would apply.

1.1.2 Activities Outside the Scope of HASQARD

The HASQARD does *not* cover sample analysis in support of the following:

- U.S. Department of Defense samples
- Hanford Radiation Control Program
- Industrial Hygiene Program
- Airborne radioactive emissions monitored under 40 CFR 61, “National Emission Standards for Hazardous Air Pollutants,” Subpart H, “National Emission Standards for Emissions of Radionuclides Other Than Radon From Department of Energy Facilities,” and WAC 246-247, “Radiation Protection—Air Emissions.”
- Exploratory research.

Exploratory research is any and all activities undertaken to investigate or study by testing and experimentation. The very nature of exploratory research leaves researchers and scientists with the latitude to use their professional judgment in the exploratory process. The exploratory research process is not constrained or limited by pre-determined QA/QC requirements. The culmination of exploratory research efforts often leads to the development of new methods, sensors, equipment, and other products. The products of the exploratory research process require qualification if used to support analytical work within the scope of HASQARD. Data generated as part of the exploratory research process, where HASQARD requirements were not followed, cannot be used for regulatory decision-making purposes.

1.2 HASQARD REVISIONS

Changes in QA/QC practices, applicable and/or appropriate environmental statutes, agreements, and DOE Orders will be reflected in revisions of this document. Comments and requests for clarification in the HASQARD are welcomed. These comments and requests enable the HASQARD to be a living, evolving document that mirrors the sampling and analysis activities of the Hanford Site.

A consensus approach will be used by the HASQARD focus group to evaluate comments. Comments will be routed to the HASQARD focus group two weeks in advance of the meeting at which the item is scheduled to be discussed. The commenter will be invited to attend the HASQARD focus group meeting to state their reasoning and participate in the resolution of the comment. The comment will be discussed regardless of the presence or absence of the commenter. The HASQARD focus group will then decide by general consensus if the comment results in changes that should be incorporated into the documents.

To support their request for HASQARD modification, commenters are encouraged to supply supporting data that defines the impacts that HASQARD requirements may have had on organizations or clients.

Meeting minutes will be distributed to the HASQARD focus group members and involved commenters. If technical changes are required in the document, the affected pages will be updated and sent to the copy holders of controlled manuals. Editorial changes will be incorporated with the next technical change to the document.

1.3 HASQARD AND QUALITY SYSTEM FOR ANALYTICAL SERVICES

Efforts to prepare Revision 4 of the HASQARD included an analysis to compare the HASQARD to the DOE *Quality System for Analytical Services*, Revision 2.6. The requirements from the DOE *Quality System for Analytical Services* that were not already in the HASQARD and were by consensus judged to be relevant, applicable, and provide added value to the HASQARD and the Hanford cleanup mission, were adopted into the HASQARD.

1.4 DATA QUALITY OBJECTIVE PROCESS

The DQO process is a strategic planning approach based on the scientific method to prepare for a data collection activity.

1.4.1 Overview of the Data Quality Objective Process

The DQO process provides a systematic procedure for defining the criteria that a data collection design should satisfy, including how many samples to collect, when and where to collect the samples, the tolerable level of decision error for the study, and balancing risk and cost in an acceptable manner.

Using the DQO process should ensure that the type, quantity, and quality of environmental data used in decision making will be appropriate for the intended application, resulting in environmental decisions that are technically and scientifically sound and legally defensible. In addition, the DQO process will guard against committing resources for data collection efforts that do not support a defensible decision or for unnecessary remediation.

The client must use the DQO planning process as the preliminary step in the development of all sampling and analysis activities, which may lead to significant environmental decisions (DOE/EM-0158P, *Sampling Quality Assurance Guidance in Support of EM Environmental*

Sampling and Analysis Activities, and EPA QA/G-4, current version, *Guidance for the Data Quality Objectives Process*. The client works with the appropriate regulator or other affected stakeholders to establish the required quality criteria to obtain approval where compliance is mandated. The client and the laboratory must then agree on the analytical approach to implement the unique quality requirements.

Appendix B of this document (Volume 1) provides the key elements for each of the seven steps of the DQO process, which must be addressed when conducting the DQO process and must also be documented.

1.4.2 Data Quality Objective Process Steps

The DQO process includes seven steps, which are briefly described below. Projects must address and document each of these seven steps. Appendix B provides further information on the seven steps of the DQO process.

- **Step 1 – State the problem:** Concisely describe the problem to be studied. Review prior studies and existing information, and create the conceptual site model to gain a sufficient understanding to define the problem.
- **Step 2 – Identify the decision:** Identify what questions the study will attempt to resolve and what actions may result.
- **Step 3 – Identify the inputs to the decision:** Identify the information that needs to be obtained and the measurements that need to be taken to resolve the decision statement.
- **Step 4 – Define the study boundaries:** Specify the population of interest, time periods, and spatial area to which decisions will apply. Determine when and where data should be collected.
- **Step 5 – Develop a decision rule:** Define the population parameter of interest, specify the action level, and integrate the previous DQO outputs into a single statement that describes the logical basis for choosing among alternative actions.
- **Step 6 – Specify tolerable limits on decision errors:** Define the decision-maker's tolerable decision error rates based on a consideration of the consequences of making an incorrect decision.
- **Step 7 – Optimize the design:** Evaluate information from the previous steps and generate alternative data collection designs. Choose the most resource-effective design that meets all DQOs.

2.0 ORGANIZATION AND RESPONSIBILITY

The organizational structure shall be documented, the lines of management authority shall be identified, and the areas of individual responsibilities shall be delineated.

2.1 MANAGEMENT POLICY

Management shall have documented policies that address and direct the implementation of safety and quality standards. These policies shall address the overall objectives and assign responsibilities (e.g., stop work authority) and the organizational independence for those personnel assigned to safety and quality oversight. Each field/laboratory's QA plan and/or documentation shall define its policy regarding commitment to ethical standards, client confidentiality, and quality performance in field/laboratory operations

2.2 STRUCTURE, RESPONSIBILITY, AND AUTHORITY

The QA plan shall describe the organizational structure, functional responsibilities, and levels of authority for those managing, performing, and assessing activities affecting quality. The QA plan shall be based on the following principles:

- Senior management shall be responsible for establishing the scope of the QA plan and implementing, assessing, and continually improving an effective quality system.
- Line management shall be responsible for achieving quality in specific activities.
- A designated individual shall be responsible for developing, implementing, and routinely monitoring the QA program.
- All personnel (e.g., samplers, field analysts, laboratory technicians, scientists, researchers, principal investigators, operators, craftspeople, clerical/support staff, and internal auditors) shall retain responsibility for the quality of their work.

2.2.1 Organizational Structure

The organizational structure and responsibilities assigned shall ensure the following:

- Quality is achieved and maintained by those assigned responsibility for performing the work.
- Quality achievement (defined as conformance to specification and control criteria) is verified by people not directly responsible for performing the work.

The organizational responsibilities shall reflect an integration of the technical, administrative, and quality functions. This integration ensures that the quality elements are an integral part of day-to-day operations.

Regulatory actions toward the organization or its parent corporation shall be reported immediately to cognizant management. This includes actions such as suspension of contracts with other Federal agencies, notices of investigations, and legal actions against the organization or its personnel.

2.2.2 Functional Responsibilities

Functional responsibilities shall include the following activities as a minimum:

- Participating with the client for planning and developing analytical work scope
- Training and personnel development
- Preparing, reviewing, approving, and issuing instructions, procedures, schedules, and procurement documents
- Identifying and controlling hardware and software
- Managing and operating facilities
- Calibrating and controlling the equipment used to measure and test
- Conducting investigations and improving methods
- Acquiring, evaluating, and reporting data
- Performing maintenance, repair, and improvements
- Controlling records.

2.2.3 Levels of Authority

Personnel designated as having QA and/or QC responsibility shall have their authority documented and be placed organizationally independent of those performing the tasks monitored. Such QA and/or QC positions will have direct access to the level of management where appropriate action can be effected (e.g., manager or director). The QA program shall identify all positions given the responsibility and authority to do the following:

- Stop unsatisfactory work. The plan shall identify the chain of command through which any employee may initiate a stop-work order where detrimental ethical, contractual, quality, safety, or health conditions exist.
- Initiate action to prevent reporting results from a measurement system that is out of control or suspect.
- Prevent further reporting of measurements until corrective action has been completed.

- Identify any method or procedure that poses quality problems.
- Recommend, initiate, or provide solutions through designated channels, and monitor effectiveness of the corrective actions.

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3.0 PERSONNEL QUALIFICATION AND TRAINING

A fundamental requirement for effective accomplishment of any mission is that all personnel be capable of performing their assigned tasks. Qualification and training programs ensure that the required capabilities are achieved and maintained by personnel.

The organization shall have a documented training program that details the processes for identifying statutory, regulatory, or professional certifications that may be required to perform certain operations. In addition, the training program described in the QA plan shall describe the processes for identifying, designing, performing, and documenting technical, quality, and project management training, as applicable.

This training program shall include initial and continuing training and qualifications, and shall be subject to an ongoing review by management to assess its effectiveness.

3.1 QUALIFICATION

The need to require formal qualification or certification of personnel performing certain specialized activities shall be evaluated and implemented where necessary.

The organization shall describe any specific qualifications or certifications necessary for personnel performing specialized activities, and describe the method for evaluating and documenting these qualifications.

3.2 TRAINING

3.2.1 Initial Training

Appropriate technical and management training, which may include classroom and on-the-job training, shall be performed and documented.

Management shall describe the initial training requirements for each job category within the organization.

3.2.2 Continuing Training

Personnel shall be provided continuing training to ensure that job proficiency is maintained. When job requirements change, the need for retraining to ensure continued satisfactory job proficiency shall be evaluated.

The organization shall describe the continuing training that is provided, to ensure the maintenance of job proficiency and the methods by which satisfactory job proficiency is evaluated.

3.3 TRAINING RECORDS

Objective evidence of personnel job proficiency shall be documented and maintained.

The QA plan shall describe the type of training records that shall be maintained to document job proficiency, initial and continuing training, and the retention period for training records. Personnel qualifications, experience, and training records shall be maintained.

4.0 PROCEDURES

A well-developed procedure is necessary to use a method effectively and with consistency. Applying a well-developed procedure can provide continuity of measurement performance over time and across multiple analysts. A reasonable minimum frequency for reviewing, updating, and re-distributing current revisions of controlled documents and procedures (e.g., standard operating procedures [SOPs]) shall be established. Deviations from established procedures, processes, or methods must be by an approved and documented process.

4.1 GENERAL FIELD AND LABORATORY OPERATIONS

Field and laboratory activities shall be conducted using techniques appropriate for the identified purpose. Field and laboratory activities shall be directed and controlled by internally approved procedures/documents. Procedures shall contain sufficient information to perform the task and shall be readily available to the user. Controls shall be in place to ensure only the most recently approved version of a procedure is used.

Administrative activities supporting field or laboratory activities shall be directed by approved procedures/documents to help ensure adequate program control. HASQARD recognizes that if a consensus standard or standard method is written in a way that it can be used as published by the operating staff in a laboratory, it does not need to be rewritten as an internal procedure. However, it requires the same procedural approval process as normally implemented in the laboratory.

4.1.1 Administrative Procedures

Administrative activities shall be covered by procedures or other implementing documents that include, but are not be limited to, the following:

- Personnel qualification and training
- Procedure preparation
- Document control
- Records control, including data security and confidentiality
- Software systems QA
- Procurement controls
- Materials management
- Assessment program
- Corrective action and quality improvement
- QA reporting.

4.1.2 Field Sampling and Operations Procedures

As appropriate, sampling or field operations shall be covered by procedures or other implementing documents that include, but are not be limited to, the following:

- Sample collection
- Sample identification
- Chain-of-custody
- Sample preservation
- Sample packaging and shipping
- Sample tracking
- Field notebooks/logbooks
- Environmental, safety, and health activities
- Waste minimization and disposition.
- Equipment calibration and maintenance
- Quality Control.

4.1.3 Field and Laboratory Analysis and Operations Procedures

As appropriate, field and laboratory activities shall be covered by procedures or other implementing documents that include, but are not be limited to, the following:

- Environmental, safety, and health activities
- Sample shipping and receipt
- Chain-of-custody
- Sample storage
- Sample preparation
- Sample analysis
- Notebooks/logbooks
- Standard preparation and handling
- Post-analysis sample handling
- Control of standards, reagents, and water quality
- Cleaning of glassware
- Waste minimization and disposition.
- Equipment calibration and maintenance
- Quality Control
- Data Reduction, Review and Reporting.

4.2 ADMINISTRATIVE PROCEDURE REQUIREMENTS

Each administrative procedure, at a minimum, shall include:

- Unique identifier
- Title

- Revision number traceable to the date issued
- Signature(s) of approval authority (dated with title)
- Applicability
- Each page shall carry the identifier and revision, at a minimum
- Pagination, including number of total pages.

Signatures of approval authority may be electronically recorded and must be traceable to the revision of the procedure.

The organization shall define all approvals required on procedures.

4.3 TECHNICAL AND TEST PROCEDURE REQUIREMENTS

Each technical or test procedure, at a minimum, shall include:

- Unique identifier
- Title
- Revision number traceable to the date issued
- Signature(s) of approval authority (dated with title)
- Applicability
- Each page shall carry the identifier and revision, at a minimum
- Pagination, including number of total pages.

Signatures of approval authority may be electronically recorded and must be traceable to the revision of the procedure.

The following information is required for technical and test procedures as appropriate to the scope and complexity of the procedure or work requested:

- Scope (e.g., parameters measured, range, matrix, expected precision, and accuracy)
- Unique terminology used
- Summary of method
- Interferences/limitations
- Approaches to address background corrections
- Apparatus and instrumentation
- Reagents and materials
- Hazards and precautions

- Sample preparation
- Apparatus and instrumentation set up
- Data acquisition system operation
- Procedures, when automatic quantitation algorithms are overridden
- Calibration/standardization and maintenance
- Procedural steps
- QC parameters and criteria
- Specify statistical methods used
- Calculations
- Assignment of uncertainty
- Forms used in context of the procedure
- Referenced documents (including the title, author[s], year published, publisher, document identifier).

The organization shall define all approvals required on procedures.

4.3.1 New Procedures

New technical procedures shall be qualified before use (see Section 4.6). New technical procedures are defined as technical procedures used for the first time that are either based on published, well-understood methods or developed in the field or laboratory.

4.4 FIELD SAMPLING ACTIVITIES

Field sampling activities shall be based on a sampling plan and established procedures for sampling of substances, materials, or products for subsequent environmental testing. Sampling plans shall document the rationale chosen for sample locations (e.g., statistical, directed, etc.). The sampling plan shall address the sampling process and the factors to be controlled to ensure the validity of the environmental test results. The sampling plan, as well as the sampling procedure (or procedures), shall be reviewed prior to field activities and available as necessary to help guide activities.

Sampling activities are conducted using a variety of equipment and procedures (e.g., procedures for sampling air, biota, ground and surface water, soil, sediment, and containerized wastes [tanks, trucks, drums, etc.]). The number and type of procedures instituted by a particular

sampling/field organization will vary greatly depending on the scope of the operation. Each sampling method shall have a procedure associated with the particular activity. The equipment and procedures shall be selected on a site-specific basis, depending on the media and the nature of the contaminant to be sampled.

The procedure shall describe the equipment needed in detail and how to properly use and maintain the equipment. The procedure shall address typical difficulties associated with the sampling activity, limitations, and any precautions required to successfully complete the task. The procedure shall specify the documentation required to record essential aspects of the event.

Unexpected situations encountered during sampling may require that changes be made to previously-approved sampling documents or sampling procedures. The criteria for change control should be documented in the project-specific SOPs, sampling analysis plans, or work control documents. Volume 2, Section 4.6, discusses change control criteria. Where field conditions require deviations, additions, or exclusions from the sampling plan and/or sampling procedures, approval by supervision is required prior to continuation of activities. It is the responsibility of the approving supervision to assess if the field conditions are significantly different to warrant stopping work. Deviations, additions, or exclusions shall be recorded in sufficient detail to explain actual activities with the appropriate sampling data and shall be included in all documents, and shall be communicated to the appropriate personnel for inclusion as necessary in documents generated as the result of the sampling activity.

4.5 FIELD AND LABORATORY ANALYSES

Analytical procedures shall, whenever possible, be derived from appropriate methods that have been published either in international, national, or regional standards/methods compendiums; by reputable technical organizations; in relevant scientific texts or journals; or as specified by the manufacturer of the equipment used. The latest valid edition of a published method shall be used unless it is not appropriate or possible to do so.

If not specifically defined in contractual or other requirement documents, or if the client specified method is inappropriate for the requested analysis, the client shall be informed as to the laboratory's proposed method prior to use. Any procedure may require formal acceptance (including acceptance by DOE or regulating body) prior to initiation of analysis.

Specific products, equipment, and instrument settings cited in published or reference methods typically represent those used during method development or subsequently evaluated for use in the method. Glassware, reagents, supplies, equipment, and settings other than those listed may be employed, provided that method performance appropriate for the intended application has been determined and documented. Changes (particularly replacements or elimination of reagents or alternate equipment) or clarifications to published methods shall be documented, preferably noted in the SOPs. Changes to a method that affect published method performance shall be documented.

Method performance must include consideration of precision, accuracy (or bias), recovery, representativeness, comparability, and sensitivity (quantitation or reporting limits) relative to the DQOs for the intended use of the analytical results.

Before initial use or before use after any technical revisions, all methodology employed must be demonstrated and documented to ensure that the procedure is capable of providing appropriate performance for its intended application. The documentation shall be maintained and available upon request by authorized representatives of those who receive any generated results. The documentation should include the performance data as well as a description of the analytical process steps in sufficient detail to allow understanding and evaluation of the method by an independent technical authority (e.g., SOP). Technical procedures shall include or reference the acceptance and performance criteria for precision, accuracy, calibration, and quantitation/reporting limit (as appropriate) established during the qualification experiments. When necessary, the published method shall be supplemented with additional details to ensure consistent application.

When the use of specific methods for a sample analysis are mandated or requested, only those methods shall be used. For a limited number of methods, the EPA has defined procedures for method-defined parameters, where the analytical result is wholly dependent on the process used to make the measurement. Examples include the use of the toxicity characteristic leaching procedure to prepare a leachate, and the flash point, pH, paint filter liquids, and corrosivity tests. In these instances, changes to the specific methods may change the end result and incorrectly identify a waste as nonhazardous. Therefore, when the measurement of such method-defined parameters is required by regulation, those methods are not subject to the flexibility afforded in other methods. Section 4.7 contains guidance and requirements to address circumstances where EPA method-defined parameter procedures cannot be implemented as written.

One time (typically on a single analytical batch) departures or changes to procedure steps are allowed if deemed necessary by the professional judgment of technical supervision to accommodate variation in sample matrix, radioactivity, chemistry, sample size, or other parameters. The departures or changes shall require approval by supervision prior to implementation. If contractually required, the client shall be notified prior to proceeding with analysis. Documentation of what was done, including the rationale for departure or change, shall be completed within one day of the supervision's approval or completion of analysis. Documentation shall be filed in the project file and the potential effects on precision, accuracy, recovery, representativeness, comparability, and sensitivity shall be discussed in the associated result case narrative. The laboratory shall track these activities and periodically evaluate if formal procedure revision is appropriate.

It is recognized that Hanford matrices and client milestones may limit a laboratory's or field's ability to conform to the above requirements. In such cases, a proposed analytical approach (e.g., test procedure, test plan) shall be documented and agreed to by the client. Adequate QC shall be included to ensure that the precision, accuracy, sensitivity, and associated limitations of the methodology are well understood on completion of the work.

Implementation of the method shall include consideration of health and safety issues, environmental, and waste management considerations.

4.6 QUALIFICATION OF METHODS/PROCEDURES

Qualification is the process of determining the suitability of a method/procedure (e.g., preparative and/or analytical) for providing useful analytical data. Performance parameters of the method, or the method from which a procedure is derived, are compared with the requirements for the analytical data.

Several approaches may be used to qualify a method/procedure, and include the following:

- When suitable reference materials are available to adequately test method performance versus matrix effect, performance is demonstrated quite easily. This test consists of analyzing a sufficient number of reference samples and comparing the results obtained to that quoted for the particular material. A simulated matrix may be the closest performance indicator available.
- When suitable reference materials are not available, two other approaches are considered reasonable. The first is comparing the new method against a known, well-established method (laboratory approved or regulator recognized, see Volume 4, Appendix B); the second is inter-laboratory comparisons. In limited cases, matrix spikes and/or surrogates may be used. This is the least desirable because of limitations associated with preparing spike and/or surrogate materials. Also, spikes and/or surrogates may behave differently than the actual sample in the process investigated.

In all cases, a suitable number of replicate determinations must be made to provide a measure of statistical control. Generally accepted standards dictate using a minimum of four replicates for each test case. Whenever possible, seven replicates should be used. This data should then be used to establish statistical control on an advisory basis until sufficient data are acquired, typically considered to be 30 data sets. A method must also be evaluated for its overall effectiveness in the areas of sensitivity, selectivity, linear range limitations, matrix or analytical precision, and accuracy and counting statistics (radiochemistry), as applicable to the method and/or analyte and depending on whether the method is preparative, analytical, or encompasses both. This requires that method testing include a method detection level determination and/or minimum detectable activity (according to Volume 4, Section 7.0), method blank evaluation, precision and accuracy determination, counter performance, uncertainty, and determination of method interferences as appropriate to the method (i.e., preparative versus determinative).

All method/procedure qualification data shall be traceable to the technical procedure(s) it supports and shall be retained on file to enable retrospective examination of the method/procedure if the need arises.

4.7 MODIFICATION OF METHOD-DEFINED PARAMETER ANALYSES

Federal regulations mandate use of SW-846 for the following nine specific applications:

- 40 Code of Federal Regulations (CFR) Part 260.22(d)(1)(i): Submission of data in support of petitions to exclude a waste produced at a particular facility (i.e., delisting petitions)
- 40 CFR 261.22(a)(1) and (2): Evaluation of waste against the corrosivity characteristic (SW-846 Methods 1110A or 9040C)
- 40 CFR 261.24(a): Leaching procedure for evaluation of a waste against the toxicity characteristic (SW-846 Methods 1310B or 1311)
- 40 CFR 264.190(a), 40 CFR 264.314(c), 40 CFR 265.190(a), and 40 CFR 265.314(d): Evaluation of a waste to determine if free liquid is a component of the waste (SW-846 Method 9095B)
- 40 CFR 266.112(b)(1): Certain analysis in support of excluding from the definition of a hazardous waste a residue that was derived from burning hazardous waste in boilers and industrial furnaces
- 40 CFR 268.32(i): Evaluation of a waste to determine if it is a liquid for purposes of certain land disposal prohibitions
- 40 CFR 268.40(a), 40 CFR 268.41(a), and 40 CFR 268.43(a): Leaching procedure for evaluating waste extract to determine compliance with land disposal treatment standards
- 40 CFR 270.19(c)(1)(iii) and (iv), and 40 CFR 270.620(b)(2)(i) (C) and (D): Analysis and approximate quantification of the hazardous constituents identified in the waste before conducting a trial burn in support of an application for a hazardous waste incineration permit (SW-846 Methods 1310B or 1311)
- 40 CFR 270.22(a)(2)(ii)(B) and 40 CFR 270.66(c)(2)(i) and (ii): Analysis conducted in support of a destruction-and-removal-efficiency trial burn waiver or boilers and industrial furnaces burning low-risk waste, and analysis and approximate quantitation conducted for a trial burn in support of an application for a permit to burn hazardous waste in a boiler and industrial furnace.

The Washington Department of Ecology addresses the testing requirements through:

- WAC 173-303-090, "Dangerous Waste Characteristics," of the Dangerous Waste Regulations.
- WAC 173-303-100, "Dangerous Waste Criteria," of the Dangerous Waste Regulations.
- Testing requirements no longer required by EPA but retained by the State of Washington.

Ecology has identified method-defined parameter procedures for determining the characteristics of ignitability for liquids, corrosivity for liquids, and toxicity where changes to the specific methods may change the end result and incorrectly identify a waste as non-hazardous. These and other specifics are addressed in Publication 97-407 “*Chemical Test Methods for Designating Dangerous Waste.*”

The following procedures shall be used when modifications to the required method-defined parameters are made. Modifications include changes to reagent composition, reagent to sample ratios, aliquot sizes, contact times/temperatures, and equipment operating parameters as appropriate to the method. Qualification requirements for such modification are discussed in Section 4.6.

4.7.1 Justifying Modification

Modifications to the method-defined parameter analysis shall be specifically described by providing a synopsis or direct quotation of the method-defined parameter requirement and a description of all changes made. The reason(s) why the requirement cannot be met and/or the technical, health and safety, environmental, and/or waste management merits of the modification(s) shall be provided. The citation of the original, method-defined parameter shall be provided. This information shall be provided either: (1) directly in the procedural text, or (2) as a summary accompanying the text. The approach taken should be based on whether the procedure has short-term or long-term application (i.e., use 1 or 2, respectively).

4.7.2 Regulatory Notification

The notification mechanism available to the laboratory requires DOE to coordinate with the regulator. The laboratory must obtain documented approval from DOE to use the new procedure before starting work. The timeframe for acceptance shall be documented and agreed upon with DOE. Information regarding regulatory acceptance considerations can be found in references such as WAC 173-303-910(2), “Petitions for Equivalent Testing or Analytical Methods,” and Title 40 CFR 136.4, “Application for and Approval of Alternate Test Procedures for Nationwide Use.”

4.7.3 Documenting the Modified Method-Defined Parameter

In cases where changes are restricted to specific sections of the required method for method-defined parameters, the text of the modification shall be provided (e.g., different instrument configuration). A complete copy of the modified method shall be provided when extensive modifications are necessary. The modified method for the method-defined parameter shall be managed as a controlled document, subject to the necessary review and approval.

The impact of the changes on the published precision, accuracy, and/or detection limit of the modified method-defined parameter shall be established by experiment. Any modification to the approved QC procedures for the method shall be described and the acceptance criteria specified (e.g., detection limit). The approach required for method qualification is described in Section 4.6.

Implementing the final modified method as a technical procedure in the laboratory requires signatures of approval that all requirements have been met. Approval signatures are required from the laboratory QA representative and a representative of laboratory management from the section where the technical procedure is to be performed.

All original laboratory test data shall be retained on file to enable retrospective examination of the method, if the need arises.

All technical procedures developed through modification of methods required for method-defined parameters shall be provided with a unique title to notify the data user that the regulatory method has been modified.

4.7.4 Reporting Results from Modified Methods/Procedures for Method-Defined Parameter Analyses

All results reported from a modified method required for method-defined parameters shall be explicitly marked as such. Reports shall include direct reference to the modified methods/procedures used. The associated case narrative shall include discussions as to the potential impacts of the modifications to the precision and accuracy of the data relative to the unmodified method. To the extent practical, modified methods required for method-defined parameters shall retain a method reference (identifier) to the original method.

5.0 CORRECTIVE ACTION AND QUALITY IMPROVEMENT

A system based on a graded approach shall be established and implemented as soon as practical to identify, document, correct, and prevent quality problems. This system shall be subject to ongoing documented review by management to assess its effectiveness.

Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items, services, and processes needing improvement.

Where the data quality is or may be impacted, the client is notified and appropriate resolution is agreed upon.

5.1 INITIATION OF CORRECTIVE ACTION

Conditions adverse to quality, including failures, malfunctions, deficiencies, defective items, out-of-control processes, and nonconformances shall be identified using a graded approach.

Examples of conditions adverse to quality include:

- Documentation errors
- Adverse trends in the analysis of standards
- Failure to follow client analytical requests and/or DQOs
- Failure to comply with approved technical and administrative procedures
- Failure to follow the preventive maintenance program
- Failures in the instrument systems or malfunctions in field equipment
- Failures and/or unacceptable results in performance evaluation sample
- Deficiencies identified during assessments
- Validation and/or verification issues negatively impacting reported results
- Recurring adverse conditions, including “near-miss” problems such as “outside of warning limits,” analysis blank problems, and other adverse trends (see Section 5.4)
- Client complaints, misidentification, or mishandling of samples.

Corrective action shall be initiated based upon the graded approach.

5.2 EVALUATING IMPACT

Management shall be responsible for problem investigations and determining corrective actions. The corrective action process shall include the following requirements: (1) determining the significance of quality problems, and (2) taking effective corrective action based on the potential impact on the data quality.

Implementation of the corrective action(s) shall be verified. The corrective action(s) is complete when the affected systems meet specifications.

5.3 CAUSAL ANALYSIS

The corrective action process shall describe the provisions for determining the cause of nonconforming items and processes. The extent of analysis shall be commensurate with the importance or the significance of the problem (i.e., graded approach).

5.4 RECURRING CONDITIONS ADVERSE TO QUALITY

The corrective action process shall describe the provisions for determining if corrective actions have not been effective in preventing recurrence of quality problems. Preventive action shall be initiated, as appropriate, considering the magnitude of potential problems. When preventive measures are implemented, their effect shall be monitored to ensure that desired quality objectives are satisfied and maintained.

Provisions for making corrective action determinations shall include, but not be limited to, the following:

- Determining the events leading to the adverse condition
- Determining the technical and work activities associated with the quality problem
- Ascertaining the quality problem's generic implications
- Determining the extent to which similar quality problems (or precursors to the problem) have been recognized
- Determining the effectiveness of any corrective actions that were taken
- Determining the impacts on the completed work
- Determining actions that can be taken by the responsible organization to preclude recurrence
- Determining if stopping the work associated with the activity is necessary.

5.5 TREND ANALYSIS

The corrective action process shall describe provisions for analyzing quality-related information to identify trends that adversely impact quality and opportunities to improve items and processes. Analysis of quality-related information shall include, where possible, identifying common work processes for item quality problems, conducting cause-and-effect analysis, and determining effective corrective and preventive actions from external sources.

As appropriate, the quality-related information to be analyzed shall include, but not be limited to, the following:

- Performance data
- Audit reports
- Surveillance reports
- Nonconformance reports
- Failure rates
- Quality-related information from external sources
- Performance indicators
- Lessons learned.

Trend analysis shall be performed in a manner and at a frequency that identifies significant quality trends and evaluates the trends for timely and appropriate corrective action. Trends determined to be adverse to quality shall be reported to the organization(s) responsible for corrective action.

5.6 CONTINUOUS QUALITY IMPROVEMENT

The process of continuous quality improvement leads to the development of a better and more responsive quality system. Quality improvement generally results from activities that:

- Prevent or minimize problems during the planning and implementation of sampling and analysis activities that may affect the quality of the results
- Detect and correct problems
- Review existing performance and identify opportunities for quality improvement.

Processes to detect and prevent quality problems shall be established and implemented. Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction shall include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items, services, and processes needing improvement.

5.7 CONTROL OF NONCONFORMANCES

Controls shall be implemented for samples/materials, parts, or components that do not conform to requirements to prevent their inadvertent use. These measures shall include, as appropriate, procedures for identification, documentation, evaluation, segregation (where practical), disposition, and notification of affected organizations.

6.0 DOCUMENTS AND RECORDS

A system shall be developed for timely preparation, review, approval, issuance, use, control, revision, and maintenance of documents that prescribe work processes and specify requirements.

Activities affecting quality shall be prescribed by documented instructions, procedures/ documents, drawings, or operator aids that include quantitative or qualitative acceptance criteria that can be used to determine if activities are satisfactorily accomplished. Additionally, a system shall be established and implemented for identifying, preparing, approving, transmitting, correcting, distributing, retaining, retrieving, and disposing of records. These systems shall ensure that records are maintained and controlled in a manner that facilitates retrospective review of all aspects of work performed to produce a reported result. These system(s) shall be subject to ongoing review by management to assess their effectiveness.

6.1 DOCUMENT CONTROL

Document control shall include measures by which documentation can be controlled, tracked, and updated in a timely manner to ensure that applicability and correctness are established. Control measures shall be used to ensure that documents are reviewed for accuracy, approved for release by authorized personnel, and distributed to and used at the location of the prescribed activity.

Documents requiring control shall be identified. Documents, including revisions, shall be reviewed by qualified personnel for conformance with technical requirements and quality system requirements and approved for release by authorized personnel. Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. Documents used to perform work shall be identified and kept current for use by personnel performing the work.

Measures shall be taken to ensure that users understand the documents to be used. Obsolete or superseded documents shall be identified and measures shall be taken to prevent their use, including removal from the workplace.

If the organization's documentation control system allows for the amendment of documents by hand pending the reissue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed, and dated.

6.2 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings that include quantitative or qualitative acceptance criteria that can be used to determine if activities are satisfactorily accomplished.

Instructions, procedures, and drawings shall be reviewed and approved by appropriate qualified individuals. Revisions to instructions, procedures, and drawings that affect the process or are technical in nature shall receive a documented level of review by impacted organizations to

ensure that the changes are appropriate. Editorial changes may be made to instructions, procedures, and drawings without review and approval.

6.3 RECORDS

Sufficient records shall be specified, prepared, reviewed, authenticated, and maintained to reflect the achievement of the required quality. Records shall include documents such as notebooks/logbooks, results of reviews, inspections, tests, assessments, monitoring of work performance, calibration records, material/sample analyses, subcontractor evaluations/results, and records for data reduction, validation, storage, and reporting. Records shall also include closely related data such as qualifications of personnel, methods, and equipment. Inspection and test records shall include, as a minimum, identification of the inspector or data recorder, type of observation, results, acceptability, and action taken to correct any deficiencies noted. The laboratory shall develop and maintain a listing of names, initials, and signatures of individuals who are responsible for signing or initialing any laboratory record.

A procedure delineating the records control system shall be established. This procedure shall include the following:

- Specifications of items, data, and processes of which records are to be controlled
- Requirements for the preparation, review, approval, and maintenance of records to accurately reflect completed work and to fulfill statutory requirements
- Requirements and responsibilities for record transmittal, distribution, change, retention, protection, preservation, traceability, archival, retrieval, and disposal
- Verification that records received are legible and are in agreement with the transmittal document
- Requirements for access to and control of the files
- Processes for the control and client confidentiality/accountability of records removed from the storage location
- Processes for filing supplemental information and disposing of superseded records
- Storage of records in a manner approved by the organizations responsible for the records
- Replacement, restoration, or substitution of lost or damaged records
- Processes for data correction, including how corrections are to be made, and establish who is authorized to change or correct data.

Documents designated to become records shall be legible, accurate, complete, and appropriate to the work accomplished.

6.3.1 Corrections to Records

Corrections to records, including documents that will become records, shall be made by drawing one line through the error, initialing and dating the error, and justifying the correction (if not self-explanatory).

When corrections are due to reasons other than transcription errors, the reason for the correction shall be documented.

6.3.2 Maintenance of Records

Maintenance of active records shall include provisions for transmittal, distribution, retention, protection, preservation, traceability, disposition, and retrievability. Records shall be protected against fire, theft, loss, environmental deterioration, vermin, and in the case of electronic records, electronic or magnetic sources.

Records shall be classified, retained, and dispositioned in accordance with the *National Archives and Records Administration Act of 1984*, and DOE Order 200.1A, *Information Technology Management*. Written approval must be received from all affected clients, prior to disposal of any records associated with DOE analytical data.

6.3.3 Notebooks/Logbooks

The organization shall define notebooks/logbooks and describe their uses within their QA program. The organization shall establish a records management system for control of notebooks/logbooks, including a minimum review frequency. Documentation reviews shall be maintained and available for review.

When notebooks/logbooks are required they shall be permanently bound or have a means to eliminate page removal/replacement (e.g., tamper seals), loose-leaf binders shall not be used. Notebooks/logbooks shall have:

- A unique identifier clearly displayed
- Sequentially-numbered pages
- Entries are made in a permanent fashion and corrections are made without obliterating the original data.
- Entries are dated and signed by the person responsible for performing the activity at the time the activity is performed.

Entries are in chronological order. When no more entries are to be made on a page, unused portions of the page will be struck out, signed/initialed, and dated.

Electronic notebooks are permitted and shall meet the same requirements for change protection and controls as hand-written hardcopy notebooks.

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7.0 SOFTWARE SYSTEMS QUALITY ASSURANCE

This section provides requirements for the acquisition, development, operation, maintenance, and retirement of computer hardware and software related to environmental sampling operations, field measurements and analyses, laboratory analyses, data reduction, and data storage. Commercial off-the-shelf software is purchased software that is typically used “as is.” Commercial off-the-shelf products are designed to be easily installed and to interoperate with existing system components. Computer hardware/software configurations integral to measurement and/or testing equipment that are calibrated for a specific purpose require calibration and appropriate QC per Volume 4 prior to use or testing. Further testing is not required unless the scope of the software usage changes or modifications are made to the hardware/software configuration

7.1 COMPUTER HARDWARE QUALITY ASSURANCE REQUIREMENTS

Computers and automated equipment, such as the Laboratory Information Management System (LIMS), are to be maintained to ensure proper function and must have appropriate environmental and operating conditions necessary to maintain the integrity of data, output files, and information.

Procedures shall be established and implemented for the maintenance of security of data, including the prevention of unauthorized access to and the unauthorized amendment of records. Electronic Data Security measures must ensure:

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

7.2 COMPUTER SOFTWARE QUALITY ASSURANCE (SQA) REQUIREMENTS

A SQA program shall be established and implemented which addresses software project management and quality planning, requirements specification, acquisition, design, development, verification and validation (including inspection and testing), configuration management, maintenance, problem reporting and corrective actions, and retirement. Software applications important to field sampling activities, field analyses and measurements, and laboratory analysis, shall be subject to appropriate controls throughout the software life cycle. Software life cycle activities are planned, performed, documented, and traceable to the software utilized. Additionally, the SQA program shall address support software, software tools, and system software.

- **Support Software** - Support software includes software tools and system software. As appropriate, the software engineering method, software acquisition method, or both shall establish the need for software tools.
- **Software Tools** - Software tools shall be evaluated, reviewed, tested, accepted for use, and placed under configuration control as part of the software development cycle of a new or revised software product. Software tools that do not affect the performance of the software need not be placed under configuration control.
- **System Software** - System software consists of the on-line computer programs used to provide basic or general functionality and facilitate the operation and maintenance of the application computer program. Examples include lower level software layers, assemblers, interpreters, diagnostics, and utilities. System software shall be evaluated, reviewed, tested, and accepted for use as part of the software development cycle of a new or revised software product. System software shall be placed under configuration change control.

Procedures shall be developed, implemented, and maintained for the following SQA life-cycle processes.

7.2.1 Software Engineering

Software design requirements shall specify technical and software engineering requirements. Software design shall identify applicable reference drawings, specifications, codes, standards, regulations, procedures, or instructions that establish software design requirement test, inspection, and acceptance criteria. Security requirements shall be specified commensurate with the risk from unauthorized access or use. Software design requirements shall be traceable throughout the software life cycle. Measures to mitigate the consequences of problems, as identified through analysis, shall be an integral part of the design. These potential problems include external and internal abnormal conditions and events that can affect the computer program.

Software design verification shall evaluate the technical adequacy of the design approach, ensure internal completeness, consistency, clarity, and correctness of the software design, and shall

verify that the software design is traceable to the software design requirements. Software design verification shall include review of test results. The software design verification shall be completed prior to approval of the computer program for use. The requirements for the software design verification activity shall be documented in the software engineering method.

7.2.2 Software Acquisition

Software acquisition includes software or software services procured or otherwise acquired. The purchaser shall be responsible for the appropriate requirements of this section upon acceptance of the software or related item (e.g., programmable device). Procurement documents shall identify requirements for supplier's reporting of software errors to the purchaser and, as appropriate, the purchaser's reporting of software errors to the supplier.

For software acquired from a commercial vendor or other third party, evidence of software QC, verification and validation (V&V), and other pertinent data shall be acquired and documented. Software verification is the process of evaluating software to determine whether the products of a given development phase satisfy the conditions imposed at the start of that phase. When V&V documentation is not available from the vendor, V&V may be performed by the end user in accordance with the requirements of this Section. Software validation is the process of evaluating software during or at the end of the development process to determine whether it satisfies specifications. If the statement of work requires that a vendor have an approved QA program, then perform verification that the vendor's software QA program and submitted documentation meet the requirements specified in the statement of work.

7.2.3 Computer Program Testing

Computer program tests, including, as appropriate, software design verification, factory acceptance tests, site acceptance tests, and in-use tests, shall be controlled. Acceptance testing shall be performed prior to approval of the computer program for use. Software verification and validation processes shall:

- Ensure the software adequately and correctly performs the intended functions
- Ensure the software does not function in a manner in which the system can be degraded
- Be planned and performed for system configuration that may impact the software
- Be documented.

Computer program test procedures shall provide for demonstrating the adherence of the computer program to the documented requirements.

- Computer programs used for design activities: The computer program test procedures shall provide for ensuring the computer program produces correct results.

- Computer programs used for operational controls: The computer program test procedures shall provide for demonstrating performance over the range of the operation of the controlled function or process.
- In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system.

The acceptance testing activity shall demonstrate that the computer program adequately and correctly performs all intended functions (i.e., specified software design requirements). Acceptance testing shall demonstrate, as appropriate, that the computer program properly handles abnormal conditions and events as well as credible failures, does not perform adverse unintended functions, and does not degrade the system either by itself or in combination with other functions or configuration items.

Acceptance testing shall be performed prior to approval of the computer program for use. Configuration items shall be under configuration change control prior to starting acceptance testing. Acceptance testing shall be planned and performed for all software design requirements. Acceptance testing ranges from a single test of all software design requirements to a series of tests performed during computer program development. Performance of a series of tests provides assurance of correct translation between activities and proper function of individual modules. Testing shall include a comprehensive acceptance test performed in the operating environment prior to use. The test plans, test cases, and test results shall be documented, reviewed, and approved prior to use of the computer program.

Observations of unexpected or unintended results shall be documented and disposition implemented prior to test result approval. The acceptance testing of changes to the computer program shall be subjected to selective retesting to detect unintended adverse effects introduced during the change. Such testing shall provide assurance that the changes have not caused unintended adverse effects in the computer program and verify that a modified system(s) or system component(s) still meets specified software design requirements.

7.2.4 Spreadsheets

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. Following validation, a printout from all spreadsheets verified shall include all information used to calculate the data.

7.2.5 Software Configuration Management

Software configuration management activities shall include documentation (e.g., software design requirements, instructions for computer program use, test plans, and result[s]), computer program(s) (e.g., source, object, backup files), and support software.

The software configuration change control process shall include initiation, evaluation, and disposition of change requests; control and approval of changes prior to implementation; and requirements for retesting and acceptance of the test results.

Working data or source files (e.g., nuclear data libraries, master gamma libraries, geometry files, efficiency files, mass spectral libraries) shall be controlled by the organization to prevent unauthorized access or inadvertent changes and controlled to document changes by authorized users.

Software version control methods must be in place to document the software version used, as well as data reports, with the date and time of generation and the software version used to generate the data report. Software that includes user defined calculations and/or macros shall also track revisions to the user-defined customization using version information.

7.2.6 Problem Reporting and Corrective Action

Method(s) for documenting, evaluating, and correcting software problems shall:

- Describe the evaluation process for determining whether a reported problem is an error or other type of problem (e.g., user mistake)
- Define the responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation.

When the problem is determined to be an error, the method shall provide, as appropriate, for:

- How the error relates to appropriate software engineering elements
- How the error impacts past and present use of the computer program
- How the corrective action impacts previous development activities
- How the users are notified of the identified error, its impact, and how to avoid the error, pending implementation of corrective actions.

7.2.7 Operation

After the software is approved for use and installed in the operating environment, the use of the software shall be controlled in accordance with approved procedures and instructions.

7.2.8 Maintenance

The appropriate SQA procedures and documents shall identify how changes to the software are controlled.

7.2.9 Retirement

During retirement, support for the software product is terminated, and the routine use of the software shall be prevented.

7.2.10 Records

The SQA processes shall define the baseline documents that are to be maintained as records. Although multiple documentation requirements are specified within this section, they can be provided as separate or as combined documents.

Records available in the laboratory to demonstrate the validity of laboratory-generated software include:

- Software description and functional requirements
- Software and spreadsheet validation and verification records
- Listing of algorithms and formulas
- Installation, operation, and maintenance records.

8.0 PROCUREMENT CONTROLS

A process shall be established and implemented to control purchased items and services.

Procured items and services shall meet established requirements and perform as specified. Prospective suppliers, including those providing subcontracted analytical services (non-Hanford Laboratories) shall be evaluated (to the applicable requirements specified in the HASQARD) and selected on the basis of specified criteria. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.

Procurement controls shall describe provisions for the following:

- Identifying applicable technical and administrative requirements from HASQARD for subcontracted services and items, including acceptance criteria
- Selecting qualified subcontractors
- Verifying that qualified subcontractors can continue to provide acceptable products and/or services
- Ensuring that purchased services, supplies, reagents, and consumable materials that affect the quality of data are inspected prior to use or otherwise verified as complying with specifications or requirements defined in the purchase order
- Receiving and maintaining procurement records, including evidence of conformance
- Documenting nonconforming items and services.

Qualified suppliers and, as necessary, sub-tier suppliers shall be monitored periodically to ensure that acceptable items and services continue to be supplied.

Procurement documents shall contain information clearly describing the item or service needed and the associated technical and quality requirements. The procurement documents shall specify the quality system elements for which the supplier is responsible and how the supplier's conformance to the customer's requirements will be verified. Procurement documents shall be reviewed for accuracy and completeness by qualified personnel prior to release. Changes to procurement documents shall receive the same level of review and approval as the original documents.

When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information shall be forwarded to appropriate management for action.

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9.0 EQUIPMENT AND MAINTENANCE

9.1 EQUIPMENT

Equipment and/or systems requiring periodic maintenance shall be identified, and the records of major equipment shall include the name, serial number or unique identification, date received and placed in service, current location, condition at receipt, manufacturer's instructions, date of calibration or date of next calibration, maintenance, and history of malfunction. In addition, the QA plan shall discuss how the availability of critical spare parts, identified in the operating guidance and/or design specifications of the systems, will be assured and maintained.

9.2 MAINTENANCE

The organization's QA plan shall describe or reference how periodic preventive and corrective maintenance of measurement or test equipment shall be performed to ensure availability and satisfactory performance of the systems. Periodic preventive and corrective maintenance of measurement and testing equipment shall be performed to ensure availability and satisfactory performance of the systems. All equipment subject to maintenance or repair shall be recalibrated as necessary before the equipment is used.

The following describes the items that shall be included in the QA plan:

- Routine inspections recommended by the manufacturer are performed before instrument operations. The frequency of these inspections is established based on the manufacturer's recommendations.
- Instrument maintenance shall be performed and documented (i.e., including the date and signatures [or initials] of personnel who performed the maintenance).

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10.0 ASSESSMENTS

Assessments document how the organization determines the suitability and effectiveness of the implemented quality system and the performance of the programs to which the quality system applies.

Assessments may be performed by agencies or groups that are not under the control of laboratory management such as regulators (e.g., EPA, Washington State Department of Ecology, Washington State Department of Health), clients, and DOE. Assessments may consist of inspections, interviews, and/or evaluations that focus on the organization's ability to meet client, program, and/or regulatory requirements. Management shall be responsible for initiating, tracking, following up, and documenting in a timely manner all corrective actions that are required as a result of the assessments.

The assessment program is used to evaluate the adequacy and effectiveness of the QA program and technical systems. Surveillances, peer reviews, and readiness reviews are acceptable assessment techniques that use observation and monitoring to provide confidence that on-going processes and activities are adequately and effectively performed.

At a minimum, the laboratory and/or field organization's assessment program shall address the following:

- Management Assessments
- Technical Assessments
- Quality System Assessments
- Performance Evaluation Assessments
- External Audits (if applicable).

The QA program shall identify each assessment element and the frequency of each assessment; the position or individual responsible for each assessment; the qualifications, responsibilities, authority, and accountabilities of the assessor(s); the format of the assessment; action owner(s); expectation for timely corrective action; expectation for timely closure of the corrective action; follow-up actions required and associated dates; and required distribution for all related documentation.

Assessments shall be scheduled on the basis of the importance of the activity to be assessed. Independent assessments shall be carried out by personnel independent of those having direct responsibility for the activity being evaluated.

10.1 MANAGEMENT ASSESSMENTS

Management assessments ensure that managers regularly assess their management processes and identify and correct problems that hinder the organization from achieving its objectives. The organization's QA program provides a solid basis for this assessment. The purpose of this assessment is to evaluate the following:

- Effectiveness of the management control systems that are established to achieve and assure quality
- Adequacy of resources and personnel available to achieve quality objectives to which the quality systems apply
- Effectiveness of training and assessment
- Applicability of data quality requirements
- Client complaints.

Management assessments identify noteworthy accomplishments, significant QA problems, and opportunities for improvement. Management assessments shall be conducted annually at a minimum.

10.2 TECHNICAL ASSESSMENTS (SURVEILLANCES)

Technical assessments are directed by the laboratory, field and/or program's QA function. This assessment measures the performance or effectiveness of a technical system and its elements with respect to documented specifications and objectives. Technical assessments consist of a review of laboratory or field operations, specific procedures, and related documentation by personnel that are qualified in accordance with their program. For example, areas of interest might include:

- Measuring and testing equipment calibration or control procedures
- Technical procedure compliance
- Identification, control, storage, and preservation of samples or standards.

Technical assessments should be conducted periodically, but at least annually.

10.3 QUALITY SYSTEM ASSESSMENTS

Quality system assessments shall be carried out by personnel independent of those having sufficient authority and direct responsibility for the activity being evaluated and that are qualified and knowledgeable about the area to be assessed in accordance with their program. Quality system assessments are directed by the laboratory, field, and/or program's QA function. These assessments measure compliance with and effectiveness of the organization's quality system and their elements with respect to documented specifications and objectives. Quality system

assessments include a review of laboratory or field operations, specific procedures, and related documentation. The quality system includes the following elements:

- Organization and Responsibility
- Personnel Qualification and Training
- Procedures
- Corrective Action and Quality Improvement
- Documents and Records
- Software Systems Quality Assurance
- Procurement Controls
- Equipment and Maintenance
- Assessments
- Quality Assurance Reporting.

Quality system assessments should be conducted periodically, but at least annually, such that over a three-year period all quality system elements are evaluated.

10.4 PERFORMANCE EVALUATION ASSESSMENTS

Performance evaluations are generally considered blind or double-blind tests introduced into a process to provide an independent evaluation tool of the quality of the process. Performance evaluations can be applied to laboratory and field operations but can also provide information regarding the effectiveness of management systems for organizations or programs, depending on when and by whom they are introduced. These assessments should be coordinated by the organization's QA function, whenever practical, to avoid any conflict of interest.

A strong performance evaluation program will typically consist of both internal and external performance measures. However, a program based on external blinds is considered the minimum acceptable.

Internal programs might include standard materials prepared in the field or laboratory or by a source independent of the activity being tested. Most of these performance evaluation programs are blind programs.

Each organization's assessment program shall identify all internal and external performance evaluation program(s) required. The QA program shall also identify the position or individual responsible for administering each program, how performance information will be disseminated, how identified corrective actions will be resolved, and the timeframe required for corrective action. This information shall be made available to regulators and clients upon request.

10.5 EXTERNAL AUDITS

External audits are performed by agencies or groups that are not under the control of laboratory management such as regulators (e.g., EPA, Ecology, Washington State Department of Health), clients, and DOE. External assessments may consist of inspections, interviews, and/or

evaluations that focus on the organization's ability to meet client, program, and/or regulatory requirements. Management shall be responsible for initiating, tracking, following-up, and documenting all corrective actions that are required as a result of external assessments in a timely manner.

11.0 QUALITY ASSURANCE REPORTING

A formal mechanism for reporting the status of the QA program to management shall be established and implemented. QA reports to management shall be issued annually, at a minimum. The reporting system shall identify the following:

- Frequency schedule for QA reports
- Report recipient
- Report preparer
- Topics to be discussed.

Reports to management on QA activities should include a summary of the results on the following:

- Performance Evaluation Assessments
- Technical System Assessments
- Management System Assessments
- External Audits, Assessments, and Surveillance Activities
- Data Quality and Validation Assessments
- Regulatory Compliance Issues
- Quality Improvement Process
- Significant QA Problems and Recommended Solutions.

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12.0 REVIEW OF REQUESTS, TENDERS AND CONTRACTS

Procedures for the review of requests, tenders, and contracts shall be established and maintained. The policies and procedures for these reviews leading to a contract for environmental testing shall ensure that the requirements, including the methods to be used, are adequately defined, documented, and understood. These policies and procedures shall ensure that the laboratory has the capability and resources to meet the requirements. These policies and procedures shall ensure that the appropriate environmental test method is selected and capable of meeting the clients' requirements.

The review shall cover any work that is subcontracted by the laboratory. If the subcontracted laboratory is required to be accredited, the current accreditation status of the laboratory must also be reviewed. Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract. The client must be informed of the results of this review if it indicates any potential conflict, deficiency, lack of appropriate accreditation status, or inability on the laboratory's part to complete the client's work.

Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable to both the laboratory and the client. The client shall be informed of any deviation from the contract. If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

Suspension of accreditation, revocation of accreditation, or voluntary withdrawal of accreditation must be reported to the client, if accreditation is required.

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13.0 REFERENCES

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[40 CFR 136](#), “Guidelines Establishing Test Procedures for the Analysis of Pollutants,” Title 40, *Code of Federal Regulations*, Part 136, as amended.

[40 CFR 260](#), “Hazardous Waste Management System: General,” Title 40, *Code of Federal Regulations*, Part 260, as amended.

[40 CFR 261](#), “Identification and Listing of Hazardous Waste,” Title 40, *Code of Federal Regulations*, Part 261, as amended.

[40 CFR 264](#), “Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities,” Title 40, *Code of Federal Regulations*, Part 264, as amended.

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[40 CFR 266](#), “Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities,” Title 40, *Code of Federal Regulations*, Part 266, as amended.

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Safe Drinking Water Act of 1974, 42 USC 300, et seq.

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[WAC 173-303](#), “Dangerous Waste Regulations,” *Washington Administrative Code*, Olympia, Washington.

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[WAC 246-247](#), “Radiation Protection—Air Emissions,” *Washington Administrative Code*, Olympia, Washington.

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APPENDIX A

GLOSSARY

Accuracy	The degree of agreement of a measurement (or an average of measurements of the same thing), X , with an accepted reference or true value, T , usually expressed as the difference between the two values, $X - T$, or the difference as a percentage of the reference or true value, $100 (X - T)/T$, and sometimes expressed as a ratio, X/T . Accuracy is a measure of the bias in a system.
Analyst	A person performing a measurement.
Analyte	The element, isotope, specie, or characteristic of a measurement.
Anomaly	Something different, abnormal, or peculiar, not easily classified.
Assessment	<p>The evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection, or surveillance.</p> <p>For data, assessment encompasses verification and validation. Data assessment (verification and/or validation) can be performed within the laboratory and/or by an independent review agency, at the discretion of the client, to the criteria of the project.</p>
Audit	A systematic and independent examination to determine if activities and related results comply with planned arrangements, are implemented effectively, and are suitable to achieve objectives.
Authenticate	The act of establishing an item as genuine, valid, or authoritative.
Batch	A group of samples that behave similarly with respect to the sampling or testing procedures being employed and that are processed as a unit. For quality control purposes, if the number of samples in a group is greater than 20, then each group of 20 samples or fewer will all be handled as a separate batch.
Bias	The systematic or persistent distortion of a measurement process that causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

Blank	<p>An artificial sample designed to monitor the introduction of artifacts into the measurement process. There are several types of blanks that monitor a variety of processes:</p>
	<p>Laboratory or preparation blank – An analytical control prepared by the laboratory that contains distilled, deionized water and reagents, which is carried through the entire analytical procedure (digested and analyzed) concurrently with samples per each sample deliverable group. An aqueous method blank is treated with the same reagents as a sample with a water matrix. A solid method blank is treated with the same reagents as a soil sample. It is a test for contamination in sample preparation and analyses.</p> <p>Holding blank – A sample that is stored and analyzed with volatile organic analysis samples at the laboratory. It is a test for contamination in sample storage and in sample preparation and analyses.</p>
Blank (cont.)	<p>Trip blank – A blank sample that travels with sample containers to the sampling site and returns unopened to the laboratory with the samples to be analyzed. The trip blank usually consists of carbon-free, deionized water. The blank measures contamination during sample transport and is typically only analyzed for volatile organic compounds.</p> <p>Field blank – A blank sample prepared in the field at the sample collection site and returned to the laboratory with the samples to be analyzed. Tests for contamination from the atmosphere and for the activities listed under trip blank. Also known as transfer blank. See Volume 2, Section 5.2.1.2.</p> <p>Equipment blank/equipment rinsate – An artificial sample usually consisting of deionized/carbon-free water designed to monitor sampling device cleanliness. Equipment blanks are opened in the field and poured over or through the sample collection device as appropriate, collected in a sample container, and returned to the laboratory as a sample. Equipment blanks may also be comprised of sand of known cleanliness. Equipment blank results may indicate that decontamination procedures were inadequate or that contamination was inherent to the equipment used.</p>
Blind sample	<p>A sample submitted for analyses whose composition is known to the submitter, but unknown to the analyst. Its identification as a check sample may be known to the analyst. A blind sample is one way to test the proficiency of a measurement system.</p> <p>A blind sample submitted for analyses whose composition and identification as a check sample is known to the submitter but unknown to the analyst is called a double-blind sample.</p>

Calibration	Comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustment.
Carrier	Carriers are stable counterparts of the radioactive isotope(s) to be measured. Carriers are added to all samples in an analytical batch such that each sample has a specific measurable quality control parameter (yield). From the time of spiking, carriers undergo all chemical processing similar to that of the sample. Carriers are not counted; a known form of the carrier is weighed to provide radiochemical yield gravimetrically or is measured by an alternative technique (e.g., inductively coupled plasma atomic emission spectrometry) to determine radiochemical yield. The mass effects of a carrier on the final sample counting configuration must be taken into account. The carrier yield is used in the data calculations to correct for any and all sources of analytical losses.
Certification	The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.
Chain of custody	An unbroken trail of accountability that ensures the physical security of samples, data, and records.
Client	The person or organization for whom items or services are furnished or work performed in response to defined requirements and expectations.
Collecting	In the context of this document, collecting is the process of withdrawing or taking samples from a designated population.
Collocated samples	Independent samples collected as close as possible to the sample point in space and time, which are intended to be identical. Used where homogenizing samples for split or duplicates is not allowed (e.g., for volatile organic analysis split samples).
Comparability	Measure of the confidence with which one data set can be compared to another.
Completeness	A measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct normal conditions.
Consensus document	A procedure, protocol, or guidance document issued by a professional standard organization based on extensive testing and peer review.
Contractor	A company that provides services and/or products to the U.S. Department of Energy.

Corrective action	Measures taken to rectify conditions adverse to quality and, where necessary, preclude repetition.
Correlation coefficient	A number (r) that indicates the degree of dependence between two variables (concentration vs. absorbance). The more dependent they are, the closer the value is to one. This is determined on the basis of the least squares function.
Data quality assessment	The scientific and statistical evaluation of data to determine if the data is of the right type, quality, and quantity to support its intended use. The data quality assessment process completes the data life cycle (i.e., planning, implementation, and assessment) that was begun by the data quality objectives process.
Data quality objectives	A strategic, systematic process for planning scientific data collection efforts. The data quality objective process helps investigators determine why data is needed, what the data represents, how the data will be used, and how much uncertainty is tolerable. By using the data quality objective process, investigators ensure that the data collected for decision making is the right type, quantity, and quality.
Data usability	The process of ensuring or determining if the quality of the data produced meets the intended use of the data.
Data validation	The process where the data package provided by the analytical provider is subjected to a rigorous review to ensure that the total data package is suitable for its intended purpose. Data that is subjected to validation is usually a subset of the total number of data packages.
Detection Limit	The minimum level at which the presence of an analyte can be reliably concluded
Document control	The act of ensuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.
Environmental medium	Any of six environmental matrices (air, water, soil, debris, bottom sediment, waste) in which physical and chemical reactions and other phenomena occur.
Equipment rinsate	See equipment blank.
Estimated quantitation limit	The lowest concentration that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions. The estimated quantitation limit is generally 5 to 10 times the method detection limit. However, it may be normally chosen within these guidelines to simplify data reporting. For many analytes, the estimated quantitation limit analyte concentration is selected as the lowest non-zero standard in the calibration curve. See Volume 4, Section 7.5.1 for details.

False negative	A term that identifies the acceptance of a test or condition as false, when in fact it is true.
False positive	A term that identifies the acceptance of a test or condition as true, when in fact it is false.
Field duplicate samples	A field sample that is split and submitted to the laboratory as two discrete field samples without the laboratory knowing the duplicate identity (blind duplicate). The relative or absolute difference between the analytical results is used to assess the precision and relative comparability of the data set.
Field split samples	A field split is a representative sample(s) from a sampling event(s) sent to a third-party laboratory (reference laboratory). Reference laboratory data is used to evaluate the project data quality objectives in terms of precision, accuracy, reproducibility, comparability, and completeness.
Field screening	An investigative technique using analytical chemistry (radiological, organic, inorganic) at or near a worksite to rapidly determine the presence or absence of environmental contaminants and the approximate concentration of specific target compounds.
Finding	A statement of fact relating to a noncompliance with previously agreed upon codes, standards, specifications, or other form of contractual or legal obligations.
Holding time	Many analytes require adherence to holding time requirements. Regulatory holding time begins at sample collection. Some regulatory holding times include collection through final analysis; others segregate the time between collection through preparation, and preparation through analysis.
Independent assessment	An assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.
Instrument detection limit	The smallest signal above background noise that an instrument can reliably detect.
Laboratory duplicate	An initial subsample of a sample that has been homogenized and then further divided into two separate subsamples, and then subjected to the entire analytical procedure after being received by the laboratory. This is used to determine the precision of a method.
Matrix	The component or substrate (e.g., surface water, drinking water) that contains the analyte of interest.
Matrix spike	An aliquot of a sample spiked with known quantities of compounds and subjected to the entire analytical procedure after being received by the laboratory. Sample spike in the field is referred to as field matrix spike.

Matrix spike duplicate	A second aliquot of the same sample as the matrix spike, with the same known quantities of compounds added as the matrix spike and subjected to the entire analytical procedure with the matrix spike.
May	Denotes permission but not a requirement.
Method detection limit	The minimum concentration of a compound that can be measured and reported with 99% confidence that the value is above zero. See Volume 4, Section 7.5.1 for details.
Nonconformance	A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate; nonfulfillment of a specified requirement.
Observation	A conclusion that presents the results of a generally subjective evaluation of implementation practices or management systems related to the area(s) under review. An observation may or may not relate to specific noncompliance(s) with agreed upon requirements, but is based on the reviewers evaluation of factual evidence.
Organic-free	<p>For volatiles, all references to water in the methods refer to reagent water in which an interferent is not observed at the method detection limit of the compounds of interest. Organic-free reagent water can be generated by passing tap water through a carbon-filter bed containing about 1 pound of activated carbon. A water purification system may be used to generate organic-free deionized water. Organic-free reagent water may also be prepared by boiling water for 15 minutes and, subsequently, while maintaining the temperature at 90°C, bubbling a contaminant-free inert gas through the water for one hour.</p> <p>For semivolatiles and nonvolatiles, all references to water in the methods refer to water in which an interferent is not observed at the method detection limit of the compounds of interest. Organic-free reagent water can be generated by passing tap water through a carbon-filter bed containing about 1 pound of activated carbon. A water purification system may be used to generate organic-free deionized water.</p>
Out-of-control	A system is said to be out-of-control when it fails to meet preselected performance criteria.
Performance evaluation	A type of audit in which the quantitative data generated from a measurement system is obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.
Precision	A measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions. Various measures of precision exist depending on the “prescribed similar conditions.”

Preventive maintenance	A program of instrument care based on scheduled activities and spare parts inventory designed to minimize instrument downtime.
Program management	The process of defining program objectives, identifying actions/tasks to accomplish those objectives, estimating the level of effort needed to complete each task, organizing and scheduling the planned task, staffing an organization to accomplish the planned tasks, assigning personnel to specific tasks, monitoring progress during the implementation, identifying problems and taking corrective actions, and recognizing tasks and program completion.
Project	An organized set of activities within a program.
Qualification (personnel)	The characteristic or abilities gained through education, training, or experience, as measured against established requirements (e.g., standards or tests), which qualify an individual to perform a required function.
Qualified (procedure)	An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.
Qualify	To qualify laboratory staff or a subcontractor, evidence is provided of meeting a performance standard for fitness by training, skill, or ability for a designated purpose. To qualify analytical procedures or computer programs, evidence is provided of performance to meet the required standard criteria.
Quality assurance	The total integrated program for assuring the reliability of monitoring and measurement data. A system for integrating the activities for planning, implementing, assessing, reporting, and quality improvement efforts to meet user requirements.
Quality assurance project plan	A formal document describing in comprehensive detail the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.
Quality control	The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer. Operational techniques and activities that are used to fulfill requirements for quality.
Quality improvement	A management program for improving the quality of operations. These management programs generally include a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.
Quantitation Limit	The minimum concentration of analyte that can be quantitatively determined with acceptable precision and bias.

Rapid turnaround	Sample analysis requiring less than standard analysis and reporting of data (e.g., 24-hour, 48-hour, 5-day). Data quality requirements may dictate either semi-quantitative or quantitative analysis and may involve preliminary reporting or full data packages. Turnaround times are normally negotiated, documented, and agreed on by the analytical organization and the client prior to the start of work.
Reagent quality	An analysis or industry-accepted grade that denotes purity or applicability for application.
Reagent water	<p>High-purity water that is generally defined as water that has been distilled, deionized, or any combination of distillation, deionization, reverse osmosis, activated carbon filtration, ion exchange, particulate filtration, or other polishing techniques.</p> <p>Each sampling and/or analysis organization is responsible for ensuring that the water used for data collection activities is of sufficient quality for the operation performed. Water quality is regularly monitored via preparative and analytical blank performance. The concentration of target analytes or interferences in the blanks shall be at a level that will not impact the results when using a particular analytical method. For organic analyses, see the definition of organic-free water.</p>
Record (quality)	A document that furnishes objective evidence of the quality of items or activities and that has been verified and authenticated as technically complete and correct. Records may include photographs, drawings, magnetic tape, and other data recording media.
Regulatory procedures	Those methods published or promulgated for laboratory use to meet the requirement of a law or government rule.
Representativeness	A measure of the degree to which data accurately and precisely represents a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition.
Run	A sequence of analyses within a continuous time period consisting of prepared samples and all associated quality control measurements as required by the customer.
Sample	(1) A single item or specimen from a larger whole or group, such as any single sample of any medium (air, water, soil, etc.). (2) A group of samples from a statistical population whose properties are studied to gain information about the whole.
Self assessment	Assessments of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

Shall/Must/Will	Denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification as long as the requirement is fulfilled.
Should	Denotes a guideline or recommendation whenever noncompliance with the specification is permissible.
Significant condition	Any state, status, incident, or situation of an environmental process or condition, or environmental technology in which the work being performed will be adversely affected such that corrective action is required to satisfy quality objectives or specifications and safety requirements.
Specification	A document stating requirements and that refers to or includes drawings or other relevant documents. Specifications should indicate the means and the criteria for determining conformance.
Spike	An aliquot of known concentration of the analyte of interest that is added to a replicate sample undergoing a chemical analysis process for purposes of providing a reference response. Spikes may have additional related terms such as blank spike, matrix spike, carrier, tracer, etc., depending on the intended use.
Procedure	A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.
Surrogate	An organic compound that is similar to the target analyte(s) in chemical composition and behavior in the analytical process, but is not normally found in the samples.
Traceability	A document trail that identifies the history of a sample, standard, or other material.
Tracer	Tracers are similar to carriers except they are radioactive and/or massless. They are added to all samples in an analytical batch such that each sample has a specific measurable quality control parameter (yield). From the time of spiking, tracers undergo the same chemical processing as the sample. Tracers are counted. The tracer yield is used in the data calculations to correct for any and all sources of analytical losses.
Uncertainty	A measure of the total variability associated with sampling and measurement that includes the two major error components: systematic error (bias) and random error (imprecision).

Valid	Having legal efficacy or force, well grounded or justifiable, being at once relevant, meaningful, logically correct, and appropriate to the end in view.
Validation	Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. In design and development, validation concerns the process of examining a product or results to determine conformance to user needs.
Verification	Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, verification concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.
Verifying	To establish the truth, accuracy, or reality.

APPENDIX B

SUMMARY OF KEY ELEMENTS OF THE DATA QUALITY OBJECTIVES PROCESS

A list of key elements is presented in this appendix that must be addressed during the project DQO process and documented. Technical reviewers shall ensure that these key elements have been adequately addressed and documented. Therefore, prior to issuing a project DQO document for review, the document writer should ensure that the key elements listed below have been adequately addressed.

The general formats as shown in Steps 1, 2, and 5 below should be used to standardize DQO documentation.

STEP 1 – STATE THE PROBLEM

Key Elements:

- Comprehensive **scoping** effort
- **Conceptual site model** based on comprehensive scoping effort
- Concise **statement of the problem(s)**, based on the conceptual site model, that provides unambiguous focus for the project.

General Format:

In order to [achieve one of the objectives of this study], data regarding [general type of contamination] is needed.

Example:

In order to [show that lead is contributing to the decrease in duck populations in the wetlands], data regarding [levels of lead in the surface water, sediments, and vegetation in the marshlands] is needed.

STEP 2 – IDENTIFY DECISIONS

Key Elements:

- **Decision statement(s)** designed to address the concerns highlighted in the problem statement
- **Principal study question(s)** that identify key unknown conditions or unresolved issues requiring environmental data
- **Alternative action(s)** that state all possible actions that might be taken once a principal study question has been resolved.

General Format:

Determine if [unknown environmental condition/issue/criterion from the problem statement] requires [choosing between two or more alternative actions].

Example:

Determine if [lead is contributing to the decrease in duck populations] and requires [remediation by removal of the lead from the bottom of the ponds] or [regulation on the types of pellets that future hunters may use] or [requires no action].

STEP 3 – IDENTIFY INPUTS

Key Elements:

- **Informational inputs** required to resolve the principal study questions identified in Step 2:
 - **Environmental variables** that require measurements
 - Sources for data
 - **Level of quality** needed for the decision(s)
 - Usability of existing data sets
 - Quality assured
 - Statistically valid
 - Agrees with conceptual site model
 - Information needed to establish action levels
 - Analytical methods and detection limits.

STEP 4 – SPECIFY BOUNDARIES

Key Elements:

- Scale of decision making:
 - **Population** of interest
 - Geographical (spatial) boundaries of the decision statement
 - **Temporal boundaries** of the decision statement
 - **Constraints** to sampling.

STEP 5 – DEFINE DECISION RULES

Key Elements:

- **Decision Rules** (“if...then” statements) that combine the following:

- Parameter of interest
 - o Population parameter
 - o Sample statistic
 - Environmental variable (chemical/physical attribute in the population quantity)
- Scale of decision making
 - o Geographic area/volume
 - o Timeframe
 - o Population
- Action level
- Alternative action(s).

General Format:

If the [population parameter of interest (4 elements)] within the [scale of decision (3 elements)] is greater than or equal to the [action level], then take [alternative action A] or take [alternative action B].

Example:

If the [true mean (as estimated by the 90% UCL of the sample mean) concentration of cadmium] within [the fly ash leachate in a container truck for a period of 1000 years] is greater than [1 mg/kg], then [the fly ash waste will be considered hazardous and will be disposed in a RCRA facility] or [the fly ash waste will be disposed of in a municipal landfill].

STEP 6 – SPECIFY ERROR TOLERANCES

Key Elements:

- **Expected range** of data values
- Possible decision errors
- **Null** and alternative hypotheses
- **Consequences** of decision errors
- **Severity** of consequences
- **Tolerable limits** on decision errors
- **Gray region** boundaries.

STEP 7 – OPTIMIZE SAMPLE DESIGN

Key Elements:

- **Select a statistical method** (equation) based on the frequency distribution histogram (probability density function) of the driver contaminant(s) of potential concern
- **Calculate the number of samples needed** to make decisions using various tolerable error limits
- Develop the aggregate unit sample collection and analysis cost equation
- Develop a cost of sampling versus uncertainty relationship (in a tabular format)
- **Select the most resource-effective data collection and analysis design** from the table that satisfies the DQOs specified in the preceding six steps.