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## LIST OF TERMS

ALARA	as low as reasonably achievable
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
CERCLA	<i>Comprehensive Environmental Response Compensation and Liability Act</i>
CFR	<i>Code of Federal Regulations</i>
DOE	U.S. Department of Energy
DQO	data quality objective
EM	Environmental Restoration and Waste Management (DOE-HQ)
EPA	U.S. Environmental Protection Agency
HASQARD	<i>Hanford Analytical Services Quality Assurance Requirements Documents</i>
HQ	DOE Headquarters
MARLAP	Multi-Agency Radiological Laboratory Analytical Protocols
MDA	Minimum detectable activity
ORP	Office of River Protection
OSHA	Occupational Safety and Health Administration
QA	quality assurance
QC	quality control
R&D	research and development
RCRA	<i>Resource Conservation and Recovery Act</i>
RL	U.S. Department of Energy, Richland Operations Office

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## 1.0 INTRODUCTION

The *Hanford Analytical Services Quality Assurance Requirements Documents* (HASQARD) Volumes 1 through 4, are issued by the U.S. Department of Energy (DOE), Richland Operations Office (RL) and Office of River Protection (ORP). The HASQARD establishes quality requirements in response to DOE Order 414.1C, *Quality Assurance*. 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 work performed by contractor and 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 *Hanford Federal Facility Agreement and Consent Order* (Tri-Party Agreement) (Ecology et al 2002) and regulatory permit applications, and applicable permit requirements 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 methods, and Volumes 1 and 4 describe the requirements for laboratory analytical methods).

## 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. Sample collection design and the field and laboratory analyses detailed in Volume 2, 3 and 4 are also based on:

- The U.S. Environmental Protection Agency (EPA), *EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5* (EPA/240/B-01/003), 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 driver for the radiochemical quality assurance/quality control (QA/QC).
- EPA 402-B-04-001A – C (Volumes I – III), *Multi-Agency Radiological Laboratory Analytical Protocols Manual (Final)* (MARLAP), 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., Tri-Party Agreement, 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 Tri-Party Agreement 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.

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.

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 Chapter 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 the 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 (CERCLA)*. 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 (OSHA), including clinical analyses
- Washington State Waste Discharge Permit Program (WAC 173-216).

Where a Hanford Site activity requires using a specific regulatory method (e.g., permits, National Pollutant Discharge Elimination System), and the regulatory method is in conflict with HASQARD, the calibration and QC requirements in the regulatory method shall take precedence over Chapters 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
- 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.

An electronic mailbox has been established to facilitate the commenting process. Commenters are requested to submit their comments and rationale to the Hanford e-mail address: “^HASQARD” (^HASQARD@rl.gov). Comments will be accepted in any format, including comments submitted on comment resolution forms (e.g., Review Comment Record or Document Review Record forms).

When a comment on the documents or a request is submitted to the e-mail address, the commenter will receive an acknowledgement that the comment has been received. The comment will be reviewed to determine if it has been previously considered.

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 DATA QUALITY OBJECTIVE PROCESS**

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

#### **1.3.1 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 Wagoner 1995). 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.

NOTE: The DOE Hanford website (<http://www.hanford.gov/dqo/index.html>) contains numerous tools, materials, software, and references to guide projects on how to implement a systematic planning process (<http://www.hanford.gov/dqo/procedures/procedures.html>) and how to perform the EPA's seven-step DQO process (<http://www.hanford.gov/dqo/keyelements.html>). Additionally, two training courses on DQOs are available and can be found on the website (<http://www.hanford.gov/dqo/training/cover.html>).

### 1.3.2 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.<sup>1</sup> 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.

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<sup>1</sup> Guidance for preparing DQO documentation can be found on the Hanford DQO website (<http://www.hanford.gov/dqo/project/workbook.html>).

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## **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 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 and its 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.

### **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 for the duration of the project or activity affected, or longer if required by statute or organizational policy.

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.

## **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.

### **4.1 GENERAL FIELD AND LABORATORY OPERATIONS**

Field and laboratory activities shall be conducted using techniques appropriate for the identified purpose and directed by approved procedures. 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 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.

Field and laboratory activities shall be directed and controlled by internally approved procedures/documents. EPA, DOE, and consensus methods (e.g., American Society for Testing Materials [ASTM], standard methods), such as those listed in Appendix B of Volume 4, shall be used where the technique is applicable to the sample matrix and the overall objective of the analysis. Objectives for analysis shall include consideration of health and safety issues, environmental and waste management considerations related to the sample material tested, and the data quality required by the client. If a regulatory-based method is not applicable to the sample matrix, a method based on proven technology and agreed on between the laboratory and the client before the start of work shall be used. Methods used for the first time, or modified, shall be qualified before routine use.

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.

#### **4.1.1 Administrative Procedures**

Administrative activities covered by procedures or other implementing documents shall include, but 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
- Assessment program
- Corrective action and quality improvement
- QA reporting.

#### **4.1.2 Sampling Procedures**

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.]). 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 required documentation to make the activity comply with established criteria. Company-specific procedure requirements may also apply.

The number and type of procedures instituted by a particular sampling/field organization will vary greatly, depending on the scope of the operation.

As appropriate, sampling or field operations covered by procedures or other implementing documents shall include, but 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.

#### **4.1.3 Field Analysis Procedures**

As appropriate, field analytical operations covered by procedures or other implementing documents shall include, but 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.

#### **4.1.4 Laboratory Procedures**

As appropriate, laboratory operations covered by procedures shall include, but not be limited to, the following:

- Environmental, safety, and health activities
- Sample shipping and receipt
- Laboratory sample chain-of-custody
- Notebooks/logbooks
- Sample storage
- Sample preparation
- Sample analysis
- Standard preparation and handling
- Post-analysis sample handling
- Control of standards, reagents, and water quality
- Cleaning of glassware
- Waste minimization and disposition.

#### **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
- Applicability.

Each page shall carry the identifier and revision, at a minimum.

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 have a unique identifier, title, revision number traceable to the date issued, and referenced documents (including the title, author[s], year published, publisher, document identifier). Each page shall carry the identifier and revision, at a minimum. 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 and standardization
- Procedural steps
- QC parameters and criteria
- Specify statistical methods used
- Calculations
- Assignment of uncertainty
- Forms used in context of the procedure.

The organization shall define all approvals required on procedures.

#### **4.3.1 New Procedures**

New technical procedures shall be qualified before use (see Section 4.3.4). 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.

#### **4.3.2 Categories of Changes**

Changes to sampling and analysis plans or changes to procedures (both regulatory and internally developed) are made for a variety of reasons. The nature of a sampling and analysis plan change can be one of three categories: minor, significant, or fundamental. Laboratory procedural changes can be one of three categories: substitution, deviation, or modification. The definitions of the sampling and analyses plan and procedure change categories are provided below. Conformance to the documentation requirements for each of these change categories shall ensure that the end-user of the data is aware of the significance of the change and the impact expected on the data. A limited number of methods must be followed as written due to the regulations encompassing how the results will be used. Section 4.3.3.2 provides direction on how to proceed prior to implementing substitution, deviation, and modification in these limited cases.

##### **4.3.2.1 Sampling and Field Analytical Plan/Procedure Changes**

Implementation of sampling and field analytical procedures may require changes to the requirements set forth in the procedure, or possibly the sampling and analysis plan when unexpected field conditions are encountered. A change management process is therefore necessary to minimize the impacts of these unforeseen circumstances. Three types of changes are defined that affect compliance with procedures and/or the sampling and analysis plan.

#### 4.3.2.1.1 Minor Change

**Definition.** Minor changes are those that have no impact on the sample or field analytical result, and little or no impact on performance or cost. Further, the change does not affect the DQOs specified in the sampling and analysis plan. The field personnel recognizing the need for a change shall consult with the task lead prior to implementing the change. Minor changes are documented in accordance with Section 4.3.3.1.1.

**Examples.** Examples of minor changes include, but are not limited to, the following:

- A change of the type of equipment used to collect samples. A coliwasa is planned to collect a representative sample from a container of liquids. When the container is opened, it is noted that the coliwasa is too short and cannot collect sample media from the bottom of the container. A peristaltic pump is determined to be acceptable to collect a representative sample through all layers of the container.
- The sampling plan specifies the locations to collect samples. When the sampler arrives at the site and begins sampling, it is noted that one of the sample locations cannot be safely accessed and must be relocated. The relocation does not in any way affect the resulting sample data or the decision that will be made using the data.
- A field analytical method requires 50 grams of sample to perform the analysis, including the QC analysis. Due to lack of sufficient sample media, there is only 30 grams available to perform the analysis and not enough to do quality control analysis. Another sample (in the set of samples) will be used to perform the quality control analysis.

#### 4.3.2.1.2 Significant Change

**Definition.** Significant changes have a considerable effect on performance or cost, but still allow for meeting the DQOs. Significant changes are documented in accordance with Section 4.3.3.1.2.

**Examples.** Examples of significant changes include, but are not limited to, the following:

- Radiological conditions present in the field require modifying the field procedure or equipment to provide protection to the sampler. The quality and representativeness of the sample is not impacted; however, the cost for modification of the sampling tool and using it in the field will significantly increase the cost of sampling.
- After arriving at the site and evaluating the conditions and requirements of the DQOs specified in the sampling and analysis plan, the number of samples that will need to be collected has increased or decreased (e.g., increased from 20 to 40 samples).

#### 4.3.2.1.3 Fundamental Change

**Definition.** A fundamental change is one that has a significant effect on the sample or the field analytical result, performance, or cost, and the change does not meet the requirements specified in the DQOs in the sampling and analysis document. Fundamental changes are documented in accordance with Section 4.3.3.1.3.

**Example.** Radiological conditions in the field prohibit the planned drilling and collection of split spoon samples for the laboratory gamma energy analyzer. An alternative data acquisition strategy is to use drive-push technology and acquire radiological contamination data by spectral gamma borehole geophysics.

#### **4.3.2.2 Laboratory Procedure Changes**

##### **4.3.2.2.1 Substitution**

**Definition.** Substitution is an adjustment in a procedure that a reasonable, technically competent person would be expected to consider equivalent. Substitution would have no significant effect on final results. This would be clearly evident in the QC data associated with the final results. Therefore, substitution would be considered inconsequential. Additional information regarding the latitude given to the laboratory can be found in Sections 2.1.1 and 2.1.2 of EPA SW-846. Documentation requirements are discussed in Section 4.3.3.2.1.

**Examples.** Examples include substitution of equivalent columns yielding equivalent performance characteristics (e.g., use of a capillary column as opposed to a packed column would not meet this definition), and substitution of different glassware that results in the same overall digestion, extraction, or separation efficiency. Ratioed sample and reagent reductions are not considered substitution.

##### **4.3.2.2.2 Deviation**

**Definition.** Deviation is divergence from the original procedure that does not adversely impact the analyst's ability to meet the precision, accuracy, detection limit, selectivity, and QC criteria of the procedure. Therefore, the decision to deviate shall be based on published literature (e.g., alternate methods) and/or known sample chemistry. Documentation requirements are discussed in Section 4.3.3.2.2.

**Examples.** Examples include using packed versus capillary column and, in limited applications, using different sample sizes accompanied by subsequent ratioed changes to all reagents and standard additions, while maintaining the same final extract concentration. In some very limited cases, deviation might include varying reagent additions to effect similar digestion and/or analytical performance to the original procedure (e.g., addition of matrix modifier). A deviation may also be an additional precipitation reaction resulting in enhanced analyte purification. Such deviations can only be considered to be valid if the originally agreed upon precision, accuracy, sensitivity, and selectivity are maintained.

**Cautions on using deviations.** The analyst is cautioned in using ratioed reductions. In some cases, significant reductions in the quantity of material tested impacts the ability to guarantee reproducible results in terms of sample matrix precision. For example, in reducing the sample preparation weight from 1.00 g to 0.1 g, the ability of the laboratory to address sample heterogeneity concerns is brought into question. However, the laboratory could perform replicate preparations to address this concern and provide more useful information related to sample heterogeneity. Note: additional documentation is required in this case.

Also, the analyst is cautioned in varying reagent additions. Matrix adjustment may be necessary to effect similar analyte and isotope performance under a given technique; however, the ability to reproduce such situations hinges on the existence of a documented record of the deviation.

#### **4.3.2.2.3 Modification**

**Definition.** Modification changes the character of a procedure, and potentially limits a procedure's ability to meet the originally stated precision, accuracy, detection limit, selectivity, and QC criteria. Because the impact of such a modification cannot be ascertained before implementation, it must be demonstrated by application. Documentation requirements are discussed in Section 4.3.3.2.3.

**Examples.** Examples include using closed vessel digestion instead of standard beaker digestion, using alternate reagents for waste management or safe handling considerations, using different sample sizes accompanied by non-ratioed reagent addition, using alternate analytical technology, and using extended holding times.

Mixed waste samples provide a good example of the need for method modification. These samples can contain high levels of radioactivity that can create the necessity for analytical procedure modifications. In particular, Hanford Site samples may contain salts that negatively impact the efficiency of published methods designed for the preparation of waters, soils, and sludges. Disposal of mixed waste also impacts the decision to use a procedure as-is or to modify it to reduce the amount of waste produced during processing. Special handling techniques might need to be employed to keep the exposure to radioactive agents to a level as low as reasonably achievable (ALARA); the ALARA principle might also impact holding times.

### **4.3.3 Change Control**

The documentation, negotiation and reporting requirements for the different categories of sampling and analyses plan changes and procedure changes vary based on the significance and magnitude of the change needed. The different categories of sampling and analyses plan changes and procedure changes have different change control requirements. The requirements that shall be met for each category of sampling and analyses plan and procedure change are detailed below;

#### **4.3.3.1 Sampling and Field Analytical Change Control**

##### **4.3.3.1.1 Minor Changes**

To ensure efficient and timely completion of sampling and field analytical tasks, minor field changes can be made by the person in charge of the activity in the field. Minor changes will be documented in the field logbook. The logbook entry shall include the change, the reason for the change, and the names and titles of those approving the change.

##### **4.3.3.1.2 Significant Changes**

The task lead will inform DOE and the regulator of significant changes and seek concurrence at a unit manager's meeting or comparable forum. This concurrence does not need to take place

before the change is implemented. Documentation of this change approval would be in the unit manager's meeting minutes or comparable record.

#### **4.3.3.1.3 Fundamental Changes**

If it is anticipated that a fundamental change will require the approval of the lead regulatory agency, the applicable DOE unit manager will be notified and involved in the decision prior to implementation. Formal revision of the sampling and analysis plan or work plan is required.

#### **4.3.3.2 Laboratory Change Control**

##### **4.3.3.2.1 Substitution**

Because substitution does not impact the final result, no documentation of change is required (see Section 4.3.2.2.1). Only the documentation necessary to allow reproducibility of results is required.

##### **4.3.3.2.2 Deviation**

Deviation requires documenting the changes made to a procedure. Documentation of deviations made shall be included in the final report narrative. Justification of the deviation should be evident in the acceptable performance associated with the final results and should also be discussed. Acceptable performance shall be demonstrated by the analyst's ability to meet or exceed the original method's precision, accuracy, detection limit, selectivity, and QC criteria. Whenever possible, the client should be notified of deviations before starting work. When a deviation is routinely used, it shall be incorporated into the procedure.

##### **4.3.3.2.3 Modification**

Modification requires the procedure to be qualified (see Sections 4.3.4 and 4.3.5), documented, approved by laboratory management, and agreed on with the client before work. Requirements for implementation and personnel training shall apply, as necessary, to all laboratory procedures. Justification of the modification should be evident in the QC data associated with the final results and should also be discussed. A modification with long-term applicability should be developed into a new laboratory procedure that is issued with a new title and code.

In certain cases, modification is permitted without qualification on client samples provided that the laboratory and client agree, in writing, and that adequate QC is addressed to permit an understanding of the precision, accuracy, sensitivity, and associated limitations of the results.

#### **4.3.4 Qualification of Methods**

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

Several approaches may be used to qualify a method, 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, Chapter 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 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 if the need arises.

Technical procedures shall include or reference the acceptance and performance criteria for precision, accuracy, calibration, and detection limit (as appropriate) established during the qualification experiments.

### **4.3.5 Modification of Required Regulatory Methods**

The following procedures shall be used when modifications to required regulatory methods are made. These procedures shall be followed **only** when the precision, accuracy, detection limits, and/or QC criteria of approved methods might be impacted (positively or negatively) because of the reasons discussed in Sections 4.3.2.2.3 and 4.3.3.2.3. Method qualification requirements are discussed in Section 4.3.4. Guidance in understanding when a particular method qualifies as a required regulatory method can be found in DOE/RL-94-97, *Selection of Analytical Methods for Mixed Waste Analysis at the Hanford Site*.

#### **4.3.5.1 Justifying Modification**

All modifications to the required regulatory method shall be specifically described by providing a synopsis or direct quotation of the regulatory method 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, required regulatory method 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 if the procedure has short-term or long-term application (i.e., use 1 or 2, respectively).

#### **4.3.5.2 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, *Code of Federal Regulations*, Part 136.4 (40 CFR 136.4), "Application for Alternate Test Procedures."

#### **4.3.5.3 Documenting the Modified Method**

In cases where changes are restricted to specific sections of the required regulatory method, the text of the modification shall be provided (e.g., different instrument configuration, different spike or surrogate compounds). A complete copy of the modified method shall be provided when extensive modifications are necessary. The modified method 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 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., using special surrogates and/or spikes, detection limit). The approach required for method qualification is described in Section 4.3.4.

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.

#### **4.3.5.4 Reporting Results from Modified Regulatory Methods**

All technical procedures developed through modification of regulatory methods shall be provided with a unique title to notify the data user that the regulatory method has been modified. To the extent practical, modified methods shall retain a method reference (identifier) to the original method.

#### **4.3.5.5 Acceptance Criteria for Modified Methods**

Technical procedures developed through modification of regulatory methods shall include the acceptance and performance criteria for precision, accuracy, calibration, and detection limit established during the qualification experiments.

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## **5.0 CORRECTIVE ACTION AND QUALITY IMPROVEMENT**

A system shall be established and implemented 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.

### **5.1 INITIATION OF CORRECTIVE ACTION**

Examples of conditions where investigation and corrective action determinations are required include the following:

- Documentation errors
- Diverse 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)
- Misidentification or mishandling of samples.

### **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) shall be complete when the affected systems meet specifications.

### **5.3 ROOT CAUSE 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.

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.

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## **6.0 DOCUMENTS AND QUALITY RECORDS**

A system shall be developed and implemented for timely preparation, review, approval, issuance, use, control, revision, and maintenance of documents that prescribe work processes and specify requirements. Additionally, a system shall be established and implemented for identifying, preparing, approving, transmitting, correcting, distributing, retaining, retrieving, and disposing of quality 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 adequacy, 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. 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.

Documents designated to become quality records shall be legible, accurate, complete, and appropriate to the work accomplished. Corrections to documents that will become quality records shall be made by drawing one line through the error, initialing and dating the error, and justifying the correction (if not self-explanatory). Changes to computerized data records shall be identified such that original and corrected entries are retrievable and the individual initiating the changes can be identified.

### **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 the same level of review and approval as the original document. Editorial changes may be made to instructions, procedures, and drawings without review and approval.

### 6.3 QUALITY RECORDS

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
- Procedures for the control and client confidentiality accountability of records removed from the storage location
- Procedures for filing of 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
- Procedures for data correction, which include how corrections are to be made and establish who is authorized to change or correct data.

Sufficient records shall be specified, prepared, reviewed, authenticated, and maintained to reflect the achievement of the required quality. Records shall include documents such as operating logs, results of reviews, inspections, tests, assessments, monitoring of work performance, material/sample analyses, calibration records, and sub-contractor evaluations/results.

Records shall also include closely related data such as qualifications of personnel, procedures, 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.

Maintenance of active records shall include provisions for transmittal, distribution, retention, protection, preservation, traceability, disposition, and retrievability.

Records shall be classified, retained, and dispositioned in accordance with the *National Archives and Records Administration Act of 1984* and DOE Order 200.1, *Information Management Program*.

## **7.0 SOFTWARE SYSTEMS QUALITY ASSURANCE**

Software systems can be separated by application into two categories: administrative and technical. Administrative software systems are used to manage the work flow or to monitor performance against administrative requirements. Examples of administrative software systems are those that control sample tracking, procedure control, training, and reporting. Technical software systems are those used to control laboratory systems and to accumulate and reduce data. Examples of technical software systems are those that provide instrument interface, calculations, calibration control, and control charts. Databases may be included in administrative or technical software.

### **7.1 CONTROL REQUIREMENTS**

Software control requirements applicable to both commercial and laboratory-developed software shall be developed, documented, and implemented. In addition, procedures for software control shall address the security systems for protection of the software.

For laboratory-developed software, a copy of the original program code shall be maintained, and all changes shall include a description of the change, authorization for the change, and test data that validates the change.

### **7.2 ACCEPTANCE TESTING**

Software testing shall include development testing, verification testing, and validation testing, when appropriate. Software shall be acceptance tested when installed, after changes, and periodically during use, as appropriate. The frequency of testing should be based on the potential for adverse impact on the laboratory and the ease in which changes can be made to the computer code. Testing may consist of performing calculations or manually checking against another software product that has been previously tested or by analysis of standards.

Documentation of the testing should include the test cases, printouts of the data or results from data generated by the software for comparison, the name of the person performing the test, and the date the test was performed. The version and manufacturer of the software shall be documented. Commercially available software may be accepted as supplied by the vendor. For vendor-supplied instrument control/data analysis software, acceptance testing may be performed by the laboratory.

### **7.3 BACKUPS**

Both software and electronic data shall be backed up at a documented frequency. The frequency of backup shall be based on the amount of data and the impact of the loss of data or software on the organization.

### **7.4 USER'S MANUALS**

Software user's manuals shall be available to personnel using the software. This documentation shall be controlled to ensure that only the current manual is available for use.

Personnel should be trained on license requirements and proper control of the software.

## **7.5 ERROR REPORTING**

Software errors found during use shall be reported to the appropriate level of management. In the case of field/laboratory-developed software, personnel shall be assigned to verify all errors and document the error notification and all corrective actions. Error handling shall include all users so that previously reported data may be evaluated and corrective actions may be tracked.

## 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 shall be evaluated 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 re-calibrated 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 the 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.

Assessment programs may consist of management system assessments, technical system assessments, quality systems, surveillances, performance evaluation assessments, peer reviews, readiness reviews, and external audits/assessments.

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

- Management system assessments
- Technical system assessments
- Performance evaluation assessments
- Quality systems.

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 SYSTEM ASSESSMENTS**

Management system assessments are directed by those immediately responsible for overseeing and/or performing the work. Managers shall assess their management practices. 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 system assessments shall be conducted annually at a minimum.

## **10.2 TECHNICAL SYSTEM ASSESSMENTS (SURVEILLANCES)**

Technical system 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 system assessments consist of a review of laboratory or field operations, specific procedures, and related documentation. For example, areas of interest might include:

- Measuring and testing equipment calibration or control procedures
- Document control procedures
- Technical procedure compliance
- Adherence to data quality requirements (i.e., data quality review)
- Identification, control, storage, and preservation of samples or standards
- Communication of client expectations
- Client complaints.

Technical system assessments should be conducted periodically and should vary, such that over time, critical elements are evaluated.

## **10.3 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 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.

#### **10.4 QUALITY SYSTEM ASSESSMENTS**

The adequacy of the quality system and its implementation shall be assessed annually as an independent assessment. An external assessment may be used to fulfill this requirement.

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## 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 CLARIFICATIONS AND INTERPRETATIONS**

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### 13.0 REFERENCES

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*Resource Conservation and Recovery Act of 1976*, 42 USC 6901, et seq.

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

WAC 173-216, "State Waste Discharge Permit Program," *Washington Administrative Code*, as amended, Olympia, Washington.

WAC 173-303, "Dangerous Waste Regulations," *Washington Administrative Code*, as amended, Olympia, Washington.

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**Appendix A**  
**GLOSSARY**

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## 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><b>Laboratory or preparation blank</b> – 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><b>Holding blank</b> – 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><b>Trip blank</b> – 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><b>Field blank</b> – 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.</p> <p><b>Equipment blank/equipment rinsate</b> – 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	<p>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.</p>
Carrier	<p>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.</p>
Certification	<p>The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.</p>
Chain of custody	<p>An unbroken trail of accountability that ensures the physical security of samples, data, and records.</p>
Client	<p>The person or organization for whom items or services are furnished or work performed in response to defined requirements and expectations.</p>

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.
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.
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	The storage time allowed between sample collection and sample analysis when designated preservation and storage techniques are employed. This is determined by the elapsed time in days from the date and time collected to the date and time of sample preparation and 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.

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.
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.
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	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. 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.

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**

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## 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 data quality objective (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 should be used to standardize DQO documentation. An electronic template (DQO e-Workbook) to document the DQO process can be downloaded for use from the DOE Hanford DQO website (<http://www.hanford.gov/dqo/project/workbook.html>).

#### 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
    - Population parameter

- Sample statistic
  - Environmental variable (chemical/physical attribute in the population quantity)
- Scale of decision making
  - Geographic area/volume
  - Timeframe
  - 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.